

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)

[<sup>XI</sup>REGULATION (EC) No 1907/2006 OF THE  
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

(Text with EEA relevance)]

[<sup>XI</sup>THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions<sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>(3)</sup>,

Whereas:

- (1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in [<sup>F1</sup>mixtures] and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.
- (2) The efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State.
- (3) A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development. That legislation should be applied in a non-discriminatory manner

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whether substances are traded on the internal market or internationally in accordance with the Community's international commitments.

- (4) Pursuant to the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, the European Union is aiming to achieve that, by 2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment.
- (5) This Regulation should apply without prejudice to Community workplace and environment legislation.
- (6) This Regulation should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.
- (7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that manufacturing of substances in the Community complies with Community law, even if those substances are exported.
- (8) Special account should be taken of the potential impact of this Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them.
- (9) The assessment of the operation of the four main legal instruments governing chemicals in the Community, i.e. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>(4)</sup>, Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations<sup>(5)</sup>, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations<sup>(6)</sup> and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances<sup>(7)</sup>, identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field, and the need to do more to protect public health and the environment in accordance with the precautionary principle.
- (10) Substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or in transit are not used within the meaning of this Regulation and should therefore be excluded from its scope. The carriage of dangerous substances and of dangerous [F<sup>1</sup>mixtures] by rail, road, inland waterways, sea or air should also be excluded from its scope as specific legislation already applies to such carriage.
- (11) To ensure workability and to maintain the incentives for waste recycling and recovery, wastes should not be regarded as substances, [F<sup>1</sup>mixtures] or articles within the meaning of this Regulation.

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- (12) An important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. This Regulation does not affect the application of Directives on worker protection and the environment, especially Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)<sup>(8)</sup> and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>(9)</sup> under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.
- (13) This Regulation should apply without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products<sup>(10)</sup> in so far as substances are used and marketed as cosmetic ingredients and are within the scope of this Regulation. A phase-out of testing on vertebrate animals for the purpose of protecting human health as specified in Directive 76/768/EEC should take place with regard to the uses of those substances in cosmetics.
- (14) This Regulation will generate information on substances and their uses. Available information, including that generated by this Regulation, should be used by the relevant actors in the application and implementation of appropriate Community legislation, for example that covering products, and Community voluntary instruments, such as the eco-labelling scheme. The Commission should consider in the review and development of relevant Community legislation and voluntary instruments how information generated by this Regulation should be used, and examine possibilities for establishing a European quality mark.
- (15) There is a need to ensure effective management of the technical, scientific and administrative aspects of this Regulation at Community level. A central entity should therefore be created to fulfil this role. A feasibility study on the resource requirements for this central entity concluded that an independent central entity offered a number of long-term advantages over other options. A European Chemicals Agency (hereinafter referred to as the Agency) should therefore be established.
- (16) This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in [F1mixtures] and in articles. This Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.
- (17) All available and relevant information on substances on their own, in [F1mixtures] and in articles should be collected to assist in identifying hazardous properties, and

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recommendations about risk management measures should systematically be conveyed through supply chains, as reasonably necessary, to prevent adverse effects on human health and the environment. In addition, communication of technical advice to support risk management should be encouraged in the supply chain, where appropriate.

- (18) Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, in particular for SMEs.
- (19) Therefore, the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency. Registered substances should be allowed to circulate on the internal market.
- (20) The evaluation provisions should provide for follow-up to registration, by allowing for checks on whether registrations are in compliance with the requirements of this Regulation and if necessary by allowing for generation of more information on the properties of substances. If the Agency in cooperation with the Member States considers that there are grounds for considering that a substance constitutes a risk to human health or the environment, the Agency should, after having included the substance in the Community rolling action plan for substance evaluation, relying on the competent authorities of Member States, ensure that this substance is evaluated.
- (21) Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, it may also be used to initiate the authorisation or restrictions procedures under this Regulation or risk management procedures under other Community legislation. Therefore it should be ensured that this information is available to the competent authorities and may be used by them for the purpose of such procedures.
- (22) The authorisation provisions should ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.
- (23) The restriction provisions should allow the manufacturing, placing on the market and use of substances presenting risks that need to be addressed, to be made subject to total or partial bans or other restrictions, based on an assessment of those risks.
- (24) In preparation for this Regulation, the Commission has launched REACH Implementation Projects (RIPs), involving relevant experts from stakeholder groups. Some of those projects aim at developing draft guidelines and tools which should help the Commission, the Agency, Member States, manufacturers, importers and

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downstream users of substances to fulfil, in concrete terms, their obligations under this Regulation. This work should enable the Commission and the Agency to make available appropriate technical guidance, in due time, with regard to the deadlines introduced by this Regulation.

- (25) The responsibility to assess the risks and hazards of substances should be given, in the first place, to the natural or legal persons that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Natural or legal persons handling chemicals should take the necessary risk management measures in accordance with the assessment of the risks of substances and pass on relevant recommendations along the supply chain. This should include describing, documenting and notifying in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance.
- (26) In order to undertake chemical safety assessments of substances effectively, manufacturers and importers of substances should obtain information on these substances, if necessary by performing new tests.
- (27) For purposes of enforcement and evaluation and for reasons of transparency, the information on these substances, as well as related information, including on risk management measures, should normally be submitted to authorities.
- (28) Scientific research and development normally takes place in quantities below one tonne per year. There is no need to exempt such research and development because substances in those quantities do not have to be registered in any case. However, in order to encourage innovation, product and process oriented research and development should be exempted from the obligation to register for a certain time period where a substance is not yet intended to be placed on the market to an indefinite number of customers because its application in [<sup>F1</sup>mixtures] or articles still requires further research and development performed by the potential registrant himself or in cooperation with a limited number of known customers. In addition, it is appropriate to provide for a similar exemption to downstream users using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.
- (29) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on substances which are intended to be released from articles and have not been registered for that use. In the case of substances of very high concern which are present in articles above tonnage and concentration thresholds, where exposure to the substance cannot be excluded and where the substance has not been registered by any person for this use, the Agency should be notified. The Agency should also be empowered to request that a registration be submitted if it has grounds for suspecting that the release of a substance from the article may present a risk to human health or the environment and the substance is present in those articles in quantities totalling over one tonne per producer or importer per year. The Agency should consider the need for a proposal for a restriction where it

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considers that the use of such substances in articles poses a risk to human health or the environment that is not adequately controlled.

- (30) The requirements for undertaking chemical safety assessments by manufacturers and importers should be defined in detail in a technical annex to allow them to meet their obligations. To achieve fair burden sharing with their customers, manufacturers and importers should in their chemical safety assessment address not only their own uses and the uses for which they place their substances on the market, but also all uses which their customers ask them to address.
- (31) The Commission, in close cooperation with industry, Member States and other relevant stakeholders, should develop guidance to fulfil the requirements under this Regulation related to [F<sup>1</sup>mixtures] (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special [F<sup>1</sup>mixtures] — such as metals incorporated in alloys. In doing so, the Commission should take full account of the work that will have been carried out within the framework of the RIPs and should include the necessary guidance on this matter in the overall REACH guidance package. This guidance should be available before the application of this Regulation.
- (32) A chemical safety assessment should not need to be performed for substances in [F<sup>1</sup>mixtures] in certain very small concentrations which are considered as not giving rise to concern. Substances in [F<sup>1</sup>mixtures] in such low concentrations should also be exempt from authorisation. These provisions should apply equally to [F<sup>1</sup>mixtures] that are solid mixtures of substances until a specific shape is given to such a [F<sup>1</sup>mixture] that transforms it into an article.
- (33) Joint submission and the sharing of information on substances should be provided for in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals. One of a group of multiple registrants should submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden. A registrant should be able to submit information directly to the Agency in certain specified cases.
- (34) Requirements for generation of information on substances should be tiered according to the volumes of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail. To reduce the possible impact on low volume substances, new toxicological and ecotoxicological information should only be required for priority substances between 1 and 10 tonnes. For other substances in that quantity range there should be incentives to encourage manufacturers and importers to provide this information.
- (35) The Member States, the Agency and all interested parties should take full account of the results of the RIPs, in particular with regard to the registration of substances which occur in nature.

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- (36) It is necessary to consider the application of Article 2(7)(a) and (b) and Annex XI to substances derived from mineralogical processes and the review of Annexes IV and V should fully take this into account.
- (37) If tests are performed, they should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes<sup>(11)</sup>, and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances<sup>(12)</sup>.
- (38) The generation of information by alternative means offering equivalence to prescribed tests and test methods should also be allowed, for example when this information comes from valid qualitative or quantitative structure activity models or from structurally related substances. To this end the Agency, in cooperation with Member States and interested parties, should develop appropriate guidance. It should also be possible not to submit certain information if appropriate justification can be provided. Based on experience gained through RIPs, criteria should be developed defining what constitutes such justification.
- (39) In order to help companies, and in particular SMEs, to comply with the requirements of this Regulation, Member States, in addition to the operational guidance documents provided by the Agency, should establish national helpdesks.
- (40) The Commission, Member States, industry and other stakeholders should continue to contribute to the promotion of alternative test methods on an international and national level including computer supported methodologies, *in vitro* methodologies, as appropriate, those based on toxicogenomics, and other relevant methodologies. The Community's strategy to promote alternative test methods is a priority and the Commission should ensure that within its future Research Framework Programmes and initiatives such as the Community Action Plan on the Protection and Welfare of Animals 2006 to 2010 this remains a priority topic. Participation of stakeholders and initiatives involving all interested parties should be sought.
- (41) For reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates. Polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.
- (42) To avoid overloading authorities and natural or legal persons with the work arising from the registration of phase-in substances already on the internal market, that registration should be spread over an appropriate period of time, without introducing undue delay. Deadlines for the registration of these substances should therefore be set.

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- (43) Data for substances already notified in accordance with Directive 67/548/EEC should be eased into the system and should be upgraded when the next tonnage quantity threshold is reached.
- (44) In order to provide a harmonised, simple system, all registrations should be submitted to the Agency. To ensure a consistent approach and efficient use of resources, it should perform a completeness check on all registrations and take responsibility for any final rejections of registrations.
- (45) The European Inventory of Existing Commercial Chemical Substances (EINECS) included certain complex substances in a single entry. UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials) may be registered as a single substance under this Regulation, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification.
- (46) To ensure that the information gathered through the registration is kept up-to-date, an obligation on registrants to inform the Agency of certain changes to the information should be introduced.
- (47) In accordance with Directive 86/609/EEC, it is necessary to replace, reduce or refine testing on vertebrate animals. Implementation of this Regulation should be based on the use of alternative test methods, suitable for the assessment of health and environmental hazards of chemicals, wherever possible. The use of animals should be avoided by recourse to alternative methods validated by the Commission or international bodies, or recognised by the Commission or the Agency as appropriate to meet the information requirements under this Regulation. To this end, the Commission, following consultation with relevant stakeholders, should propose to amend the future Commission Regulation on test methods or this Regulation, where appropriate, to replace, reduce or refine animal testing. The Commission and the Agency should ensure that reduction of animal testing is a key consideration in the development and maintenance of guidance for stakeholders and in the Agency's own procedures.
- (48) This Regulation should be without prejudice to the full and complete application of the Community competition rules.
- (49) In order to avoid duplication of work, and in particular to reduce testing involving vertebrate animals, the provisions concerning preparation and submission of registrations and updates should require sharing of information where this is requested by any registrant. If the information concerns vertebrate animals, the registrant should be obliged to request it.
- (50) It is in the public interest to ensure the quickest possible circulation of test results on human health or environmental hazards of certain substances to those natural or legal persons which use them, in order to limit any risks associated with their use. Sharing of information should occur where this is requested by any registrant, in particular in the case of information involving tests on vertebrate animals, under conditions that ensure a fair compensation for the company that has undertaken the tests.



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- (51) In order to strengthen the competitiveness of Community industry and to ensure that this Regulation is applied as efficiently as possible, it is appropriate to make provision for the sharing of data between registrants on the basis of fair compensation.
- (52) In order to respect the legitimate property rights of those generating testing data, the owner of such data should, for a period of 12 years, be able to claim compensation from those registrants who benefit from that data.
- (53) In order to allow a potential registrant of a phase-in substance to proceed with his registration, even if he cannot reach agreement with a previous registrant, the Agency, on request, should allow use of any summary or robust study summary of tests already submitted. The registrant who receives these data should be obliged to pay a contribution to the costs to the owner of the data. For non-phase-in substances, the Agency may ask for evidence that a potential registrant has paid the owner of a study before the Agency gives permission for the potential registrant to use that information in his registration.
- (54) In order to avoid duplication of work, and in particular to avoid duplication of testing, registrants of phase-in substances should pre-register as early as possible with a database managed by the Agency. A system should be established in order to provide for the establishment of Substance Information Exchange Forums (SIEF) to help exchange of information on the substances that have been registered. SIEF participants should include all relevant actors submitting information to the Agency on the same phase-in substance. They should include both potential registrants, who must provide and be supplied with any information relevant to the registration of their substances, and other participants, who may receive financial compensation for studies they hold but are not entitled to request information. In order to ensure the smooth functioning of that system they should fulfil certain obligations. If a member of a SIEF does not fulfil his obligations, he should be penalised accordingly but other members should be enabled to continue preparing their own registration. In cases where a substance has not been pre-registered, measures should be taken to help downstream users find alternative sources of supply.
- (55) Manufacturers and importers of a substance on its own or in a [<sup>F1</sup>mixture] should be encouraged to communicate with the downstream users of the substance with regard to whether they intend to register the substance. Such information should be provided to a downstream user sufficiently in advance of the relevant registration deadline if the manufacturer or importer does not intend to register the substance, in order to enable the downstream user to look for alternative sources of supply.
- (56) Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. This important responsibility should also apply throughout the supply chain to enable all actors to meet their responsibility in relation to management of risks arising from the use of substances.

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- (57) As the existing safety data sheet is already being used as a communication tool within the supply chain of substances and [F<sup>1</sup>mixtures], it is appropriate to develop it further and make it an integral part of the system established by this Regulation.
- (58) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if those uses are not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks. For the same reason, downstream users should manage the risks arising from their uses of substances. In addition, it is appropriate that any producer or importer of an article containing a substance of very high concern should provide sufficient information to allow safe use of such an article.
- (59) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. These requirements should only apply above a total quantity of one tonne of substance or [F<sup>1</sup>mixture]. In any case, however, the downstream users should consider the use and identify and apply appropriate risk management measures. Downstream users should report certain basic information on use to the Agency.
- (60) For enforcement and evaluation purposes, downstream users of substances should be required to report to the Agency certain basic information if their use is outside the conditions of the exposure scenario detailed in the safety data sheet communicated by their original manufacturer or importer and to keep such reported information up-to-date.
- (61) For reasons of workability and proportionality, it is appropriate to exempt downstream users using low quantities of a substance from such reporting.
- (62) Communication up and down the supply chain should be facilitated. The Commission should develop a system categorising brief general descriptions of uses taking into account the outcomes of the RIPs.
- (63) It is also necessary to ensure that generation of information is tailored to real information needs. To this end evaluation should require the Agency to decide on the programmes of testing proposed by manufacturers and importers. In cooperation with Member States, the Agency should give priority to certain substances, for instance those which may be of very high concern.
- (64) In order to prevent unnecessary animal testing, interested parties should have a period of 45 days during which they may provide scientifically valid information and studies that address the relevant substance and hazard end-point, which is addressed by the testing proposal. The scientifically valid information and studies received by the Agency should be taken into account for decisions on testing proposals.
- (65) In addition, it is necessary to instil confidence in the general quality of registrations and to ensure that the public at large as well as all stakeholders in the chemicals industry have confidence that natural or legal persons are meeting the obligations placed upon

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- them. Accordingly, it is appropriate to provide for recording which information has been reviewed by an assessor possessing appropriate experience, and for a percentage of registrations to be checked for compliance by the Agency.
- (66) The Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to human health or the environment, including by reason of their presence on the internal market in high volumes, on the basis of evaluations performed. Based on the criteria for prioritising substances developed by the Agency in cooperation with the Member States a Community rolling action plan for substance evaluation should be established, relying on Member State competent authorities to evaluate substances included therein. If a risk equivalent to the level of concern arising from the use of substances subject to authorisation arises from the use of isolated intermediates on site, the competent authorities of the Member States should also be allowed to require further information, when justified.
- (67) Collective agreement within the Agency's Member State Committee on its draft decisions should provide the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market. If one or more Member States or the Agency do not agree to a draft decision, it should be adopted subject to a centralised procedure. If the Member State Committee fails to reach unanimous agreement, the Commission should adopt a decision in accordance with a Committee procedure.
- (68) Evaluation may lead to the conclusion that action should be taken under the restriction or authorisation procedures or that risk management action should be considered in the framework of other appropriate legislation. Information on the progress of evaluation proceedings should therefore be made public.
- (69) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.
- (70) Adverse effects on human health and the environment from substances of very high concern should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, and with a view to progressively substituting these substances with a suitable safer substance. Risk management measures should be applied to ensure, when substances are manufactured, placed on the market and used, that exposure to these substances including discharges, emissions and losses, throughout the whole life-cycle is below

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the threshold level beyond which adverse effects may occur. For any substance for which authorisation has been granted, and for any other substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects. Measures to ensure adequate control should be identified in any Chemical Safety Report. These measures should be applied and, where appropriate, recommended to other actors down the supply chain.

- (71) Methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed taking into account the outcomes of RIPs. The relevant Annex may be amended on the basis of these methodologies to allow thresholds where appropriate to be used while ensuring a high level of protection of human health and the environment.
- (72) To support the aim of eventual replacement of substances of very high concern by suitable alternative substances or technologies, all applicants for authorisation should provide an analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information on any research and development the applicant is undertaking or intends to undertake. Furthermore, authorisations should be subject to time-limited review whose periods would be determined on a case-by-case basis and normally be subject to conditions, including monitoring.
- (73) Substitution of a substance on its own, in a [F<sup>1</sup>mixture] or in an article should be required when manufacture, use or placing on the market of that substance causes an unacceptable risk to human health or to the environment, taking into account the availability of suitable safer alternative substances and technologies, and the socio-economic benefits from the uses of the substance posing an unacceptable risk.
- (74) Substitution of a substance of very high concern by suitable safer alternative substances or technologies should be considered by all those applying for authorisations of uses of such substances on their own, in [F<sup>1</sup>mixtures] or for incorporation of substances into articles by making an analysis of alternatives, the risks involved in using any alternative and the technical and economic feasibility of substitution.
- (75) The possibility of introducing restrictions on the manufacturing, placing on the market and use of dangerous substances, [F<sup>1</sup>mixtures] and articles applies to all substances falling within the scope of this Regulation, with minor exemptions. Restrictions on the placing on the market and the use of substances which are carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, for their use by consumers on their own or in [F<sup>1</sup>mixtures] should continue to be introduced.
- (76) Experience at international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case-by-case basis. The criteria in Annex XIII should be reviewed taking into account the current and any new experience in the identification of these substances and if appropriate, be amended with a view to ensuring a high level of protection for human health and the environment.

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- (77) In view of workability and practicality considerations, both as regards natural or legal persons, who have to prepare application files and take appropriate risk management measures, and as regards the authorities, who have to process authorisation applications, only a limited number of substances should be subjected to the authorisation procedure at the same time and realistic deadlines should be set for applications, while allowing certain uses to be exempted. Substances identified as meeting the criteria for authorisation should be included in a candidate list for eventual inclusion in the authorisation procedure. Within this list, substances on the Agency's work programme should be clearly identified.
- (78) The Agency should provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments.
- (79) A total ban on a substance would mean that none of its uses could be authorised. It would therefore be pointless to allow the submission of applications for authorisation. In such cases the substance should be removed from the list of substances for which applications can be submitted and added to the list of restricted substances.
- (80) The proper interaction between the provisions on authorisation and restriction should be ensured in order to preserve the efficient functioning of the internal market and the protection of human health, safety and the environment. Restrictions that exist when the substance in question is added to the list of substances for which applications for authorisation can be submitted, should be maintained for that substance. The Agency should consider whether the risk from substances in articles is adequately controlled and, if it is not, prepare a dossier in relation to introduction of further restrictions for substances for which the use requires authorisation.
- (81) In order to provide a harmonised approach to the authorisation of the uses of particular substances, the Agency should issue opinions on the risks arising from those uses, including whether or not the substance is adequately controlled and on any socio-economic analysis submitted to it by third parties. These opinions should be taken into account by the Commission when considering whether or not to grant an authorisation.
- (82) To allow effective monitoring and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance.
- (83) It is suitable in these circumstances that final decisions granting or refusing authorisations be adopted by the Commission pursuant to a regulatory procedure in order to allow for an examination of their wider implications within the Member States and to associate the latter more closely with the decisions.
- (84) In order to accelerate the current system the restriction procedure should be restructured and Directive 76/769/EEC, which has been substantially amended and adapted several times, should be replaced. In the interests of clarity and as a starting point for this new accelerated restriction procedure, all the restrictions developed under that Directive should be incorporated into this Regulation. Where appropriate, the application of

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Annex XVII of this Regulation should be facilitated by guidance developed by the Commission.

- (85) In relation to Annex XVII Member States should be allowed to maintain for a transitional period more stringent restrictions, provided that these restrictions have been notified according to the Treaty. This should concern substances on their own, substances in [F<sup>1</sup>mixtures] and substances in articles, the manufacturing, the placing on the market and the use of which is restricted. The Commission should compile and publish an inventory of these restrictions. This would provide an opportunity for the Commission to review the measures concerned with a view to possible harmonisation.
- (86) It should be the responsibility of the manufacturer, importer and downstream user to identify the appropriate risk management measures needed to ensure a high level of protection for human health and the environment from the manufacturing, placing on the market or use of a substance on its own, in a [F<sup>1</sup>mixture] or in an article. However, where this is considered to be insufficient and where Community legislation is justified, appropriate restrictions should be laid down.
- (87) In order to protect human health and the environment, restrictions on the manufacture, placing on the market or use of a substance on its own, in a [F<sup>1</sup>mixture] or in an article may include any condition for, or prohibition of, the manufacture, placing on the market or use. Therefore it is necessary to list such restrictions and any amendments thereto.
- (88) In order to prepare a restrictions proposal and in order for such legislation to operate effectively, there should be good cooperation, coordination and information between the Member States, the Agency, other bodies of the Community, the Commission and the interested parties.
- (89) In order to give Member States the opportunity to submit proposals to address a specific risk for human health and the environment, they should prepare a dossier in conformity with detailed requirements. The dossier should set out the justification for Community-wide action.
- (90) In order to provide a harmonised approach to restrictions, the Agency should fulfil a role as coordinator of this procedure, for example by appointing the relevant rapporteurs and verifying conformity with the requirements of the relevant Annexes. The Agency should maintain a list of substances for which a restriction dossier is being prepared.
- (91) In order to give the Commission the opportunity to address a specific risk for human health and the environment that needs to be addressed Community wide, it should be able to entrust the Agency with the preparation of a restriction dossier.
- (92) For reasons of transparency, the Agency should publish the relevant dossier including the suggested restrictions while requesting comments.
- (93) In order to finalise the procedure in due time, the Agency should submit its opinions on the suggested action and its impact on the basis of a draft opinion prepared by a rapporteur.
- (94) In order to speed up the procedure for restrictions, the Commission should prepare its draft amendment within a specific time limit of receiving the Agency's opinions.

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- (95) The Agency should be central to ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. The Agency should also play a pivotal role in coordinating communication around this Regulation and in its implementation. The confidence in the Agency of the Community institutions, the Member States, the general public and interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency.
- (96) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of this Regulation.
- (97) The effective communication of information on chemical risks and how they can be managed is an essential part of the system established by this Regulation. Best practice from the chemicals and other sectors should be considered in the preparation of guidance by the Agency to all stakeholders.
- (98) In the interests of efficiency, the staff of the Agency Secretariat should perform essentially technical-administrative and scientific tasks without calling on the scientific and technical resources of the Member States. The Executive Director should ensure the efficient execution of the Agency's tasks in an independent manner. To ensure that the Agency fulfils its role, the composition of the Management Board should be designed to represent each Member State, the Commission and other interested parties appointed by the Commission in order to ensure the involvement of stakeholders, and the European Parliament and to secure the highest standard of competence and a broad range of relevant expertise in chemicals safety or the regulation of chemicals, whilst ensuring that there is relevant expertise in the field of general financial and legal matters.
- (99) The Agency should have the means to perform all the tasks required to carry out its role.
- (100) A Commission Regulation should specify the structure and amounts of fees, including specifying the circumstances under which a proportion of the fees will be transferred to the relevant Member State competent authority.
- (101) The Management Board of the Agency should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations and appoint the Executive Director.
- (102) Through a Committee for Risk Assessment and a Committee for Socio-economic Analysis, the Agency should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence.
- (103) Through a Member State Committee, the Agency should aim to reach agreement amongst Member States' authorities on specific issues which require a harmonised approach.
- (104) It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis are

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based on the broadest possible scientific and technical expertise appropriate which is available within the Community. To the same end, these Committees should be able to rely on additional particular expertise.

- (105) In the light of the increased responsibility of natural or legal persons for ensuring safe use of chemicals, enforcement needs to be strengthened. The Agency should therefore provide a Forum for Member States to exchange information on and to coordinate their activities related to the enforcement of chemicals legislation. The currently informal cooperation between Member States in this respect would benefit from a more formal framework.
- (106) A Board of Appeal should be set up within the Agency to guarantee processing of appeals for any natural or legal person affected by decisions taken by the Agency.
- (107) The Agency should be financed partly by fees paid by natural or legal persons and partly by the general budget of the European Communities. The Community budgetary procedure should remain applicable as far as any subsidies chargeable to the general budget of the European Communities are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors in accordance with Article 91 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(13)</sup>.
- (108) Where the Commission and Agency consider it appropriate, it should be possible for representatives of third countries to participate in the work of the Agency.
- (109) The Agency should contribute, through cooperation with organisations having interests in the harmonisation of international regulations, to the role of the Community and the Member States in such harmonisation activities. To promote broad international consensus the Agency should take account of existing and emerging international standards in the regulation of chemicals such as the Globally Harmonised System (GHS) of classification and labelling of chemicals.
- (110) The Agency should provide the infrastructure needed for natural or legal persons to meet their obligations under the data-sharing provisions.
- (111) It is important to avoid confusion between the mission of the Agency and the respective missions of the European Medicines Agency (EMA) established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>(14)</sup>, the European Food Safety Authority (EFSA) established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(15)</sup> and the Advisory Committee on Safety, Hygiene and Health Protection at Work set up by the Council Decision of 22 July 2003<sup>(16)</sup>. Consequently, the Agency should establish rules of procedure where cooperation with the EFSA or the Advisory Committee on Safety,



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Hygiene and Health Protection at Work is necessary. This Regulation should otherwise be without prejudice to the competence conferred on the EMEA, the EFSA and the Advisory Committee on Safety, Hygiene and Health Protection at Work by Community legislation.

- (112) In order to achieve the functioning of the internal market for substances on their own or in [F<sup>1</sup> mixtures], while at the same time ensuring a high level of protection for human health and the environment, rules should be established for a classification and labelling inventory.
- (113) The classification and labelling for any substance either subject to registration or covered by Article 1 of Directive 67/548/EEC and placed on the market should therefore be notified to the Agency to be included in the inventory.
- (114) To ensure a harmonised protection for the general public, and, in particular, for persons who come into contact with certain substances, and the proper functioning of other Community legislation relying on the classification and labelling, an inventory should record the classification in accordance with Directive 67/548/EEC and Directive 1999/45/EC agreed by manufacturers and importers of the same substance, if possible, as well as decisions taken at Community level to harmonise the classification and labelling of some substances. This should take full account of the work and experience accumulated in connection with the activities under Directive 67/548/EEC, including the classification and labelling of specific substances or groups of substances listed in Annex I of Directive 67/548/EEC.
- (115) Resources should be focused on substances of the highest concern. A substance should therefore be added to Annex I of Directive 67/548/EEC if it meets the criteria for classification as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, as a respiratory sensitiser, or in respect of other effects on a case-by-case basis. Provision should be made to enable competent authorities to submit proposals to the Agency. The Agency should give its opinion on the proposal while interested parties should have an opportunity to comment. The Commission should take a decision subsequently.
- (116) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of this Regulation as well as trends in this field. Conclusions drawn from findings in the reports will be useful and practical tools for reviewing this Regulation and, where necessary, for formulating proposals for amendments.
- (117) EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures. The Agency and Member States should allow access to information in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information<sup>(17)</sup>, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European

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- Parliament, Council and Commission documents<sup>(18)</sup> and with the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, to which the European Community is a party.
- (118) Disclosure of information under this Regulation is subject to the specific requirements of Regulation (EC) No 1049/2001. That Regulation sets binding deadlines for the release of information as well as procedural guarantees, including the right of appeal. The Management Board should adopt the practical arrangements for application of those requirements to the Agency.
- (119) Apart from their participation in the implementation of Community legislation, Member State competent authorities should, because of their closeness to stakeholders in the Member States, play a role in the exchange of information on risks of substances and on the obligations of natural or legal persons under chemicals legislation. At the same time, close cooperation between the Agency, the Commission and the competent authorities of the Member States is necessary to ensure the coherence and efficiency of the global communication process.
- (120) In order for the system established by this Regulation to operate effectively, there should be good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement.
- (121) In order to ensure compliance with this Regulation, Member States should put in place effective monitoring and control measures. The necessary inspections should be planned, carried out and their results should be reported.
- (122) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance, as non-compliance can result in damage to human health and the environment.
- (123) The measures necessary for the implementation of this Regulation and certain amendments to it should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(19)</sup>.
- (124) In particular, power should be conferred on the Commission to amend the Annexes in certain cases, to set rules on test methods, to vary the percentage of dossiers selected for compliance checking and to modify the criteria for their selection, and to set the criteria defining what constitutes adequate justification that testing is technically not possible. Since these measures are of general scope and are designed to amend non-essential elements of this Regulation or supplement this Regulation by adding new non-essential elements thereto, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (125) It is essential that chemicals be regulated in an effective and timely manner during the transition to full applicability of the provisions of this Regulation and, in particular, during the start-up period of the Agency. Provision should therefore be made for the Commission to provide the necessary support towards the setting up of the Agency,

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- including the conclusion of contracts and the appointment of an Executive Director *ad interim* until the Agency's Management Board can appoint an Executive Director itself.
- (126) To take full advantage of the work performed under Regulation (EEC) No 793/93 as well as under Directive 76/769/EEC and to avoid such work being lost, the Commission should be empowered during the start-up period to initiate restrictions based on that work without following the full restrictions procedure laid down in this Regulation. All those elements should be used, as soon as this Regulation enters into force, to support risk reduction measures.
- (127) It is appropriate for the provisions of this Regulation to enter into force in a staggered way to smooth the transition to the new system. Moreover, a gradual entry into force of the provisions should allow all parties involved, authorities, natural or legal persons as well as stakeholders, to focus resources in the preparation for new duties at the right times.
- (128) This Regulation replaces Directive 76/769/EEC, Commission Directive 91/155/EEC<sup>(20)</sup>, Commission Directive 93/67/EEC<sup>(21)</sup>, Commission Directive 93/105/EC<sup>(22)</sup>, Commission Directive 2000/21/EC<sup>(23)</sup>, Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94<sup>(24)</sup>. These Directives and Regulations should therefore be repealed.
- (129) For the sake of consistency, Directive 1999/45/EC which already addresses matters covered by this Regulation should be amended.
- (130) Since the objectives of this Regulation, namely laying down rules for substances and establishing a European Chemicals Agency, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (131) The Regulation observes the fundamental rights and principles which are acknowledged in particular in the Charter of Fundamental Rights of the European Union<sup>(25)</sup>. In particular, it seeks to ensure full compliance with the principles of environmental protection and sustainable development guaranteed by Article 37 of that Charter,

HAVE ADOPTED THIS REGULATION:

#### **Editorial Information**

- XI** Substituted by [Corrigendum to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation \(EEC\) No 793/93 and Commission Regulation \(EC\) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC \(Official Journal of the European Union L 396 of 30 December 2006\).](#)

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### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

### Modifications etc. (not altering text)

- C1** Regulation: power to amend conferred (9.11.2021 for specified purposes, 28.2.2022 in so far as not already in force) by Environment Act 2021 (c. 30), s. 147(1)(b)(6), Sch. 21 paras. 1, 3-7 (with s. 144); S.R. 2022/54, art. 2(1)(p)

## TITLE I

### GENERAL ISSUES

#### CHAPTER 1

#### Aim, scope and application

##### *Article 1*

#### Aim and scope

1 The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances <sup>F2</sup>... while enhancing competitiveness and innovation.

2 This Regulation lays down provisions on substances and [<sup>F1</sup>mixtures] within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in [<sup>F1</sup>mixtures] or in articles and to the placing on the market of [<sup>F1</sup>mixtures].

3 This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F2** Words in Art. 1(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 1; 2020 c. 1, Sch. 5 para. 1(1)

## Article 2

### Application

- 1 This Regulation shall not apply to:
- a radioactive substances within the scope of [F<sup>3</sup>retained EU law that transposed Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation];
  - b substances, on their own, in a [F<sup>1</sup>mixture] or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
  - c non-isolated intermediates;
  - d the carriage of dangerous substances and dangerous substances in dangerous [F<sup>1</sup>mixtures] by rail, road, inland waterway, sea or air.
- 2 Waste as defined in [F<sup>4</sup>Article 3(1) of Directive 2008/98/EC] of the European Parliament and of the Council <sup>(26)</sup> is not a substance, [F<sup>1</sup>mixture] or article within the meaning of Article 3 of this Regulation.
- [F<sup>5</sup>2A For the purposes of this Regulation, “Directive 2008/98/EC” means that Directive as last amended by Directive (EU) 2018/851, and read in accordance with paragraphs 2B and 2C.
- 2B Article 5 is to be read as if—
- a in paragraph 1, “Member States shall take appropriate measures to ensure that” were omitted;
  - b after paragraph 1 there were inserted—
    - 1A a in accordance with any regulations setting out detailed criteria on the application of the conditions in paragraph 1 to specific substances or objects; and
    - b having regard to any guidance published by the appropriate authority or the appropriate agency for the purposes of this Article.;
  - c paragraphs 2 and 3 were omitted.
- 2C Article 6 is to be read as if—
- a in paragraph 1, “Member States shall take appropriate measures to ensure that” were omitted;
  - b after paragraph 1 there were inserted—
    - 1A a in accordance with any regulations or retained direct EU legislation setting out detailed criteria on the application of the conditions in paragraph 1 to specific types of waste; and
    - b having regard to any guidance published by the appropriate authority or the appropriate agency for the purposes of this Article.;
  - c in paragraph 2—
    - i the first subparagraph were omitted;
    - ii in the second subparagraph, for “Those detailed criteria” there were substituted “Any detailed criteria set out in guidance as referred to in paragraph 1A”;
    - iii the third and fourth subparagraphs were omitted;
  - d paragraph 3 were omitted;

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- e in paragraph 4—
- i in the first subparagraph—
    - aa in the first sentence, for the words from the beginning to “Member State”, there were substituted “Where criteria have not been set out as referred to in paragraph 1A(a), the appropriate agency”;
    - bb the second sentence were omitted;
  - ii in the second subparagraph—
    - aa for “Member States” there were substituted “The appropriate agency”;
    - bb “by competent authorities” were omitted.
- 2D In paragraphs 2B and 2C, “appropriate agency” means—
- a the Environment Agency, in relation to England;
  - b the Natural Resources Body for Wales, in relation to Wales;
  - c the Scottish Environment Protection Agency, in relation to Scotland.]
- 3 [F6The Secretary of State] may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a [F1mixture] or in an article, where necessary in the interests of defence.
- F7 4 .....
- 5 The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used:
- [F8a in medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;]
  - b in food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
    - (i) [F9as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;]
    - (ii) [F10as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council;]
    - (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(27)</sup>;
    - (iv) [F11in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.]
- 6 The provisions of Title IV shall not apply to the following [F1mixtures] in the finished state, intended for the final user:
- [F12a medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;]
  - [F13b cosmetic products as defined in Regulation (EC) No 1223/2009 on cosmetic products;]
  - [F14c medical devices which are invasive or used in direct physical contact with the human body in so far as legislation relating to the classification and labelling of dangerous

- substances and mixtures applies to them which ensures the same level of information provision and protection as Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures;]
- d food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
- (i) [F15as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;]
  - (ii) [F15as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council;]
  - (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;
  - (iv) [F16;in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.]
- 7 The following shall be exempted from Titles II, V and VI:
- a substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
  - b substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;
  - c substances on their own or in [F1mixtures], registered in accordance with Title II, exported [F17from Great Britain] by an actor in the supply chain and re-imported [F18into Great Britain] by the same or another actor in the same supply chain who shows that:
    - (i) the substance being re-imported is the same as the exported substance;
    - (ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;
  - d substances, on their own, in [F1mixtures] or in articles, which have been registered in accordance with Title II and which are recovered in [F19Great Britain] if:
    - (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
    - (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.
- 8 On-site isolated intermediates and transported isolated intermediates shall be exempted from:
- a Chapter 1 of Title II, with the exception of Articles 8 and 9; and
  - b Title VII.
- 9 The provisions of Titles II and VI shall not apply to polymers.



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### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F3** Words in Art. 2(1)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 2(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Art. 2(2A)-(2D) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(4)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(2)**); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 2(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Art. 2(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(6)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 2(5)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Art. 2(5)(b)(i) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 2(5)(b)(ii) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Art. 2(5)(b)(iv) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 2(6)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Art. 2(6)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Art. 2(6)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Art. 2(6)(d)(i)(ii) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Art. 2(6)(d)(iv) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Art. 2(7)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(9)(a)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(3)**); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 2(7)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(9)(b)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(3)**); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 2(7)(d) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(10)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(4)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)



## CHAPTER 2

### Definitions and general provision

#### *f<sup>20</sup>* Article 2A

##### **The Agency**

1 The functions and powers of the Agency under the REACH legislation are to be functions and powers of the HSE.

Accordingly, any reference to the Agency in the REACH legislation must be read as meaning the HSE.

2 The general incidental powers of the HSE are to be exercisable for the purpose of carrying out the functions of the Agency under the REACH legislation.

But that does not limit the powers which the HSE has under the REACH legislation.

3 The non-REACH functions of the HSE are not limited by the functions of the Agency under the REACH legislation.

Accordingly, the HSE is not prevented from carrying out non-REACH functions in relation to a matter just because any of the functions of the Agency under the REACH legislation is also exercisable, or has been exercised, in relation to that matter.

4 The power of the Secretary of State under section 12(2)(a) of HASWA 1974 to give directions (as read with section 12(4) of HASWA 1974) is to be exercisable with respect to the functions of the Agency under the REACH legislation.

The Secretary of State may not give any such directions with regard to the enforcement of the REACH legislation in any particular case.

The Secretary of State must consider any request made by any of the other appropriate authorities for the Secretary of State to give a direction by virtue of this paragraph.

The function of giving directions by virtue of this section is subject to the consent requirement in Article 4A (whether or not there has been a request under the previous subparagraph).

5 In this Article—

“general incidental powers” means the powers which the HSE has under—

a section 13 of HASWA 1974, and

b Schedule 2 to HASWA 1974;

“HASWA 1974” means the Health and Safety at Work etc. Act 1974;

“HSE” means the Health and Safety Executive;

“non-REACH function” means any function which arises otherwise than under the REACH legislation;

“REACH legislation” means—

a this Regulation,

b any instrument made under this Regulation, and

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- c any retained direct EU legislation that was originally made under EU REACH.

#### Textual Amendments

**F20** Arts. 2A, 2B inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), [Sch. 1 para. 3](#) (as amended by S.I. 2020/1577, regs. 1(1)(b), [4\(5\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### Article 2B

#### Advice from Environment Agency or other environmental regulators to Agency

- 1 The Agency must comply with paragraph 2 when exercising—
  - a its functions under—
    - i Article 7(5),
    - ii Article 9(4), (7) and (8),
    - iii Article 21,
    - iv Articles 40(1) and (3), 41(1), (3) and (5), 42(1), 43, 44, 45, 46(1) and (3), 48, 49, 51 and 52,
    - v Articles 58(3) and (4) and 59(1), (2), (3), (6) and (7),
    - vi Article 64(1), (3), (4), (5) and (6),
    - vii Articles 69, 70 and 71, and
  - b any of its other functions under this Regulation,
 if, and to the extent that, the exercise of the function involves consideration of any relevant environmental issues.
- 2 The Agency must—
  - a obtain the advice of the Environment Agency before exercising the function concerned, and
  - b use the advice obtained when exercising the function concerned.
- 3 Whenever the advice of the Environment Agency is sought by the Agency under this Article, the Environment Agency must collaborate with the other environmental regulators when formulating the advice.
- 4 If, as part of a collaboration under paragraph 3, one of the other environmental regulators gives advice to the Environment Agency, the Environment Agency must pass that advice on to the Agency if that other environmental regulator requires it to do so.
- 5 In this Article—
 

“other environmental regulator” means—

  - a in relation to Wales, the Natural Resources Body for Wales;
  - b in relation to Scotland, the Scottish Environment Protection Agency;

“relevant environmental issue” means—

  - a exposure of the environment to chemicals;
  - b exposure of humans to chemicals in the environment;

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- c assessment of the potential effect of chemicals on the environment;
- d measures aimed at controlling the release of chemicals into the environment.]

#### Textual Amendments

**F20** Arts. 2A, 2B inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 3](#) (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), [4\(5\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

### Article 3

#### Definitions

For the purposes of this Regulation:

- A1. [<sup>F21</sup>EU REACH: means Regulation [\(EC\) No 1907/2006](#) of the European Parliament and of the Council as it has effect in EU law;]
- A2. [<sup>F21</sup>appropriate authority: means—
  - a the Secretary of State, in relation to England;
  - b the Scottish Ministers, in relation to Scotland;
  - c the Welsh Ministers, in relation to Wales;]
- 1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- 2. [<sup>F1</sup>mixture]: means a mixture or solution composed of two or more substances;
- 3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
- 4. producer of an article: means any natural or legal person who makes or assembles an article within [<sup>F22</sup>Great Britain];
- 5. polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
  - (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
  - (b) less than a simple weight majority of molecules of the same molecular weight.

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In the context of this definition a ‘ monomer unit ’ means the reacted form of a monomer substance in a polymer;

6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;
7. registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
8. manufacturing: means production or extraction of substances in the natural state;
9. manufacturer: means any natural or legal person established within [F23Great Britain] who manufactures a substance within [F23Great Britain];
10. import: means the physical introduction into [F24Great Britain];
- 10A. [F25protected NI import: has the meaning given by Article 139A(2);]
- 10B. [F25qualifying Northern Ireland good: has the meaning given to it from time to time in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;]
11. importer: means any natural or legal person established within [F26Great Britain] who is responsible for import;
12. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
13. downstream user: means any natural or legal person established within [F27Great Britain], other than the manufacturer or the importer, who uses a substance, either on its own or in a [F1mixture], in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;
14. distributor: means any natural or legal person established within [F28Great Britain], including a retailer, who only stores and places on the market a substance, on its own or in a [F1mixture], for third parties;
15. intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):
  - (a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
  - (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

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- (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;
- 16. site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
- 17. actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain;
- 18. [<sup>F29</sup>Agency: see Article 2A;]
- 18A. [<sup>F29</sup>ECHA: means the European Chemicals Agency established under EU REACH;]
- 19. <sup>F30</sup> .....
- 20. phase-in substance: means a substance which meets at least one of the following criteria:
  - (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
  - (b) [<sup>F31</sup>it was manufactured in the [<sup>F32</sup>European Community], or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, but not placed on the market by the manufacturer or importer, at least once in the 15 years before [<sup>F33</sup>1 June 2007], provided the manufacturer or importer has documentary evidence of this;
  - (c) it was placed on the market in the [<sup>F34</sup>European Community], or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, by the manufacturer or importer before [<sup>F35</sup>1 June 2007] and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive;]
- 21. notified substance: means a substance for which a notification [<sup>F36</sup>was] submitted and which could be placed on the market in accordance with Directive 67/548/EEC;
- 22. product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in [<sup>F1</sup>mixtures] or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
- 23. scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;

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24. use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
25. registrant's own use: means an industrial or professional use by the registrant;
26. identified use: means a use of a substance on its own or in a [F<sup>1</sup>mixture], or a use of a [F<sup>1</sup>mixture], that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
27. full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;
28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;
29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;
30. per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
31. restriction: means any condition for or prohibition of the manufacture, use or placing on the market;
32. supplier of a substance or a [F<sup>1</sup>mixture]: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a [F<sup>1</sup>mixture], or a [F<sup>1</sup>mixture];
33. supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;
34. recipient of a substance or a [F<sup>1</sup>mixture]: means a downstream user or a distributor being supplied with a substance or a [F<sup>1</sup>mixture];
35. recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;
36. SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises <sup>(28)</sup>[F<sup>37</sup>]and, in its application for the purposes of this paragraph, the Annex to that Recommendation has effect with the following modifications—
  - a in Article 2(1)—
    - i the reference to EUR 50 million has effect as a reference to £43.650 million;
    - ii the reference to EUR 43 million has effect as a reference to £37.539 million;

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- b in Article 2(2) the reference to EUR 10 million has effect as a reference to £8.730 million;
  - c in Article 2(3) the reference to EUR 2 million has effect as a reference to £1.746 million;
  - d in Article 3(2)—
    - i in point (a), the reference to EUR 1,250,000 has effect as a reference to £1,091,250;
    - ii in point (d), the reference to EUR 10 million has effect as a reference to £8.730 million;]
37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;
39. substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
40. not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;
41. alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.
42. [<sup>F38</sup>GB mandatory classification and labelling list: the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.]
43. [<sup>F38</sup>GB notification database: the database established in accordance with Article 42 of Regulation (EC) No 1272/2008.]
44. [<sup>F39</sup>relevant medical device: means a medical device within the scope of—
- a the Medical Devices Regulations 2002;
  - b Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law; or
  - c Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices as it has effect in EU law;]

*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

45. [F39 relevant accessory to a medical device: means an accessory to a medical device within the scope of—
- a the Medical Devices Regulations 2002;
  - b Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law; or
  - c Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices as it has effect in EU law.]

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F21** Art. 3(A1)(A2) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(2)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(6)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 3(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(3)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(7)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 3(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(4)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(8)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 3(10) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(5)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(9)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F25** Art. 3(10A)(10B) inserted (31.12.2020) by S.I. 2019/758, reg. 1(1), **Sch. 1 para. 4(5A)** (as inserted by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1577), regs. 1(1)(b), **4(10)**); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Art. 3(11) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(6)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(11)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Art. 3(13) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(6)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(11)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Art. 3(14) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(6)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(11)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Art. 3(18)(18A) substituted for Art. 3(18) (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Art. 3(19) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(8)**; 2020 c. 1, Sch. 5 para. 1(1)
- F31** Substituted by Council Regulation (EU) No 517/2013 of 13 May 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, transport policy, energy, taxation, statistics, trans-European networks, judiciary and fundamental rights, justice, freedom and security, environment, customs union, external relations, foreign, security and defence policy and institutions, by reason of the accession of the Republic of Croatia.
- F32** Words in Art. 3(20)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F33** Words in Art. 3(20)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 3(20)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F35** Words in Art. 3(20)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F36** Word in Art. 3(21) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(10)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 3(36) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(11)**; 2020 c. 1, Sch. 5 para. 1(1)
- F38** Art. 3(42)(43) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 2** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(a)**); 2020 c. 1, Sch. 5 para. 1(1)
- F39** Art. 3(44)(45) inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **3**

#### Article 4

#### General provision

Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

#### <sup>F40</sup> Article 4A

#### The consent requirement

1 Where any provision of this Regulation states that a function is subject to the consent requirement in this Article, the function may be exercised in a particular instance only if the person exercising it has obtained the consent or consents (if any) required by paragraphs 2 to 4.

2 The consent of the Scottish Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 54 of the Scotland Act 1998), whether or not the exercise of the function also relates to a part of Great Britain other than Scotland.

3. The consent of the Welsh Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006) whether or not the exercise of the function also relates to a part of Great Britain other than Wales.]

#### Textual Amendments

- F40** Art. 4A inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 5** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(12)(a)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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#### Modifications etc. (not altering text)

- C2** Art. 4A(1) modified (9.11.2021 for specified purposes, 28.2.2022 in so far as not already in force) by Environment Act 2021 (c. 30), s. 147(1)(b)(6), **Sch. 21 para. 3(2)** (with s. 144); S.R. 2022/54, art. 2(1) (p)

## TITLE II

### REGISTRATION OF SUBSTANCES

#### CHAPTER 1

#### General obligation to register and information requirements

##### Article 5

#### No data, no market

Subject to Articles 6, 7 [<sup>F41</sup>and 21], substances on their own, in [<sup>F1</sup>mixtures] or in articles shall not be manufactured in [<sup>F42</sup>Great Britain] or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F41** Words in Art. 5 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 6(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F42** Words in Art. 5 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 6(b)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(13) (a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)

##### Article 6

#### General obligation to register substances on their own or in [<sup>F1</sup>mixtures]

1 Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more [<sup>F1</sup>mixture] (s), in quantities of one tonne or more per year shall submit a registration to the Agency.

2 For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.

3 Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

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- a the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
  - b the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.
- 4 A submission for registration shall be accompanied by the fee required in accordance with Title IX.

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006 \(Text with EEA relevance\).](#)

### Article 7

#### Registration and notification of substances in articles

1 Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

- a the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- b the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2 Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

- a the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- b the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3 Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4 The information to be notified shall include the following:

- a the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
- b the registration number(s) referred to in Article 20(1), if available;
- c the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
- d the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
- e a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);

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f the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

5 The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

- a the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- b the Agency has grounds for suspecting that:
  - (i) the substance is released from the articles, and
  - (ii) the release of the substance from the articles presents a risk to human health or the environment;
- c the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6 Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7 <sup>[F43]</sup>Paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).

8 <sup>[F44]</sup>Any measures for the implementation of paragraphs 1 to 7 shall be adopted by regulations made by the Secretary of State. Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this paragraph is subject to the consent requirement in Article 4A.]

#### Textual Amendments

**F43** Word in Art. 7(7) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 7(2); 2020 c. 1, Sch. 5 para. 1(1)

**F44** Art. 7(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 7(3); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 8

##### Only representative of a <sup>[F45]</sup>non-Great British] manufacturer

1 A natural or legal person established outside <sup>[F46]</sup>Great Britain] who manufactures a substance on its own, in <sup>[F1]</sup>mixtures] or in articles, formulates a <sup>[F1]</sup>mixture] or produces an article that is imported into <sup>[F46]</sup>Great Britain] may by mutual agreement appoint a natural or legal person established in <sup>[F46]</sup>Great Britain] to fulfil, as his only representative, the obligations on importers under this Title.

2 The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

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3 If a representative is appointed in accordance with paragraphs 1 and 2, the [F47 non-Great British] manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F45** Words in Art. 8 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 8(2)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(14)**); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in Art. 8(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 8(3)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(15)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in Art. 8(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 8(4)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(16)**); 2020 c. 1, Sch. 5 para. 1(1)

### Article 9

#### Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1 Articles 5, 6, 7, 17, 18 and 21 shall not apply for [F48 a five-year exemption period] to a substance manufactured in [F49 Great Britain] or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

[F50 1A In paragraph 1 “five-year exemption period” means a period of five years beginning when Articles 5, 6, 7, 17, 18 and 21 would otherwise apply to the substance (if it were not manufactured or imported as mentioned in paragraph 1).]

2 For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:

- a the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI;
- b the identity of the substance, as specified in section 2 of Annex VI;
- c the classification of the substance as specified in section 4 of Annex VI, if any;
- d the estimated quantity as specified in section 3.1 of Annex VI;
- e the list of customers referred to in paragraph 1, including their names and addresses.

The notification shall be accompanied by the fee required in accordance with Title IX.

The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3 The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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Agency, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the <sup>F51</sup>appropriate authorities that request it].

4 The Agency may decide to impose conditions with the aim of ensuring that the substance or the <sup>F1</sup>mixture] or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a <sup>F1</sup>mixture] or article and that remaining quantities will be re-collected for disposal after the exemption period.

In such cases, the Agency may ask the notifier to provide additional necessary information.

5 In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.

6 The manufacturer or importer or producer of articles shall comply with any conditions imposed by the Agency in accordance with paragraph 4.

7 The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, or for substances that are not placed on the market, for a further maximum of ten years, upon request if the manufacturer or importer or producer of articles can demonstrate that such an extension is justified by the research and development programme.

8 The Agency shall forthwith communicate any draft decisions to the <sup>F52</sup>appropriate authorities that request them].

When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any comments made by <sup>F53</sup>the appropriate authorities].

9 The Agency and the <sup>F54</sup>appropriate authorities] shall always keep confidential the information submitted in accordance with paragraphs 1 to 8.

10 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 4 and 7 of this Article.

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006 \(Text with EEA relevance\).](#)
- F48** Words in Art. 9(1) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 9(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F49** Words in Art. 9(1) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 9(2)(b)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(17)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F50** Art. 9(1A) inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 9(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F51** Words in Art. 9(3) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 9(4)**; 2020 c. 1, Sch. 5 para. 1(1)



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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| <p><b>F52</b> Words in Art. 9(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), <b>Sch. 1 para. 9(5)(a)</b>; 2020 c. 1, Sch. 5 para. 1(1)</p> <p><b>F53</b> Words in Art. 9(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), <b>Sch. 1 para. 9(5)(b)</b>; 2020 c. 1, Sch. 5 para. 1(1)</p> <p><b>F54</b> Words in Art. 9(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), <b>Sch. 1 para. 9(6)</b>; 2020 c. 1, Sch. 5 para. 1(1)</p> |
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## Article 10

### Information to be submitted for general registration purposes

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

- (a) a technical dossier including:
- (i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;
  - (ii) the identity of the substance as specified in section 2 of Annex VI;
  - (iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
  - (iv) the classification and labelling of the substance as specified in section 4 of Annex VI;
  - (v) guidance on safe use of the substance as specified in Section 5 of Annex VI;
  - (vi) study summaries of the information derived from the application of Annexes VII to XI;
  - (vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
  - (viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
  - (ix) proposals for testing where listed in Annexes IX and X;
  - (x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;
  - (xi) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Except in cases covered under Article 25(3) [<sup>F55</sup>or Article 27(6)], the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

#### Textual Amendments

**F55** Words in Art. 10(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 10; 2020 c. 1, Sch. 5 para. 1(1)

### Article 11

#### Joint submission of data by multiple registrants

1 When a substance is intended to be manufactured in [<sup>F56</sup>Great Britain] by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.

2 Each registrant need only comply with paragraph 1 for items of information specified in Article 10(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 12.

3 A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

- a it would be disproportionately costly for him to submit this information jointly; or
- b submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
- c he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

4 A submission for registration shall be accompanied by the fee required in accordance with Title IX.



**Textual Amendments**

- F56** Words in Art. 11(1) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 11](#) (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), [4\(18\)\(a\)\(b\)](#)); 2020 c. 1, Sch. 5 para. 1(1)

*Article 12***Information to be submitted depending on tonnage**

1 The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:

- a the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one tonne or more per year per manufacturer or importer;
- b the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III;
- c the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;
- d the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;
- e the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.

2 As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.

3 This Article shall apply to producers of articles adapted as necessary.

*Article 13***General requirements for generation of information on intrinsic properties of substances**

1 Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

2 These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. [<sup>F57</sup>The Secretary of State,] following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the [<sup>F58</sup>Test Methods Regulation], and the Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. [<sup>F59</sup>Amendments to the Test Methods Regulation may be made by regulations made by the Secretary of State. Amendments to the Annexes of this Regulation may be made by regulations made by the Secretary of State. Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament. The functions of making regulations under this paragraph are subject to the consent requirement in Article 4A.]

3 Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in [<sup>F60</sup>the Test Methods Regulation] or in accordance with other international test methods recognised by <sup>F61</sup>... the Agency as being appropriate. <sup>F62</sup>...

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

4 Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in [<sup>F63</sup>the Good Laboratory Practice Regulations 1999] or other international standards recognised as being equivalent by <sup>F64</sup>... the Agency and with the provisions of [<sup>F65</sup>the Animals (Scientific Procedures) Act 1986], if applicable.

5 If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex VI.

[<sup>F66</sup> In this Article “Test Methods Regulation” means Commission Regulation (EU) No 440/2008.]

#### Textual Amendments

- F57** Words in Art. 13(2) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Words in Art. 13(2) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(2)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in Art. 13(2) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F60** Words in Art. 13(3) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F61** Words in Art. 13(3) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F62** Words in Art. 13(3) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F63** Words in Art. 13(4) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 12(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F64** Words in Art. 13(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 12(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F65** Words in Art. 13(4) substituted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 12(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F66** Art. 13(6) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 12(5)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 14

### Chemical safety report and duty to apply and recommend risk reduction measures

1 <sup>[F67A]</sup> chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a <sup>[F1]</sup>mixture] or in an article or a group of substances.

<sup>[F12]</sup> A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:

- a the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;
- b 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.]

3 A chemical safety assessment of a substance shall include the following steps:

- a human health hazard assessment;
- b physicochemical hazard assessment;
- c environmental hazard assessment;
- d persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

<sup>[F14]</sup> If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- a hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- b hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- c hazard class 4.1;
- d hazard class 5.1,

or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:]

- a exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
- b risk characterisation.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.

5 The chemical safety report need not include consideration of the risks to human health from the following end uses:

- a in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food <sup>(29)</sup> ;
- b in cosmetic products within the scope of [<sup>F68</sup>Regulation (EC) No 1223/2009 on cosmetic products].

6 Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.

7 Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F67** Word in Art. 14(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 13(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F68** Words in Art. 14(5)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 13(3)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 2

### Substances regarded as being registered

#### Article 15

#### Substances in plant protection and biocidal products

[<sup>F69</sup> 1 The following are regarded as being registered, and the registration as completed, for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title—

- a active substances manufactured or imported for use in plant protection products only and included in the approvals register in relation to at least one constituent territory;
- b co-formulants manufactured or imported for use in plant protection products only and not included in the unacceptable co-formulants register in relation to the whole of the UK;
- c any substance in relation to which the applicant has been notified in accordance with Article 9(3) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

1A In paragraph 1—

- a in point (a)—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- i “approvals register” means the register maintained in accordance with Article 27A of Regulation (EC) No 1107/2009;
  - ii “constituent territory” has the meaning given by Article 3A of Regulation (EC) No 1107/2009;
- b in point (b), “unacceptable co-formulants register” means the register maintained in accordance with Article 27B of Regulation (EC) No 1107/2009.]

[<sup>F70</sup> 2 Active substances manufactured or imported for use in biocidal products only and included either in the GB List or the Simplified Active Substance List defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products or Annex II of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, subject to the transitional measures detailed in Article 89 of Regulation (EU) No 528/2012, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.]

#### Textual Amendments

- F69** Art. 15(1)(1A) substituted for Art. 15(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), 25; 2020 c. 1, Sch. 5 para. 1(1)
- F70** Art. 15(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 2 para. 3 (as amended by S.I. 2020/1567, reg. 1(2), Sch. 2 para. 2(b)); 2020 c. 1, Sch. 5 para. 1(1)

### Article 16

#### Duties of <sup>F71</sup>... registrants of substances regarded as being registered

<sup>F72</sup> 1 .....

2 Articles 21, 22 and 25 to [<sup>F73</sup>27] shall not apply to uses of substances regarded as registered according to Article 15.

#### Textual Amendments

- F71** Words in Art. 16 heading omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 14(2); 2020 c. 1, Sch. 5 para. 1(1)
- F72** Art. 16(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 14(3); 2020 c. 1, Sch. 5 para. 1(1)
- F73** Word in Art. 16(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 14(4); 2020 c. 1, Sch. 5 para. 1(1)

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*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## CHAPTER 3

### Obligation to register and information requirements for certain types of isolated intermediates

#### Article 17

##### Registration of on-site isolated intermediates

1 Any manufacturer of an on-site isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

2 A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:

- a the identity of the manufacturer as specified in Section 1 of Annex VI;
- b the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
- c the classification of the intermediate as specified in Section 4 of Annex VI;
- d any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
- e a brief general description of the use, as specified in Section 3.5 of Annex VI;
- f details of the risk management measures applied.

Except in cases covered under Article 25(3) [<sup>F74</sup>or Article 27(6)], the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3 Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

If these conditions are not fulfilled, the registration shall include the information specified in Article 10.

#### Textual Amendments

**F74** Words in Art. 17(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 15; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 18

##### Registration of transported isolated intermediates

1 Any manufacturer or importer of a transported isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

2 A registration for a transported isolated intermediate shall include all the following information:

- a the identity of the manufacturer or importer as specified in Section 1 of Annex VI;
- b the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
- c the classification of the intermediate as specified in Section 4 of Annex VI;
- d any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
- e a brief general description of the use, as specified in Section 3.5 of Annex VI;
- f information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25(3) [<sup>F75</sup>or Article 27(6)], the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3 A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII in addition to the information required under paragraph 2.

For the generation of this information, Article 13 shall apply.

4 Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an) other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

- a the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
- b procedural and control technologies shall be used that minimise emission and any resulting exposure;
- c only properly trained and authorised personnel handle the substance;
- d in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- e in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
- f substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 10.

#### Textual Amendments

**F75** Words in Art. 18(2) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 15](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## Article 19

### Joint submission of data on isolated intermediates by multiple registrants

1 When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in [<sup>F76</sup>Great Britain] by one or more manufacturers and/or imported by one or more importers, the following shall apply.

Subject to paragraph 2 of this Article, the information specified in Article 17(2)(c) and (d) and Article 18(2)(c) and (d) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as ‘ the lead registrant ’ ).

Each registrant shall subsequently submit separately the information specified in Article 17(2)(a), (b), (e) and (f) and Article 18(2)(a),(b), (e) and (f).

2 A manufacturer or importer may submit the information referred to in Article 17(2)(c) or (d) and Article 18(2)(c) or (d) separately if:

- a it would be disproportionately costly for him to submit this jointly; or
- b submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
- c he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the manufacturer or importer shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

3 A submission for registration shall be accompanied by the fee required in accordance with Title IX.

#### Textual Amendments

**F76** Words in Art. 19(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 16 (as amended by S.I. 2020/1577, regs. 1(1)(b), 4(19)(a)(b)); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 4

### Common provisions for all registrations

## Article 20

### Duties of the Agency

1 The Agency shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Agency.



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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2 The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 or under Articles 17 or 18, as well as the registration fee referred to in Article 6(4), Article 7(1) and (5), Article 17(2) or Article 18(2), have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

The Agency shall undertake the completeness check within three weeks of the submission date<sup>F77</sup>....

If a registration is incomplete, the Agency shall inform the registrant, before expiry of the three-week<sup>F78</sup>... period referred to in the second subparagraph, as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.

The Agency shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

3 Once the registration is complete, the Agency shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. The Agency shall without delay communicate the registration number and registration date to the registrant concerned. The registration number shall be used for all subsequent correspondence regarding registration.

4 The Agency shall notify the [<sup>F79</sup>appropriate authorities that request the notification] within 30 days of the submission date, that the following information is available in the Agency database:

- a the registration dossier together with the submission or registration number;
- b the submission or registration date;
- c the result of the completeness check; and
- d any request for further information and deadline set in accordance with the third subparagraph of paragraph 2.

F80  
...

F80  
...

The Agency shall forthwith notify the [<sup>F81</sup>appropriate authorities that request the notification] when any further information submitted by the registrant is available on the Agency database.

5 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 2 of this Article.

6 Where additional information for a particular substance is submitted to the Agency by a new registrant, the Agency shall notify the existing registrants that this information is available on the database for the purposes of Article 22.

#### Textual Amendments

**F77** Words in Art. 20(2) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 17\(2\)\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F78** Words in Art. 20(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 17(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F79** Words in Art. 20(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 17(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F80** Words in Art. 20(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 17(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F81** Words in Art. 20(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 17(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 21

### Manufacturing and import of substances

1 A registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the submission date, without prejudice to Article 27(8).

**F82** ...

In the case of an update of a registration according to Article 22 a registrant may continue the manufacture or import of the substance, or the production or import of the article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the update date, without prejudice to Article 27(8).

2 If the Agency has informed the registrant that he is to submit further information in accordance with the third subparagraph of Article 20(2), the registrant may start the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from the Agency within the three weeks after receipt by the Agency of the further information necessary to complete his registration, without prejudice to Article 27(8).

3 If a lead registrant submits parts of the registration on behalf of one or more other registrants, as provided for in Articles 11 or 19, any of the other registrants may manufacture or import the substance or produce or import the articles only after the expiry of the time-limit laid down in paragraph 1 or 2 of this Article and provided that there is no indication to the contrary from the Agency in respect of the registration of the lead registrant acting on behalf of the others and his own registration.

#### Textual Amendments

- F82** Words in Art. 21(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 18**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 22

### Further duties of registrants

1 Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:

- a any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- b any change in the composition of the substance as given in Section 2 of Annex VI;
- c changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;
- d new identified uses and new uses advised against as in Section 3.7 of Annex VI for which the substance is manufactured or imported;
- e new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;
- f any change in the classification and labelling of the substance;
- g any update or amendment of the chemical safety report or Section 5 of Annex VI;
- h the registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal shall be developed;
- i any change in the access granted to information in the registration.

The Agency shall communicate this information to the [F83 appropriate authorities that request it].

2 A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 or take into account a decision made in accordance with Articles 60 and 73, within the deadline specified in that decision. The Agency shall notify the [F84 appropriate authorities that request it] that the information is available on its database.

3 The Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration. In cases where the update is in accordance with Article 12(2) and with paragraph 1(c) of this Article then the Agency shall check the completeness of the information supplied by the registrant and Article 20(2) shall apply adapted as necessary.

4 In cases covered by Articles 11 or 19, each registrant shall submit separately the information specified in paragraph 1(c) of this Article.

5 An update shall be accompanied by the relevant part of the fee required in accordance with Title IX.

#### Textual Amendments

**F83** Words in Art. 22(1) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 19(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F84** Words in Art. 22(2) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 19(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## CHAPTER 5

### Transitional provisions applicable to phase-in substances and notified substances

#### <sup>F85</sup> Article 23

#### Specific provisions for phase-in substances

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#### Textual Amendments

**F85** Art. 23 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 20**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 24

#### Notified substances

<sup>F86</sup> 1

2 If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 12, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 10 and 12, unless it has already been submitted in accordance with those Articles.

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#### Textual Amendments

**F86** Art. 24(1) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 21**; 2020 c. 1, Sch. 5 para. 1(1)

## TITLE III

### DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

#### CHAPTER 1

#### Objectives and general rules

#### Article 25

#### Objectives and general rules

1 In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

2 The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.

3 Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation [<sup>F87</sup>, or under EU REACH before IP completion day] at least 12 years previously can be used for the purposes of registration by another manufacturer or importer.

#### Textual Amendments

**F87** Words in Art. 25(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 22 (as amended by S.I. 2020/1313, regs. 1(3), 6(2)); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 2

### [<sup>F88</sup>Rules for registrants of substances]

#### Article 26

#### Duty to inquire prior to registration

1 Every potential registrant <sup>F89</sup>... shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:

- a his identity as specified in Section 1 of Annex VI, with the exception of the use sites;
- b the identity of the substance, as specified in Section 2 of Annex VI;
- c which information requirements would require new studies involving vertebrate animals to be carried out by him;
- d which information requirements would require other new studies to be carried out by him.

2 If the same substance has previously not been registered, the Agency shall inform the potential registrant accordingly.

3 If [<sup>F90</sup>there is a previous registration of the same substance that is less than 12 years old], the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them.

[<sup>F91</sup>A registration of a substance is less than 12 years old if—

- a in a case where the registration came into existence under Article 127A, the existing EU registration (as defined in Article 127D) began less than 12 years before the potential registrant's enquiry to the Agency;
- b in any other case, the registration under this Regulation began less than 12 years before the potential registrant's enquiry to the Agency.]

Studies involving vertebrate animals shall not be repeated.

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 27.

4 If several potential registrants have made an inquiry in respect of the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants.

#### Textual Amendments

- F89** Words in Art. 26(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 24(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F90** Words in Art. 26(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 24(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F91** Words in Art. 26(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 24(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 27

#### Sharing of existing data in the case of registered substances

1 Where [<sup>F92</sup>there is a previous registration of a substance that is less than 12 years old] as referred to in Article 26(3), the potential registrant:

- a shall, in the case of information involving tests on vertebrate animals; and
- b may, in the case of information not involving tests on vertebrate animals,

request from the previous registrant(s) the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.

[<sup>F93</sup> 2 Within one month of a request for information being made according to paragraph 1, the owner of the study shall provide proof of the cost of the information to the potential registrant(s) requesting it. The potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.]

3 The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following cost sharing guidance based on those principles which is adopted by the Agency in accordance with Article 77(2)(g). Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

4 On agreement on the sharing of the information, the previous registrant shall [<sup>F94</sup> within two weeks of receipt of payment,] make available to the new registrant the agreed information and shall give the new registrant the permission to refer to the previous registrant's full study report.

[<sup>F95</sup> 5 If the previous registrant as referred to in paragraph 1 refuses to provide either proof of the cost of that study or the study itself to a potential registrant, or there is failure to reach an agreement referred to in paragraph 4, the potential registrant(s) shall inform the Agency and the previous registrant(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the previous registrant(s).]

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

6 Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier, subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 77(2)(g). Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

7 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 6 of this Article.

8 The registration waiting period in accordance with Article 21(1) for the new registrant shall be extended by a period of four months, if the previous registrant so requests.

#### Textual Amendments

- F92** Words in Art. 27(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F93** Art. 27(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F94** Words in Art. 27(4) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F95** Art. 27(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(5)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

- F88** Title 3 Ch. 2 title substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 23**; 2020 c. 1, **Sch. 5 para. 1(1)**

## CHAPTER 3

### Rules for phase-in-substances

#### <sup>F96</sup> Article 28

### Duty to pre-register for phase-in substances

#### Textual Amendments

- F96** Arts. 28-30 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 26**; 2020 c. 1, Sch. 5 para. 1(1)



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

*F96 Article 29*

**Substance Information Exchange Forums**

**Textual Amendments**

**F96** Arts. 28-30 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 26**; 2020 c. 1, Sch. 5 para. 1(1)

*F96 Article 30*

**Sharing of data involving tests**

**Textual Amendments**

**F96** Arts. 28-30 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 26**; 2020 c. 1, Sch. 5 para. 1(1)

TITLE IV

**INFORMATION IN THE SUPPLY CHAIN**

*Article 31*

**Requirements for safety data sheets**

1 The supplier of a substance or a [F1mixture] shall provide the recipient of the substance or [F1mixture] with a safety data sheet compiled in accordance with Annex II:

- [F1a] where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or]
- b where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or
- c where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

2 Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a [F1mixture] and the actor in the supply chain has prepared a chemical safety assessment for that [F1mixture], it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the [F1mixture] instead of with the chemical safety report for each substance in the [F1mixture].



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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[<sup>F13</sup> The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains:

- a in an individual concentration of  $\geq 1$  % by weight for non-gaseous mixtures and  $\geq 0,2$  % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or
- b in an individual concentration of  $\geq 0,1$  % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or
- c a substance [<sup>F97</sup>in relation to which the law of any part of Great Britain provides] workplace exposure limits.]

[<sup>F14</sup> The safety data sheet need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.]

5 The safety data sheet shall be supplied in [<sup>F98</sup>English and may also be supplied in any other language.]

6 The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/ [<sup>F1</sup>mixture] and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

7 Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).

[<sup>F18</sup> A safety data sheet shall be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied.]

- 9 Suppliers shall update the safety data sheet without delay on the following occasions:
- a as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
  - b once an authorisation has been granted or refused;
  - c once a restriction has been imposed.

The new, dated version of the information, identified as ‘Revision: (date)’, shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or [<sup>F1</sup>mixture] within the preceding 12 months. Any updates following registration shall include the registration number.

<sup>F99</sup> 10 .....

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006 \(Text with EEA relevance\).](#)
- F97** Words in Art. 31(3)(c) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 27(2)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(20)**); 2020 c. 1, Sch. 5 para. 1(1)
- F98** Words in Art. 31(5) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 27(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F99** Art. 31(10) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 27(4)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 32

##### **Duty to communicate information down the supply chain for substances on their own or in [<sup>F1</sup>mixtures] for which a safety data sheet is not required**

1 Any supplier of a substance on its own or in a [<sup>F1</sup>mixture] who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:

- a the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- b if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;
  - c details of any restriction imposed under Title VIII;
  - d any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex XI.
- 2 The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a [F1mixture]<sup>F100</sup>....
- 3 Suppliers shall update this information without delay on the following occasions:
- a as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
  - b once an authorisation has been granted or refused;
  - c once a restriction has been imposed.

In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or [F1mixture] within the preceding 12 months. Any updates following registration shall include the registration number.

#### Textual Amendments

**F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

**F100** Words in Art. 32(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 28; 2020 c. 1, Sch. 5 para. 1(1)

### Article 33

#### Duty to communicate information on substances in articles

1 Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2 On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### Article 34

#### Duty to communicate information on substances and [F<sup>1</sup>mixtures] up the supply chain

Any actor in the supply chain of a substance or a [F<sup>1</sup>mixture] shall communicate the following information to the next actor or distributor up the supply chain:

- (a) new information on hazardous properties, regardless of the uses concerned;
- (b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

### Article 35

#### Access to information for workers

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or [F<sup>1</sup>mixtures] that they use or may be exposed to in the course of their work.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

### Article 36

#### Obligation to keep information

1 Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or [F<sup>1</sup>mixture]. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request <sup>F101</sup>... to the Agency [F<sup>102</sup> or to any appropriate authority], without prejudice to Titles II and VI.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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2 In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or [F<sup>1</sup>mixture] concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F101** Words in Art. 36(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 29(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F102** Words in Art. 36(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 29(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## TITLE V

### DOWNSTREAM USERS

#### Article 37

#### Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

1 A downstream user or distributor may provide information to assist in the preparation of a registration.

2 Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a [F<sup>1</sup>mixture] with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

3 For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 14 either before he next supplies the substance on its own or in a [F<sup>1</sup>mixture] to the downstream user making the request referred to in paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.

F103 ...

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d).

4 A downstream user of a substance on its own or in a [F1mixture] shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.

A downstream user need not prepare such a chemical safety report in any of the following cases:

- a a safety data sheet is not required to be communicated with the substance or [F1mixture] in accordance with Article 31;
- b a chemical safety report is not required to be completed by his supplier in accordance with Article 14;
- c the downstream user uses the substance or [F1mixture] in a total quantity of less than one tonne per year;
- d the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;
- e the substance is present in a [F1mixture] in a concentration lower than any of the concentrations set out in Article 14(2);
- f the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

5 Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:

- a the safety data sheet(s) supplied to him;
- b his own chemical safety assessment;
- c any information on risk management measures supplied to him in accordance with Article 32.

6 Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.

7 Downstream users shall keep their chemical safety report up to date and available.

8 A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 14(5).

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F103** Words in Art. 37(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 30**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 38

### Obligation for downstream users to report information

1 Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 6 or 18, the downstream user shall report to the Agency the information specified in paragraph 2 of this Article, in the following cases:

- a the downstream user has to prepare a chemical safety report in accordance with Article 37(4); or
- b the downstream user is relying on the exemptions in Article 37(4)(c) or (f).

2 The information reported by the downstream user shall include the following:

- a his identity and contact details as specified in Section 1.1 of Annex VI;
- b the registration number(s) referred to in Article 20(3), if available;
- c the identity of the substance(s) as specified in Section 2.1 to 2.3.4 of Annex VI;
- d the identity of the manufacturer(s) or the importer(s) or other supplier as specified in Section 1.1 of Annex VI;
- e a brief general description of the use(s), as specified in Section 3.5 of Annex VI, and of the conditions of use(s);
- f except where the downstream user is relying on the exemption in Article 37(4)(c), a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.

3 The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.

4 A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.

5 Except where a downstream user is relying on the exemption in Article 37(4)(c), reporting in accordance with paragraphs 1 to 4 of this Article shall not be required in respect of a substance, on its own or in a [F1 mixture], used by the downstream user in quantities of less than one tonne per year for that particular use.

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### Article 39

#### **Application of downstream user obligations**

1 Downstream users shall be required to comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

2 Downstream users shall be required to comply with the requirements of Article 38 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

## TITLE VI

### EVALUATION

#### CHAPTER 1

##### **Dossier evaluation**

### Article 40

#### **Examination of testing proposals**

[<sup>F1</sup> The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances above 100 tonnes per year with uses resulting in widespread and diffuse exposure, provided they fulfil the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008:

- a hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- b hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- c hazard class 4.1;
- d hazard class 5.1.]

2 Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with paragraph 3.



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

3 On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51:

- a a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex I;
- b a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;
- c a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;
- d a decision rejecting the testing proposal;
- e a decision in accordance with points (a), (b) or (c), if several registrants or downstream users of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users, as appropriate, to perform the test on behalf of all of them.

4 The registrant or downstream user shall submit the information required to the Agency by the deadline set.

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006 \(Text with EEA relevance\).](#)

### Article 41

#### Compliance check of registrations

- 1 The Agency may examine any registration in order to verify any of the following:
  - a that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;
  - b that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;
  - c that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;
  - d that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.
- 2 The list of dossiers being checked for compliance by the Agency shall be made available to <sup>F104</sup>the appropriate authorities that request it].
- 3 On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.

4 The registrant shall submit the information required to the Agency by the deadline set.

5 <sup>F105</sup> The registration dossiers selected by the Agency for compliance checking must include—

- a until 27 October 2027, not less than 20% of the registration dossiers received by the Agency for substances referred to in Article 127P(4B)(a);
- b until 27 October 2030, not less than 20% of the registration dossiers received by the Agency for substances referred to in Article 127P(4B)(b);
- c until 27 October 2035, not less than 20% of the registration dossiers received by the Agency for substances referred to in Article 127P(4B)(c).]

<sup>F106</sup> In this paragraph, references to registration dossiers do not include the dossiers referred to in Article 127B(9).]

<sup>F107</sup>6 .....

<sup>F108</sup>7 The Secretary of State may, by regulations, make provision to modify the effect of paragraph 5 by—

- a modifying the percentage of dossiers to be selected;
- b modifying the criteria which determine the dossiers to which priority is to be given.

Regulations under this paragraph may amend paragraph 5.

The Secretary of State must consult the Agency before making regulations under this paragraph.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this paragraph is subject to the consent requirement in Article 4A.]

#### Textual Amendments

**F104** Words in Art. 41(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 31(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F105** Words in Art. 41(5) substituted (19.7.2023) by The REACH (Amendment) Regulations 2023 (S.I. 2023/722), regs. 1(2), **3(2)(a)**

**F106** Words in Art. 41(5) inserted (19.7.2023) by The REACH (Amendment) Regulations 2023 (S.I. 2023/722), regs. 1(2), **3(2)(b)**

**F107** Art. 41(6) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 31(4)**; 2020 c. 1, Sch. 5 para. 1(1)

**F108** Art. 41(7) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 31(5)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Article 42

### Check of information submitted and follow-up to dossier evaluation

1 The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.

2 Once the dossier evaluation is completed, the Agency shall notify the [F109 appropriate authorities that request the notification] of the information obtained and any conclusions made. F110 ... The Agency shall use the information obtained from this evaluation for the purposes of Article 44.

#### Textual Amendments

**F109** Words in Art. 42(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 32(a); 2020 c. 1, Sch. 5 para. 1(1)

**F110** Words in Art. 42(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 32(b); 2020 c. 1, Sch. 5 para. 1(1)

## Article 43

### Procedure and time periods for examination of testing proposals

1 In the case of non phase-in substances, the Agency shall prepare a draft decision in accordance with Article 40(3) within 180 days of receiving a registration or downstream user report containing a testing proposal.

2 In the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 40(3):

<sup>F111</sup>a .....

<sup>F111</sup>b .....

c by 1 June [F112 2023] for any registrations [F113 containing testing proposals received by ECHA] by 1 June 2018.

3 The list of registration dossiers being evaluated under Article 40 shall be made available to [F114 appropriate authorities that request it].

#### Textual Amendments

**F111** Art. 43(2)(a)(b) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 33(2)(a); 2020 c. 1, Sch. 5 para. 1(1)

**F112** Word in Art. 43(2)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 33(2)(b)(i); 2020 c. 1, Sch. 5 para. 1(1)

**F113** Words in Art. 43(2)(c) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 33(2)(b)(ii); 2020 c. 1, Sch. 5 para. 1(1)

**F114** Words in Art. 43(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 33(3); 2020 c. 1, Sch. 5 para. 1(1)

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

## CHAPTER 2

### Substance evaluation

#### Article 44

#### Criteria for substance evaluation

1 <sup>[F115]</sup>The] Agency shall in cooperation with the <sup>[F116]</sup>appropriate authorities] develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider:

- a hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
- b exposure information;
- c tonnage, including aggregated tonnage from the registrations submitted by several registrants.

2 The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft <sup>F117</sup>... rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. <sup>[F118]</sup>The Agency must submit its draft rolling action plan to the appropriate authorities within 12 months of IP completion day and give the appropriate authorities the opportunity to comment on it. The Agency must submit a draft annual update to its rolling action plan by 31 May in each subsequent year and give the appropriate authorities the opportunity to comment on it. The Agency must adopt a final rolling annual action plan for each year (after taking account of any comments made on the draft by the appropriate authorities) and must publish it on its website.]

<sup>F119</sup>  
...

#### Textual Amendments

- F115** Word in Art. 44(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 34(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F116** Words in Art. 44(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 34(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F117** Word in Art. 44(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 34(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F118** Words in Art. 44(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 34(3)(a)(ii)** (as amended by S.I. 2019/1144, regs. 1, **3(2)(a)(b)**) (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**) and S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, Sch. 5 para. 1(1)
- F119** Words in Art. 44(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 34(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Article 45

### [<sup>F120</sup>Evaluation of substances on the rolling action plan]

1 The Agency shall be responsible for <sup>F121</sup>... ensuring that substances on the <sup>F122</sup>... rolling action plan are evaluated. <sup>F123</sup>...

<sup>F124</sup> 2 .....

<sup>F124</sup> 3 .....

<sup>F124</sup> 4 .....

<sup>F124</sup> 5 .....

#### Textual Amendments

**F120** Art. 45 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 35(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F121** Words in Art. 45(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 35(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

**F122** Word in Art. 45(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 35(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

**F123** Words in Art. 45(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 35(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

**F124** Art. 45(2)-(5) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 35(4)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 46

### Requests for further information and check of information submitted

1 If the [<sup>F125</sup>Agency] considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the <sup>F126</sup>... rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.

2 The registrant shall submit the information required to the Agency by the deadline set.

3 The [<sup>F127</sup>Agency] shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

4 The [<sup>F128</sup>Agency] shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2 <sup>F129</sup>.... If this deadline is exceeded, the evaluation shall be deemed to be finished.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

#### Textual Amendments

- F125** Word in Art. 46(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 36(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F126** Word in Art. 46(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 36(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F127** Word in Art. 46(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 36(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F128** Word in Art. 46(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 36(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F129** Words in Art. 46(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 36(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 47

#### Coherence with other activities

1 An evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Title. Where information on intrinsic properties of a substance has been generated by reference to structurally related substance(s), the evaluation may also cover these related substances. In cases where a decision on an evaluation has been previously taken in accordance with Article 51 or Article 52, any draft decision requiring further information under Article 46 may be justified only by a change of circumstances or acquired knowledge.

<sup>F130</sup> 2 .....

#### Textual Amendments

- F130** Art. 47(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 37**; 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F131</sup> Article 48

#### Follow-up to substance evaluation

Once the substance evaluation has been completed, the Agency must consider how to use the information obtained from this evaluation for the purposes of Article 59(3) and Article 69(4). The Agency must inform the appropriate authorities and the registrant of its conclusions as to whether or how to use the information obtained.]

#### Textual Amendments

- F131** Art. 48 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 38**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## CHAPTER 3

### Evaluation of intermediates

#### Article 49

##### Further information on on-site isolated intermediates

For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, where the [<sup>F132</sup>Agency] considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:

- (a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;
- (b) examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

[<sup>F133</sup>Where the appropriate authority in relation to the part of Great Britain where the site is located considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, that appropriate authority may request the Agency to take the steps set out in points (a) and (b) of the first paragraph.

The Agency must inform the appropriate authorities that request them of the results of an assessment under this Article.]

#### Textual Amendments

**F132** Word in Art. 49 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 39(a); 2020 c. 1, Sch. 5 para. 1(1)

**F133** Words in Art. 49 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 39(b) (as amended by S.I. 2020/1577, regs. 1(1)(b), 4(21)); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 4

### Common provisions

#### Article 50

##### Registrants' and downstream users' rights

1 The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency.<sup>F134</sup>...



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

2 If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform the Agency of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use. The Agency shall inform the <sup>F135</sup>appropriate authorities that request it, when a registrant has informed the Agency in accordance with this paragraph].

3 The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the draft decision. In such cases, the registrant, or downstream user, shall inform the Agency of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report. The Agency shall inform the <sup>F136</sup>appropriate authorities that request it, when a registrant has informed the Agency in accordance with this paragraph].

4 Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 46 in either or both of the following cases:

- a where the <sup>F137</sup>Agency] prepares a dossier in accordance with Annex XV concluding that there is a potential long-term risk to human health or the environment justifying the need for further information;
- b where the exposure to the substance manufactured or imported by the registrant(s), or to the substance in the article produced or imported by the registrant(s), or to the substance used by the downstream user(s) contributes significantly to that risk.

The procedure in Articles 69 to 73 shall apply *mutatis mutandis*.

#### Textual Amendments

**F134** Words in Art. 50(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 40(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F135** Words in Art. 50(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 40(3)**; 2020 c. 1, Sch. 5 para. 1(1)

**F136** Words in Art. 50(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 40(3)**; 2020 c. 1, Sch. 5 para. 1(1)

**F137** Word in Art. 50(4)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 40(4)**; 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F138</sup> Article 51

#### Adoption of decisions under dossier evaluation

1 This Article applies where the Agency has notified its draft decision in accordance with Article 40 or 41.

2 If the Agency receives no comments from the registrant or downstream user, the Agency must make its decision in the version notified under paragraph 1.

3 If the Agency receives any comments from the registrant or downstream user, the Agency must—

- a take the comments into account, and



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- b make its decision (whether that is to make the decision in the version notified or vary the decision notified).

4 The Agency must notify the registrant or downstream user and the appropriate authorities of the decision made under paragraph 2 or 3.

5 An appeal may be brought, in accordance with Articles 91, 92 and 93 against a decision made under paragraph 2 or 3.]

#### Textual Amendments

**F138** Art. 51 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 41**; 2020 c. 1, Sch. 5 para. 1(1)

### *F139* Article 52

#### **Adoption of decisions under substance evaluation**

1 This Article applies where the Agency has circulated its draft decision in accordance with Article 46.

2 If the Agency receives no comments from the registrant or the downstream user, the Agency must make its decision in the version circulated under paragraph 1.

3 If the Agency receives any comments from the registrant or the downstream user, the Agency must—

- a take the comments into account, and
- b make its decision (whether that is to make the decision in the version circulated or vary the decision circulated).

4 The Agency must notify the registrant or the downstream user, and the appropriate authorities, of the decision made under paragraph 2 or 3.

5 An appeal may be brought, in accordance with Articles 91, 92 and 93 against a decision made under paragraph 2 or 3.]

#### Textual Amendments

**F139** Art. 52 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 42**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 53

#### **Cost sharing for tests without an agreement between registrants and/or downstream users**

1 Where registrants or downstream users are required to perform a test as a result of a decision taken under this Title, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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2 If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

3 In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.

4 The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

#### Article 54

### Publication of information on evaluation

By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

## TITLE VII

### AUTHORISATION

#### CHAPTER 1

### Authorisation requirement

#### Article 55

### Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the good functioning of the [F<sup>140</sup>market in Great Britain] while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

#### Textual Amendments

**F140** Words in Art. 55 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 43** (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), **4(22)**); 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## Article 56

### General provisions

1 A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

- a the use(s) of that substance on its own or in a [F<sup>1</sup>mixture] or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
- b the use(s) of that substance on its own or in a [F<sup>1</sup>mixture] or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
- c the date referred to in Article 58(1)(c)(i) has not been reached; or
- d the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
- e in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

2 A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.

3 Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.

4 Paragraphs 1 and 2 shall not apply to the following uses of substances:

- a uses in plant protection products within the scope of [F<sup>141</sup>Regulation (EC) No 1107/2009];
- b uses in biocidal products within the scope of [F<sup>142</sup>Regulation (EU) No 528/2012];
- c use as motor fuels covered by [F<sup>143</sup>the Motor Fuel (Composition and Content) Regulations 1999];
- d uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

5 In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

- a uses in cosmetic products within the scope of [F<sup>144</sup>Regulation (EC) No 1223/2009];
- b uses in food contact materials within the scope of Regulation (EC) No 1935/2004.

6 Paragraphs 1 and 2 shall not apply to the use of substances when they are present in [F<sup>1</sup>mixtures]:

- a for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);
- [F<sup>1</sup>b for all other substances, below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which result in the classification of the mixture as hazardous.]

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F141** Words in Art. 56(4)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 44(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F142** Words in Art. 56(4)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 44(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F143** Words in Art. 56(4)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 44(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F144** Words in Art. 56(5)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 44(3)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 57

#### Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

- (a) [<sup>F1</sup>substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;
- (b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;
- (c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008;]
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
- (f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and

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repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

## Article 58

### Inclusion of substances in Annex XIV

1 <sup>F145</sup>The Secretary of State may, by regulations, include in Annex 14 substances referred to in Article 57. The regulations must specify for each substance:]

- a the identity of the substance as specified in Section 2 of Annex VI;
- b the intrinsic property (properties) of the substance referred to in Article 57;
- c transitional arrangements:
  - (i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use;
  - (ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;
- d review periods for certain uses, if appropriate;
- e uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

2 Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific <sup>F146</sup>... legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

3 Prior to a decision to include substances in Annex XIV, the Agency shall <sup>F147</sup>... recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

- a PBT or vPvB properties; or
- b wide dispersive use; or
- c high volumes.

The number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIV [<sup>F148</sup>within 12 months of IP completion day]. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV.

4 Before the Agency sends its recommendation to the [<sup>F149</sup>appropriate authorities] it shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 118 and 119 on access to information. The Agency shall invite all interested

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parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

The Agency shall update its recommendation, taking into account the comments received.

5 Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a [F1 mixture] or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV.

6 A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in (an) article(s).

7 Substances for which all uses have been prohibited under Title VIII or by other F150 ... legislation shall not be included in Annex XIV or shall be removed from it.

[F151 8 The Secretary of State may, by regulations, remove from Annex 14 substances which as a result of new information no longer meet the criteria of Article 57.]

[F1529 Regulations under paragraph 1 or 8 are to be made by statutory instrument; and a statutory instrument containing regulations under paragraph 1 or 8 is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under paragraph 1 or 8 is subject to the consent requirement in Article 4A.]

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F145** Words in Art. 58(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F146** Word in Art. 58(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F147** Words in Art. 58(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F148** Words in Art. 58(3) substituted (31.12.2020) by virtue of S.I. 2019/758, **Sch. 1 para. 45(4)(b)** (as amended by The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144), regs. 1, **3(3)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**) and S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F149** Words in Art. 58(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F150** Word in Art. 58(7) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(6)**; 2020 c. 1, Sch. 5 para. 1(1)
- F151** Art. 58(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F152** Art. 58(9) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(8)**; 2020 c. 1, Sch. 5 para. 1(1)



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## Article 59

### Identification of substances referred to in Article 57

1 The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).

[<sup>F153</sup>1A The Agency must include in its candidate list every substance that is included in ECHA's candidate list under Article 59(1) of EU REACH immediately before IP completion day.]

2 [<sup>F154</sup>An appropriate authority] may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57. [<sup>F1</sup>The dossier may be limited, if appropriate, to a reference to an entry in [<sup>F155</sup>the GB mandatory classification and labelling list].] The Agency shall make this dossier available to the [<sup>F156</sup>appropriate authorities].

3 [<sup>F157</sup>The Agency] may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 <sup>F158</sup>.... [<sup>F1</sup>The dossier may be limited, if appropriate, to a reference to an entry in [<sup>F159</sup>the GB mandatory classification and labelling list].] The Agency shall make this dossier available [<sup>F160</sup>to the appropriate authorities].

4 The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.

<sup>F161</sup> 5 .....

6 If the Agency does not receive <sup>F162</sup>... any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3).

7 When comments are <sup>F163</sup>... received, the Agency [<sup>F164</sup>must consider the comments and make a decision on the identification of the substance within 45 days of the deadline specified in paragraph 4].

<sup>F165</sup> 8 .....

<sup>F165</sup> 9 .....

10 The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.

#### Textual Amendments

**F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

**F153** Art. 59(1A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 46(2) (as amended by S.I. 2020/1313, regs. 1(3), 6(2)); 2020 c. 1, Sch. 5 para. 1(1)

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- F154** Words in Art. 59(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F155** Words in Art. 59(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 4** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(c)**); 2020 c. 1, Sch. 5 para. 1(1)
- F156** Words in Art. 59(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F157** Words in Art. 59(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F158** Words in Art. 59(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F159** Words in Art. 59(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 4** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(c)**); 2020 c. 1, Sch. 5 para. 1(1)
- F160** Words in Art. 59(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F161** Art. 59(5) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F162** Words in Art. 59(6) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(6)**; 2020 c. 1, Sch. 5 para. 1(1)
- F163** Words in Art. 59(7) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(7)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F164** Words in Art. 59(7) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F165** Art. 59(8)(9) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(8)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 2

### Granting of authorisations

#### Article 60

### Granting of authorisations

1 The [F166Secretary of State] shall be responsible for taking decisions on applications for authorisations in accordance with this Title. [F167That responsibility of the Secretary of State is subject to the provisions of this Title which make the exercise of certain functions subject to the consent requirement in Article 4A.]

2 Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the [F168Agency so far as the opinion relates to the elements] referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the [F169Secretary of State] shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.



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The [<sup>F169</sup>Secretary of State] shall not consider the risks to human health arising from the use of a substance in a [<sup>F170</sup>relevant medical device].

3 Paragraph 2 shall not apply to:

- a substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;
- b substances meeting the criteria in Article 57(d) or (e);
- c substances identified under Article 57(f) having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties.

4 If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account [<sup>F171</sup>the elements] referred to in Article 64(4)(a) and (b):

- a the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
- b the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
- c the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);
- d available information on the risks to human health or the environment of any alternative substances or technologies.

5 When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the [<sup>F172</sup>Secretary of State], including:

- a whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;
- b the technical and economic feasibility of alternatives for the applicant.

6 A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII.

7 An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.

8 Authorisations shall be subject to a time-limited review without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring. The duration of the time-limited review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate.

9 The authorisation shall specify:

- a the person(s) to whom the authorisation is granted;
- b the identity of the substance(s);
- c the use(s) for which the authorisation is granted;
- d any conditions under which the authorisation is granted;
- e the time-limited review period;
- f any monitoring arrangement.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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10 Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.

#### Textual Amendments

- F166** Words in Art. 60(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F167** Words in Art. 60(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F168** Words in Art. 60(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F169** Words in Art. 60(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F170** Words in Art. 60(2) substituted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), 4
- F171** Words in Art. 60(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F172** Words in Art. 60(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(5)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 61

#### Review of authorisations

1 Authorisations granted in accordance with Article 60 shall be regarded as valid until the [<sup>F173</sup>Secretary of State] decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.

A holder of an authorisation granted in accordance with Article 60 shall submit an update of the analysis of alternatives referred to in Article 62(4)(e), including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan submitted under Article 62(4)(f). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall submit a substitution plan, including a timetable for proposed actions by the applicant. If the holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis contained in the original application.

If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.

If any other elements of the original application have changed, he shall also submit updates of these element(s).

When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorisation in the context of the review shall be taken in accordance with the procedure referred to in Article 64 applied *mutatis mutandis*.

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[<sup>F174</sup>The function of deciding under this paragraph whether to amend or withdraw the authorisation is subject to the consent requirement in Article 4A.]

- 2 Authorisations may be reviewed at any time if:
- a the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or
  - b new information on possible substitutes becomes available.

The [<sup>F175</sup>Secretary of State] shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 64.

[<sup>F176</sup>Any of the other appropriate authorities may request the Secretary of State to carry out a review of an authorisation under this paragraph.]

3 In its review decision the [<sup>F177</sup>Secretary of State] may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorisation, if under the changed circumstances it would not have been granted or if suitable alternatives in accordance with Article 60(5) become available. In the latter case the [<sup>F177</sup>Secretary of State] shall require the holder of the authorisation to present a substitution plan if he has not already done so as part of his application or update.

In cases where there is a serious and immediate risk for human health or the environment, the [<sup>F177</sup>Secretary of State] may suspend the authorisation pending the review, taking into account the principle of proportionality.

[<sup>F178</sup>Where the Secretary of State is carrying out a review of an authorisation under this paragraph, any of the other appropriate authorities may request the Secretary of State to suspend the authorisation while the review is being carried out.

The function of deciding under the first subparagraph whether to amend or withdraw the authorisation, and the function of deciding under the second subparagraph whether to suspend the authorisation, are subject to the consent requirement in Article 4A.]

4 If an environmental quality standard <sup>F179</sup>... is not met, the authorisations granted for the use of the substance concerned may be reviewed.

5 If the [<sup>F180</sup>river basin] environmental objectives <sup>F181</sup>... are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

6 If a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants <sup>(30)</sup>, the [<sup>F182</sup>Secretary of State] shall withdraw the authorisation for that use.

[<sup>F183</sup>7 In this Article—

- a “environmental quality standard” means the set of requirements which must be fulfilled at a given time in relation to a given environment or particular part thereof, as set out in retained EU law;
- c “river basin district in Scotland” means an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003;
- d “river basin environmental objectives” means—
  - i in relation to the Northumbria River Basin District, the environmental objectives referred to in the WFD Regulations as applied by regulation 5 of the

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- Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003;
- ii in relation to the Solway Tweed River Basin District, the environmental objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004;
- iii in relation to any other river basin district within the meaning of the WFD Regulations, the environmental objectives referred to in those Regulations;
- iv in relation to a river basin district in Scotland, the environmental objectives set under section 9(1)(a) of the Water Environment and Water Services (Scotland) Act 2003;
- e “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017.]

#### Textual Amendments

- F173** Words in Art. 61(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F174** Words in Art. 61(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F175** Words in Art. 61(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F176** Words in Art. 61(2) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F177** Words in Art. 61(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F178** Words in Art. 61(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F179** Words in Art. 61(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F180** Words in Art. 61(5) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F181** Words in Art. 61(5) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F182** Words in Art. 61(6) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F183** Art. 61(7) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(8)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(23)**); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 62

#### Applications for authorisations

- 1 An application for an authorisation shall be made to the Agency.
- 2 Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.
- 3 Applications may be made for one or several substances, that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications

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may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.

- 4 An application for authorisation shall include the following information:
  - a the identity of the substance(s), as referred to in Section 2 of Annex VI;
  - b the name and contact details of the person or persons making the application;
  - c a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in [F1mixtures] and/or the incorporation of the substance in articles, where this is relevant;
  - d unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;
  - e an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
  - f where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.
- 5 The application may include:
  - a a socio-economic analysis conducted in accordance with Annex XVI;
  - b a justification for not considering risks to human health and the environment arising either from:
    - i emissions of a substance from an installation for which a permit [F184to carry out an activity referred to in Annex I to Directive 2010/75/EU was granted in accordance with retained EU law]; or
    - [F185;ii discharges of a substance from a point source governed by retained EU law that transposed the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy.]
- 6 The application shall not include the risks to human health arising from the use of a substance in a [F186relevant medical device].
- 7 An application for an authorisation shall be accompanied by the fee required in accordance with Title IX.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F184** Words in Art. 62(5)(b)(i) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 49(2)(a); 2020 c. 1, Sch. 5 para. 1(1)
- F185** Art. 62(5)(b)(ii) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 49(2)(b); 2020 c. 1, Sch. 5 para. 1(1)
- F186** Words in Art. 62(6) substituted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), 5

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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### Article 63

#### Subsequent applications for authorisation

1 If an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.

2 If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.

3 Before referring to any previous application in accordance with paragraphs 1 and 2, the subsequent applicant shall update the information of the original application as necessary.

### Article 64

#### Procedure for authorisation decisions

1 The Agency shall acknowledge the date of receipt of the application. [<sup>F187</sup>The Agency must give its draft opinion within ten months of the date of receipt of the application].

2 The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

[<sup>F188</sup> 3 In preparing its opinion, the Agency must first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Agency must request additional information to bring the application into conformity with the requirements of Article 62. The Agency may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. The Agency, and any scientific adviser providing the Agency with scientific knowledge and advice in relation to the opinion, must take into account any information submitted by third parties.]

[<sup>F189</sup>3A In paragraph 3 “scientific adviser” means a person who the Agency has commissioned (in compliance with the duty imposed by Article 77(A1)) to provide it with scientific knowledge and advice.]

4 The draft [<sup>F190</sup>opinion] shall include the following elements:

- a <sup>F191</sup>... An assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;
- b <sup>F192</sup>... An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

5 The Agency shall send [<sup>F193</sup>its draft opinion] to the applicant by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.

If the applicant does not wish to comment, the Agency shall send [<sup>F194</sup>its final opinion to the appropriate authorities] and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. The [<sup>F195</sup>Agency] shall consider the comments and adopt [<sup>F196</sup>its] final [<sup>F197</sup>opinion] within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the [<sup>F197</sup>opinion], with the written argumentation attached, to the [<sup>F198</sup>appropriate authorities] and the applicant.

6 The Agency shall determine in accordance with Articles 118 and 119 which parts of its [<sup>F199</sup>opinion] and parts of any attachments thereto should be made publicly available on its website.

7 In cases covered by Article 63(1), the Agency shall treat the applications together, provided the deadlines for the first application can be met.

[<sup>F200</sup> 8 The Secretary of State must make a decision granting or refusing the authorisation within six months of receipt of the opinion from the Agency.

The function in this paragraph of deciding whether to grant or refuse the authorisation is subject to the consent requirement in Article 4A.]

9 Summaries of the [<sup>F201</sup>decisions of the Secretary of State], including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, shall be published [<sup>F202</sup>by the Secretary of State] and shall be made publicly available in a database established and kept up to date by the Agency.

10 In cases covered by Article 63(2), the deadline set out in paragraph 1 of this Article shall be shortened to five months.

#### Textual Amendments

- F187** Words in Art. 64(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F188** Art. 64(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F189** Art. 64(3A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F190** Word in Art. 64(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F191** Words in Art. 64(4)(a) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F192** Words in Art. 64(4)(b) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F193** Words in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F194** Words in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F195** Word in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F196** Word in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F197** Word in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F198** Words in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F199** Word in Art. 64(6) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F200** Art. 64(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(8)**; 2020 c. 1, Sch. 5 para. 1(1)
- F201** Words in Art. 64(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(9)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F202** Words in Art. 64(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(9)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 3

### Authorisations in the supply chain

#### Article 65

#### Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a [<sup>F1</sup>mixture], shall include the authorisation number on the label before they place the substance or a [<sup>F1</sup>mixture] containing the substance on the market for an authorised use <sup>F203</sup>.... This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F203** Words in Art. 65 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 51**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 66

#### Downstream users

1 Downstream users using a substance in accordance with Article 56(2) shall notify the Agency within three months of the first supply of the substance.



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

2 The Agency shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. The Agency shall grant access to this register to the [<sup>F204</sup>appropriate authorities].

**Textual Amendments**

**F204** Words in Art. 66(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 52; 2020 c. 1, Sch. 5 para. 1(1)

TITLE VIII

**RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, [<sup>F1</sup>MIXTURES] AND ARTICLES**

CHAPTER 1

**General issues**

*Article 67*

**General provisions**

1 A substance on its own, in a [<sup>F1</sup>mixture] or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

2 Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by [<sup>F205</sup>Regulation 1223/2009], with regard to restrictions addressing the risks to human health within the scope of that [<sup>F206</sup>Regulation].

<sup>F207</sup> 3 .....

**Textual Amendments**

**F205** Words in Art. 67(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 53(2)(a); 2020 c. 1, Sch. 5 para. 1(1)

**F206** Word in Art. 67(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 53(2)(b); 2020 c. 1, Sch. 5 para. 1(1)

**F207** Art. 67(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 53(3); 2020 c. 1, Sch. 5 para. 1(1)

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

## CHAPTER 2

### Restrictions process

#### Article 68

#### Introducing new and amending current restrictions

1 When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances,<sup>F208</sup> ... Annex XVII shall be amended [F209by regulations made by the Secretary of State which provide for the adoption of new restrictions or the amendment of] current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in [F1mixtures] or in articles, pursuant to the procedure set out in Articles 69 to 73. [F210In exercising the power to make regulations under this paragraph, the Secretary of State] shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.

[F12 For a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers [F211the Secretary of State may propose restrictions. The function of proposing restrictions is subject to the consent requirement in Article 4A. The Secretary of State may, by regulations, amend Annex 17 to give effect to a proposed restriction.] Articles 69 to 73 shall not apply.]

[F2123 Regulations under paragraph 2 of this Article are to be made by statutory instrument; and a statutory instrument containing regulations made under paragraph 2 of this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under paragraph 2 of this Article is subject to the consent requirement in Article 4A.]

#### Textual Amendments

- F208** Words in Art. 68(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 54(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F209** Words in Art. 68(1) substituted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 54(2)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F210** Words in Art. 68(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 54(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F211** Words in Art. 68(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 54(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F212** Art. 68(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 54(4)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## Article 69

### Preparation of a proposal

1 If [<sup>F213</sup>an appropriate authority] considers that the manufacture, placing on the market or use of a substance on its own, in a [<sup>F1</sup>mixture] or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XV.

2 After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.

3 Within 12 months of the receipt of the request from [<sup>F214</sup>an appropriate authority] in paragraph 1 and if this dossier demonstrates that action <sup>F215</sup>... is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

[<sup>F216</sup> 4 If the Agency considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, the Agency must prepare a dossier which conforms to the requirements and format of the relevant sections of Annex 15. If this dossier demonstrates that action is necessary, beyond any measures already in place, the Agency must initiate the restrictions process and must inform those who submitted a registration for that substance.

The Agency must refer to any dossier, chemical safety report or risk assessment submitted to it under this Regulation. The Agency must also refer to any relevant risk assessment submitted for other regulatory purposes. To this end other public bodies carrying out a similar task must provide information to the Agency on request.]

[<sup>F217</sup> 5 The Agency must maintain a list of substances for which a dossier conforming to the requirements of Annex 15 is planned or underway for the purposes of a proposed restriction.]

[<sup>F218</sup> 5A The Agency or an appropriate authority may propose the re-examination of an existing restriction listed in Annex 17.

If the Agency is proposing the re-examination, it must notify the appropriate authorities of the proposal. If an appropriate authority is proposing a re-examination, it must notify the Agency and the other appropriate authorities of the proposal. Where a re-examination is proposed (by the Agency or an appropriate authority), the Secretary of State must decide, on the basis of evidence presented by whoever proposed the re-examination, whether the re-examination should take place. That function of deciding whether the re-examination should take place is subject to the consent requirement in Article 4A. If the Secretary of State decides that the re-examination should take place, the Agency must carry out the re-examination.]

6 Without prejudice to Articles 118 and 119, the Agency shall make publicly available on its website all dossiers conforming with Annex XV including the restrictions suggested pursuant to paragraphs 3 and 4 of this Article without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly within six months of the date of publication:

- a comments on dossiers and the suggested restrictions;

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- b a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions. It shall conform to the requirements in Annex XVI.

#### Textual Amendments

- F213** Words in Art. 69(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F214** Words in Art. 69(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F215** Words in Art. 69(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F216** Art. 69(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F217** Art. 69(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F218** Art. 69(5A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(6)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 70

#### Agency opinion: [<sup>F219</sup> risk assessment]

Within nine months of the date of publication referred to in Article 69(6), the [<sup>F220</sup> Agency] shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the [<sup>F221</sup> dossier], and the views of interested parties referred to in Article 69(6)(a).

#### Textual Amendments

- F219** Words in Art. 70 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 56(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F220** Word in Art. 70 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 56(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F221** Word in Art. 70 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 56(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 71

#### Agency opinion: [<sup>F222</sup> socio-economic analysis]

<sup>1</sup> Within 12 months of the date of publication referred to in Article 69(6), the [<sup>F223</sup> Agency] shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

2 The [F<sup>224</sup>Agency] shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under Article 69(6) (b) and under paragraph 1 of this Article.

F<sup>225</sup> 3 .....

#### Textual Amendments

- F222** Words in Art. 71 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 57(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F223** Word in Art. 71(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 57(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F224** Word in Art. 71(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 57(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F225** Art. 71(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 57(4)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 72

#### Submission of an opinion to the [F<sup>226</sup>appropriate authorities]

1 The Agency shall submit to the [F<sup>227</sup>appropriate authorities] without delay [F<sup>228</sup>its opinions on risk assessment and socio-economic analysis] on restrictions suggested for substances on their own, in [F<sup>1</sup>mixtures] or in articles. If [F<sup>229</sup>the Agency does] not formulate an opinion by the deadline set in Article 70 and Article 71(1) the Agency shall inform the [F<sup>230</sup>appropriate authorities] accordingly, stating the reasons.

2 Without prejudice to Articles 118 and 119 the Agency shall publish [F<sup>231</sup>its opinions] on its website without delay.

3 The Agency shall provide the [F<sup>232</sup>appropriate authorities that request them] with all documents and evidence submitted to or considered by it.

#### Textual Amendments

- F226** Words in Art. 72 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F227** Words in Art. 72(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F228** Words in Art. 72(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F229** Words in Art. 72(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F230** Words in Art. 72(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F231** Words in Art. 72(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F232** Words in Art. 72(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(5)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### Article 73

#### [<sup>F233</sup>Restriction decisions]

1 If the conditions laid down in Article 68 are fulfilled, the [<sup>F234</sup>Secretary of State must propose] a draft amendment to Annex XVII, within three months of receipt of [<sup>F235</sup>the Agency's opinions]. [<sup>F236</sup>The functions of deciding whether to propose a draft amendment, and of proposing a draft amendment, are subject to the consent requirement in Article 4A.]

Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the [<sup>F237</sup>Secretary of State] shall annex a detailed explanation of the reasons for the differences.

[<sup>F238</sup>2 The Secretary of State may, by regulations, amend Annex 17 to include the draft amendment.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.]

#### Textual Amendments

- F233** Art. 73 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F234** Words in Art. 73(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F235** Words in Art. 73(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F236** Words in Art. 73(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(3)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F237** Words in Art. 73(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F238** Art. 73(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(4)**; 2020 c. 1, Sch. 5 para. 1(1)

## TITLE IX

### FEES AND CHARGES

#### Article 74

##### Fees and charges

1 [<sup>F239</sup>The Secretary of State may, by regulations, specify the fees] that are required according to Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2), Article 18(2), Article 19(3), Article 22(5) [<sup>F240</sup>and Article 62(7)].

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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[<sup>F241</sup>Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.]

2 A fee need not be paid for a registration of a substance in a quantity of between 1 and 10 tonnes where the registration dossier contains the full information in Annex VII.

3 <sup>F242</sup> ...

In the case of Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2) and Article 18(2), the structure and amount of fees shall take account of the tonnage range of the substance being registered.

In all cases, a reduced fee shall be set for SMEs.

In the case of Article 11(4), the structure and amount of fees shall take into account whether information has been submitted jointly or separately.

In the case of a request made under Article 10(a)(xi), the structure and amount of fees shall take into account the work required by the Agency in assessing the justification.

<sup>F243</sup> 4 .....

5 The Agency may collect charges for other services it provides.

#### Textual Amendments

- F239** Words in Art. 74(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 60(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F240** Words in Art. 74(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 60(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F241** Words in Art. 74 inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 60(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F242** Words in Art. 74(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 60(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F243** Art. 74(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 60(5)**; 2020 c. 1, Sch. 5 para. 1(1)

## TITLE X

### AGENCY

#### <sup>F244</sup> Article 75

### Establishment and review

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### Textual Amendments

**F244** Art. 75 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 61**; 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F245</sup> Article 76

#### Composition

### Textual Amendments

**F245** Art. 76 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 61**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 77

#### Tasks

<sup>F246</sup>A1 When forming opinions the Agency must take relevant scientific knowledge and advice into account (including any relevant knowledge and advice relating to socio-economic matters).

A2 The Agency may take any such knowledge or advice into account when forming an opinion only if—

- a the knowledge or advice has been commissioned by the Agency, from one or more suitably qualified or experienced persons who are independent of the Agency, for the purposes of forming the opinion concerned, or
- b the knowledge or advice—
  - i is already in existence (whether within the Agency or externally),
  - ii is produced within the Agency for the purposes of forming the opinion concerned, or
  - iii is, in accordance with Article 2B, produced by the Environment Agency or one of the other environmental regulators in connection with the Agency forming the opinion concerned and then passed on to the Agency, and the Agency considers that it is appropriate to take it into account, rather than to commission knowledge or advice in compliance with point (a).

The knowledge or advice that the Agency may take into account in compliance with point (b)(i) includes knowledge or advice which has previously been commissioned by the Agency from one or more suitably qualified or experienced persons who are independent of the Agency for the purposes of forming a previous opinion on any matter.

A3 The Agency must comply with this paragraph if—

- a it is forming—
  - i an opinion in connection with deciding whether to grant an authorisation under Article 60,



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- ii an opinion under Article 70 as to whether suggested restrictions are appropriate in reducing the risk to human health or the environment, or
  - iii an opinion under Article 71 on suggested restrictions and on the related socio-economic impact, and
- b it only takes into account knowledge or advice that is not commissioned in compliance with paragraph A2(a) for the purposes of forming that opinion.

The Agency must—

- a produce an explanation of why it considered that it was appropriate to take only that knowledge or advice into account,
- b publish the explanation, and
- c send a copy of the explanation to the appropriate authorities.

A4 When exercising its functions, the Agency must act in a way that ensures a high degree of transparency.

A5 The Agency must produce and publish a statement of how it will comply with paragraphs A1, A2 and A4.

The Agency must produce and publish the first statement within the period of 3 months beginning with the day after IP completion day.

The Agency must consult such persons as it considers appropriate before producing the first, or any subsequent, statement.

A6 The statement must include—

- a information about the qualifications or relevant experience that are suitable in order for persons to be commissioned to provide knowledge or advice to the Agency,
- b examples of situations in which the Agency envisages that it might be appropriate to take existing knowledge or advice (rather than knowledge or advice commissioned as mentioned in paragraph A2(a)) into account.

A7 Paragraphs A1 to A6 do not limit the Agency's duties under Article 2B.]

1 The Agency shall provide the [<sup>F247</sup>appropriate authorities] with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2 [<sup>F248</sup>The Agency] shall undertake the following tasks:

- <sup>F249</sup>a .....
- <sup>F249</sup>b .....
- <sup>F249</sup>c .....
- <sup>F249</sup>d .....
- <sup>F1</sup>(e) establishing and maintaining database(s) with information on all registered substances<sup>F250</sup> ....] It shall make the information identified in Article 119(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified.<sup>F251</sup> ...;
- f making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 119(1);
- g providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;

- <sup>F252</sup>h .....  
 i providing guidance to stakeholders <sup>F253</sup>... on communication to the public of information on the risks and safe use of substances, on their own, in [<sup>F1</sup>mixtures] or in articles;  
 j providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1);  
 k preparing explanatory information on this Regulation for other stakeholders;  
 l at the <sup>F254</sup>... request [<sup>F255</sup>of any appropriate authority], providing technical and scientific support for steps to improve cooperation [<sup>F256</sup>with] international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;  
 m keeping a Manual of Decisions and Opinions <sup>F257</sup>... regarding interpretation and implementation of this Regulation;  
 n notification of decisions taken by the Agency;  
 o provision of formats for submission of information to the Agency.
- <sup>F258</sup> 3 .....  
<sup>F258</sup> 4 .....

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F246** Arts. 77(A1)-(A7) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(2)** (as amended by S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, Sch. 5 para. 1(1)
- F247** Words in Art. 77(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F248** Words in Art. 77(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F249** Art. 77(2)(a)-(d) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F250** Words in Art. 77(2)(e) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F251** Words in Art. 77(2)(e) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F252** Art. 77(2)(h) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F253** Words in Art. 77(2)(i) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F254** Word in Art. 77(2)(l) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(f)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F255** Words in Art. 77(2)(l) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(f)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F256** Word in Art. 77(2)(l) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(f)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F257** Words in Art. 77(2)(m) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(4)(g)**; 2020 c. 1, Sch. 5 para. 1(1)
- F258** Art. 77(3)(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 62(5)**; 2020 c. 1, Sch. 5 para. 1(1)

*F259 Article 78*

**Powers of the Management Board**

**Textual Amendments**

- F259** Arts. 78-82 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 63**; 2020 c. 1, Sch. 5 para. 1(1)

*F259 Article 79*

**Composition of the Management Board**

**Textual Amendments**

- F259** Arts. 78-82 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 63**; 2020 c. 1, Sch. 5 para. 1(1)

*F259 Article 80*

**Chairmanship of the Management Board**

**Textual Amendments**

- F259** Arts. 78-82 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 63**; 2020 c. 1, Sch. 5 para. 1(1)

*F259 Article 81*

**Meetings of the Management Board**

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

#### Textual Amendments

**F259** Arts. 78-82 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 63](#); 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F259</sup> Article 82

### Voting of the Management Board

#### Textual Amendments

**F259** Arts. 78-82 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 63](#); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 83

#### [<sup>F260</sup> Annual report by the Agency to the appropriate authorities ]

<sup>F261</sup> 1 .....

<sup>F261</sup> 2 .....

3 Each year, the [<sup>F262</sup>Agency] shall submit the following to the [<sup>F263</sup>Secretary of State] for approval:

- a a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction [<sup>F264</sup>prepared by the Agency], the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; [<sup>F265</sup>the Agency's compliance with Article 77(A1) by taking into account scientific knowledge and advice (including knowledge and advice relating to socio-economic matters);] complaints received and the action taken<sup>F266</sup>....;
- b a draft work-programme for the coming year;
- c the draft annual accounts;
- d the draft forecast budget for the coming year;
- e a draft multiannual work programme.

[<sup>F267</sup>The Agency must provide any draft submitted to the Secretary of State under points (a) to (e) to the other appropriate authorities at the same time it is submitted to the Secretary of State.

The Secretary of State must consult the other appropriate authorities before giving approval to any draft submitted under points (a) to (e).]

#### Textual Amendments

**F260** Art. 83 heading substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 64\(2\)](#); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F261** Art. 83(1)(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F262** Word in Art. 83(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(4)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F263** Words in Art. 83(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(4)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F264** Words in Art. 83(3)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(4)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F265** Words in Art. 83(3)(a) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(4)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F266** Words in Art. 83(3)(a) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F267** Words in Art. 83(3)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 64(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

*F268 Article 84*

**Appointment of the Executive Director**

**Textual Amendments**

- F268** Arts. 84-87 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 65**; 2020 c. 1, Sch. 5 para. 1(1)

*F268 Article 85*

**Establishment of the Committees**

**Textual Amendments**

- F268** Arts. 84-87 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 65**; 2020 c. 1, Sch. 5 para. 1(1)

*F268 Article 86*

**Establishment of the Forum**

**Textual Amendments**

- F268** Arts. 84-87 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 65**; 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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<sup>F268</sup> Article 87

**Rapporteurs of Committees and use of experts**

**Textual Amendments**

**F268** Arts. 84-87 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 65**; 2020 c. 1, Sch. 5 para. 1(1)

Article 88

**Qualification and interests**

[<sup>F269</sup>1 The details of the suitably qualified or experienced persons that provide advice to the Agency under Article 77(A2)(a) must be made public. Individuals may request that their names not be made public if they believe that such publication could place them at risk. The Agency must decide whether to agree to such requests. When details are published, the professional qualifications of each suitably qualified or experienced person must be specified.]

2 [<sup>F270</sup>Suitably qualified or experienced persons that provide advice to the Agency pursuant to Article 77(A2)(a)] shall make a declaration of commitment to fulfil their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing and, without prejudice to paragraph 1, be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.

<sup>F271</sup> 3 .....

**Textual Amendments**

**F269** Art. 88(1) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 66(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F270** Words in Art. 88(2) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 66(3)**; 2020 c. 1, Sch. 5 para. 1(1)

**F271** Art. 88(3) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 66(4)**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F272</sup> Article 89

**Establishment of the Board of Appeal**

.....

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F272** Art. 89 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 67**; 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F273</sup> Article 90

## Members of the Board of Appeal

### Textual Amendments

**F273** Art. 90 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 67**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 91

## Decisions subject to appeal

1 An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), [<sup>F274</sup>Article 51 and Article 52].

[<sup>F275</sup>1A An appeal pursuant to paragraph 1 lies to the First-tier Tribunal.]

2 An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

[<sup>F276</sup>3 On an appeal pursuant to paragraph 1, the First-tier Tribunal—

a may dismiss the appeal, or

b if it allows the appeal may—

i quash the decision and (if appropriate) remit the matter to the Agency, or

ii substitute for the decision any other decision which could have been made by the Agency.]

### Textual Amendments

**F274** Words in Art. 91(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 68(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F275** Art. 91(1A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 68(3)**; 2020 c. 1, Sch. 5 para. 1(1)

**F276** Art. 91(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 68(4)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Article 92

### Persons entitled to appeal <sup>F277</sup> ...

1 Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former.

<sup>F278</sup> 2 .....

<sup>F278</sup> 3 .....

#### Textual Amendments

**F277** Words in Art. 92 heading omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 69(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F278** Art. 92(2)(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 69(3)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 93

### [<sup>F279</sup> Change of decision where appeal made]

[<sup>F280</sup> 1 If—

- a an appeal against a decision is brought pursuant to Article 91, and
- b the Agency considers the appeal to be admissible and well founded,

the Agency may rectify the decision within the period of 30 days beginning with the day when the appeal is brought.]

<sup>F281</sup> 2 .....

<sup>F281</sup> 3 .....

<sup>F281</sup> 4 .....

#### Textual Amendments

**F279** Art. 93 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 70(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F280** Art. 93(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 70(3)**; 2020 c. 1, Sch. 5 para. 1(1)

**F281** Art. 93(2)-(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 70(4)**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F282</sup> Article 94

### Actions before the Court of First Instance and the Court of Justice

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F282** Art. 94 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 71**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 95

### Conflicts of opinion with other bodies

1 The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of other [<sup>F283</sup>public bodies] carrying out a similar task in relation to issues of common concern.

2 Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.

3 Where there is a fundamental conflict over scientific or technical points <sup>F284</sup>..., the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the [<sup>F285</sup>appropriate authorities] clarifying the scientific and/or technical points of conflict.

### Textual Amendments

**F283** Words in Art. 95(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 72(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F284** Words in Art. 95(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 72(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F285** Words in Art. 95(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 72(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F286</sup> Article 96

### The budget of the Agency

### Textual Amendments

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F286</sup> Article 97

### Implementation of the budget of the Agency

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 98*

**Combating fraud**

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 99*

**Financial rules**

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 100*

**Legal personality of the Agency**

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 101*

**Liability of the Agency**

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 102*

**Privileges and immunities of the Agency**

**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 103*

**Staff rules and regulations**

**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 104*

**Languages**

**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 105*

**Duty of confidentiality**

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 106*

**Participation of third countries**

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*F286 Article 107*

**Participation of international organisations**

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**Textual Amendments**

**F286** Arts. 96-107 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 73**; 2020 c. 1, Sch. 5 para. 1(1)

*Article 108*

**Contacts with stakeholder organisations**

The [<sup>F287</sup>Agency must develop appropriate contacts with] relevant stakeholder organisations.

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**Textual Amendments**

**F287** Words in [Art. 108](#) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 74**; 2020 c. 1, Sch. 5 para. 1(1)

*Article 109*

**Rules on transparency**

To ensure transparency, the [<sup>F288</sup>Agency must] adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in [<sup>F1</sup>mixtures] or in articles which is not of a confidential nature.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F288** Words in Art. 109 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 75**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 110

### Relations with relevant [<sup>F289</sup>public] bodies

1 The Agency shall cooperate with other [<sup>F290</sup>public] bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.

2 The [<sup>F291</sup>Agency, having consulted the Food Standards Agency and Food Standards Scotland] shall establish rules of procedure concerning substances for which an opinion has been sought in a food safety context. <sup>F292</sup>...

This Title shall not otherwise affect the competences vested in the [<sup>F293</sup>Food Standards Agency and Food Standards Scotland].

3 This Title shall not affect the competences vested in the [<sup>F294</sup>Medicines and Healthcare products Regulatory Agency].

<sup>F295</sup> 4 .....

### Textual Amendments

- F289** Word in Art. 110 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F290** Word in Art. 110(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F291** Words in Art. 110(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F292** Words in Art. 110(2) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F293** Words in Art. 110(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F294** Words in Art. 110(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F295** Art. 110(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 76(5)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 111

### Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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[<sup>F296</sup>Manufacturers], importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1).

For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.

#### Textual Amendments

**F296** Word in Art. 111 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 77; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F297</sup>TITLE XI

### [<sup>F297</sup>CLASSIFICATION AND LABELLING INVENTORY

#### <sup>F297</sup>Article 112

##### Scope

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#### <sup>F297</sup>Article 113

##### Obligation to notify the Agency

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#### <sup>F297</sup>Article 114

##### Classification and labelling inventory

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#### <sup>F297</sup>Article 115

##### Harmonisation of classification and labelling

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#### <sup>F297</sup>Article 116

##### Transitional arrangements]

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F297** Deleted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

## TITLE XII

### INFORMATION

#### Article 117

#### Reporting

**F298** 1 .....

2 Every five years, the Agency shall submit to the [<sup>F299</sup>appropriate authorities] a report on the operation of this Regulation. The Agency shall include in its report [<sup>F300</sup>sections on evaluation and enforcement,] information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately.

The first report shall be submitted by [<sup>F301</sup>1 April 2022].

3 Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the [<sup>F302</sup>appropriate authorities] a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.

The first report shall be submitted by [<sup>F303</sup>1 April 2022].

4 Every five years, the [<sup>F304</sup>Secretary of State, in cooperation with the other appropriate authorities, must] publish a general report on:

- a the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and;
- b the amount and distribution of funding made available by the [<sup>F305</sup>appropriate authorities] for the development and evaluation of alternative test methods.

The first report shall be published by [<sup>F306</sup>1 April 2023].

### Textual Amendments

**F298** Art. 117(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 78(2); 2020 c. 1, Sch. 5 para. 1(1)

**F299** Words in Art. 117(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 78(3)(a)(i); 2020 c. 1, Sch. 5 para. 1(1)

**F300** Words in Art. 117(2) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 78(3)(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)

**F301** Words in Art. 117(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 1 para. 78(3)(b); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F302** Words in Art. 117(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 78(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F303** Words in Art. 117(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 78(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F304** Words in Art. 117(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 78(5)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F305** Words in Art. 117(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 78(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F306** Words in Art. 117(4)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 78(5)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 118

### Access to information

**F307** 1 .....

2 Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:

- a details of the full composition of a [<sup>F1</sup>mixture];
- b without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or [<sup>F1</sup>mixture], including information about its precise use as an intermediate;
- c the precise tonnage of the substance or [<sup>F1</sup>mixture] manufactured or placed on the market;
- d links between a manufacturer or importer and his distributors or downstream users.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.

3 The [<sup>F308</sup>Agency] shall adopt the practical arrangements for <sup>F309</sup>... appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request <sup>F310</sup>....

**F311** 4 .....

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F307** Art. 118(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 79(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F308** Word in Art. 118(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 79(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F309** Words in Art. 118(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 79(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F310** Words in Art. 118(3) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 79(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F311** Art. 118(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 79(4)**; 2020 c. 1, Sch. 5 para. 1(1)



## Article 119

### Electronic public access

1 The following information held by the Agency on substances whether on their own, in [F<sup>1</sup>mixtures] or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):

- [F<sup>1</sup>a without prejudice to paragraph 2(f) and (g) of this Article, the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
- hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
  - hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
  - hazard class 4.1;
  - hazard class 5.1;]
- b if applicable, the name of the substance as given in EINECS;
- c the classification and labelling of the substance;
- d physicochemical data concerning the substance and on pathways and environmental fate;
- e the result of each toxicological and ecotoxicological study;
- f any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
- g the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;
- h analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

2 The following information on substances whether on their own, in [F<sup>1</sup>mixtures] or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

- a if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
- b the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;
- c the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);
- d information, other than that listed in paragraph 1, contained in the safety data sheet;
- e the trade name(s) of the substance;
- [F<sup>1</sup>f subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for non-phase-in substances referred to in paragraph 1(a) of this Article for a period of six years;]
- [F<sup>1</sup> subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:]
- (i) as an intermediate;

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (ii) in scientific research and development;
- (iii) in product and process orientated research and development.

#### Textual Amendments

**F1** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).

### Article 120

#### Cooperation with [<sup>F312</sup>other] countries and international organisations

Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of [<sup>F313</sup>another country or an international organisation in accordance with an agreement concluded between the United Kingdom and the other country or international organisation,] provided that both the following conditions are met:

- (a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;
- (b) the [<sup>F314</sup>other country or international organisation concerned] protects the confidential information as mutually agreed.

#### Textual Amendments

**F312** Word in Art. 120 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 80(2)**; 2020 c. 1, Sch. 5 para. 1(1)

**F313** Words in Art. 120 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 80(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F314** Words in Art. 120(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 80(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

### TITLE XIII

#### [<sup>F315</sup>PROVISION OF INFORMATION]

#### <sup>F316</sup> Article 121

#### Appointment

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F316** Art. 121 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 82**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F317</sup> Article 122

### Cooperation between competent authorities

### Textual Amendments

**F317** Art. 122 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 82**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 123

### Communication to the public of information on risks of substances

The [<sup>F318</sup>Agency] shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Agency, in consultation with [<sup>F319</sup>the appropriate authorities] and stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in [<sup>F1</sup>mixtures] or in articles <sup>F320</sup>....

### Textual Amendments

**F1** Substituted by [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006 \(Text with EEA relevance\)](#).

**F318** Word in Art. 123 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 83(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F319** Words in Art. 123 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 83(b)**; 2020 c. 1, Sch. 5 para. 1(1)

**F320** Words in Art. 123 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 83(c)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 124

### Other responsibilities

**F321**  
...

[<sup>F322</sup>The Agency must establish a national helpdesk] to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in particular in relation to the

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registration of substances in accordance with Article 12(1), in addition to the operational guidance documents provided by the Agency under Article 77(2)(g).

#### Textual Amendments

- F321** Words in Art. 124 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 84(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F322** Words in Art. 124 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 84(b)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

- F315** Title 13 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 81**; 2020 c. 1, **Sch. 5 para. 1(1)**

## TITLE XIV

### ENFORCEMENT

#### <sup>F323</sup> Article 125

#### Tasks of the Member States

#### Textual Amendments

- F323** Art. 125 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 85**; 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F324</sup> Article 126

#### Penalties for non-compliance

#### Textual Amendments

- F324** Art. 126 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 85**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 127

### Report

The report referred to in Article [<sup>F325</sup>117(2)] shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken <sup>F326</sup>... during the previous reporting period. <sup>F327</sup>...

#### Textual Amendments

- F325** Word in Art. 127 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 86(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F326** Words in Art. 127 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 86(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F327** Words in Art. 127 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 86(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## [<sup>F328</sup>TITLE 14A

### EU WITHDRAWAL: TRANSITIONAL PROVISION

#### Article 127A

##### Existing EU registrations which have effect as GB registrations

- 1 An existing EU registration under Articles 6, 7(1), 7(5) or 24(1) of EU REACH has effect on and after IP completion day as a GB registration (the “transferred GB registration”) if the registration—
  - a has a current connection with Great Britain, or
  - b has a relevant past connection with Great Britain (but does not have a current connection with Great Britain).
- 2 A registration has a current connection with Great Britain if—
  - a the registrant immediately before IP completion day is a person established in Great Britain (a “current GB registrant”), and
  - b a registration of the substance concerned by the current GB registrant is a registration of a kind that could be submitted on IP completion day under Article 6 or 7(1) or (5) of this Regulation.
- 3 A registration has a relevant past connection with Great Britain if—
  - a the registrant at any time in the period beginning with 29 March 2017 and ending immediately before IP completion day was a person established in Great Britain (a “former GB registrant”), and
  - b a registration of the substance concerned by the former GB registrant is a registration of a kind that could be submitted on IP completion day under Article 6 or 7(1) or (5) of this Regulation.
- 4 Where an existing EU registration has effect by virtue of this Article as a transferred GB registration, it has effect—

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- a if it is an existing EU registration under Article 6 of EU REACH, as a transferred GB registration under Article 6 of this Regulation;
- b if it is an existing EU registration under Article 7(1) of EU REACH, as a transferred GB registration under Article 7(1) of this Regulation;
- c if it is an existing EU registration under Article 7(5) of EU REACH, as a transferred GB registration under Article 7(5) of this Regulation;
- d if it is an existing EU registration that existed by virtue of Article 24(1) of EU REACH, as a transferred GB registration that exists by virtue of Article 6 of this Regulation.

6 Where a registration that has a relevant past connection with Great Britain has effect as a transferred GB registration by virtue of this Article, the former GB registrant becomes the registrant in relation to the transferred GB registration on IP completion day.

If two or more persons have been former GB registrants at different times in the period beginning with 29 March 2017 and ending immediately before IP completion day, only the person who was the former GB registrant most recently before IP completion day is to become registrant in relation to the transferred GB registration by virtue of this paragraph.

#### *Article 127B*

#### **Application of this Regulation to transferred GB registrations**

1 The other Titles of this Regulation apply to a transferred GB registration as they would apply to the registration—

- a if it had been submitted on IP completion day to the Agency under Article 6 or 7(1) or (5) (as the case may be);
- b in a case where the existing EU registration came into existence by virtue of Article 24(1) of EU REACH, if it had been submitted on IP completion day to the Agency under Article 6.

Accordingly, no registration under that Article needs to be submitted.

2 But, in their application to the transferred GB registration, the other Titles of this Regulation have effect with the modifications set out in the following provisions of this Article.

3 In the case of—

- a a transferred GB registration under Article 6, no fee is payable under Article 6(4);
- b a transferred GB registration under Article 7, no fee is payable under Article 7(1) or (5).

4 The registrant must submit—

- a the Article 10 information referred to in Article 10(a)(i), (ii), and (iii), and any relevant indication under Article 10(a)(viii), to the Agency within the 120 day post-IP completion period;
- b the other Article 10 information to the Agency within the relevant post-IP completion period.

Where the existing EU registration existed by virtue of Article 24(1) of EU REACH, the duty under this paragraph does not apply in relation to a transferred GB registration unless Article 24(2) applied in relation to the notified substance concerned before IP completion day.

5 The technical dossier that is submitted in accordance with point (a) in Article 10 does not need to include the proposals for testing mentioned in paragraph (ix) if, before IP completion day, ECHA has made a decision under Article 40(3) of EU REACH in relation to the testing proposals included in the technical dossier that was included in the existing EU registration.

For further provision about certain cases where there is an existing EU decision on a testing proposal, see Article 127I.

6 The registrant must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-IP completion period.

7 Article 20 has effect with the following provision substituted for paragraphs 1 to 3—

1 The Agency must assign a submission date to each transferred GB registration, which must be the date on which the registrant complies with paragraph 4(a) or (b) of Article 127B.

2 The Agency may undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.

3 Once the registrant has complied with paragraph 4(a) of Article 127B, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration..

8 Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

1 A registrant of a transferred GB registration may continue the manufacture or import of a substance or production or import of an article from IP completion day, subject to any indication to the contrary from the Agency in accordance with Article 20(2)..

9 The Agency is not required by Article 41(5) to carry out compliance checking of dossiers relating to transferred GB registrations in the tonnage bands of over 100 to 1,000 tonnes or over 1,000 tonnes.

10 The reference in Article 43(1) to the preparation of a draft decision within 180 days of receiving a registration has effect as a reference to the preparation of a draft decision within 180 days of receipt of the information required by Article 10(a)(ix) under paragraph 4.

### *Article 127C*

#### **Decisions of ECHA relating to existing EU registrations**

1 This Article applies in relation to an existing EU registration which has effect as a transferred GB registration under Article 127A.

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2 Any existing ECHA decision which relates to the registration has effect on and after IP completion day as a decision of the Agency which relates to the transferred GB registration.

3 The registrant must—

- a notify the Agency, within the 120 day post-IP completion period, of any existing ECHA decision which relates to the registration, and
- b if required to do so by the Agency, supply the Agency, within the period specified by the Agency, with copies of any existing ECHA decision which relates to the registration.

4 The Agency may extend any period of time specified in an existing ECHA decision.

5 The other Titles of this Regulation apply to the decision as they would apply to it if it had been made by the Agency on IP completion day.

6 In this Article “existing ECHA decision” means a decision which has been made by ECHA under any provision of EU REACH and which is valid immediately before IP completion day.

#### *Article 127D*

#### **Interpretation of Articles 127A to 127C**

1 In Articles 127A to 127C—

“Article 10 information” means the information which a registration is required to include by virtue of Article 10;

“existing EU registration” means a registration of a substance with ECHA which is subsisting immediately before IP completion day;

“transferred GB registration” has the meaning given in Article 127A(1);

“GB registration” means a registration of a substance with the Agency.

#### *Article 127E*

#### **Pre-IP completion downstream users and distributors that are to continue to be regarded as downstream users**

1 This Article applies in a case where—

- a a person is—
  - i an existing GB downstream user under EU REACH, or
  - ii an existing GB distributor under EU REACH,
 in relation to a substance (the “GB user or distributor”), and
- b there is a protected transitional import of the substance by the GB user or distributor.

2 There is a protected transitional import of the substance by the GB user or distributor if—

- a the substance is imported to Great Britain on its own, in a mixture or in an article,
- b the GB user or distributor is the importer in relation to the import,
- c the import occurs during the relevant post-IP completion period, and
- d either—
  - i the person who supplies the substance, mixture or article to the GB user or distributor for the import is a registrant or a downstream user under EU REACH as respects the substance as it is imported (the “relevant supplier”), or



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- ii an only representative appointed under Article 8(1) of EU REACH by the manufacturer, formulator or producer of the substance, mixture or article is a registrant under EU REACH as respects the substance as it is imported.
- 3 The GB user or distributor is to be treated for the purposes of this Regulation—
- a as a downstream user as respects any protected transitional imports of the substance by them (if they are an existing GB downstream user under EU REACH), or
  - b as a distributor as respects any protected transitional imports of the substance by them (if they are an existing GB distributor under EU REACH).
- 4 For the purposes of deciding whether the requirement in paragraph 2(d)(i) is met in relation to a particular import, it does not matter whether the relevant supplier is—
- a the person from which the GB user or distributor obtained supplies of the substance, mixture or article before IP completion day (and therefore the person in relation to which the GB user was a downstream user or distributor under EU REACH), or
  - b a different person.
- 5 For the purposes of deciding whether the requirement in paragraph 2(d)(ii) is met in relation to a particular import, it does not matter whether the manufacturer, formulator or producer who has appointed the only representative is—
- a the person who was the manufacturer, formulator or producer of supplies of the substance, mixture or article which the GB user or distributor obtained before IP completion day, or
  - b a different person.
- 6 The provisions of this Regulation that apply to importers, including in respect of protected NI imports, do not apply to the GB user or distributor in relation to the protected transitional import of the substance by the GB user or distributor.
- 7 If the GB user or distributor imports the substance into Great Britain in quantities of 1 to 10 tonnes per year, they must within the 300 day post-IP completion period—
- a supply the Agency with the information referred to in point (a)(i) of Article 10;
  - b supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB user or distributor;
  - c supply the Agency with the information referred to in points (a) to (d) of Article 32(1) and otherwise comply with Article 32;
  - d supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB user or distributor;
  - e supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (c) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB user or distributor imports into Great Britain by protected transitional imports);
  - f if any part of the import is a protected NI import, notify the Agency of the quantity of the import that is a protected NI import.
- 8 If the GB user or distributor imports the substance into Great Britain in quantities of 10 tonnes or more per year, they must within the 300 day post-IP completion period—
- a supply the Agency with the information referred to in point (a)(i) of Article 10;
  - b supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB user or distributor;
  - c supply the Agency with the information referred to in—

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- i Article 14(6) to the extent that information is available to the GB user or distributor,
    - ii Article 31, and
    - iii Article 32(1)(a) to (d);
  - d otherwise comply with Articles 14(6), 31 and 32;
  - e supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB user or distributor;
  - f supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (c) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB user or distributor imports into Great Britain by protected transitional imports);
  - g if any part of the import is a protected NI import, notify the Agency of the quantity of the import that is a protected NI import.
- 9 The GB user or distributor must provide the Agency with updated information of the kind required by paragraph 7 or 8, in particular where the GB user or distributor begins to import the substance—
- a from a different relevant supplier, or
  - b from a different manufacturer, formulator or producer who (as described in paragraph 2(d)(ii)) has appointed an only representative that is a registrant under EU REACH.

10 This Article ceases to apply to the GB user or distributor as respects a protected transitional import of the substance by them if they become a registrant or downstream user under this Regulation, or a notification is made under Article 139A, in relation to the substance as so imported by them.

For that purpose, a person is not to be treated as having become a downstream user because they are treated as one in accordance with paragraph 3(a).

11 Paragraphs 7, 8 and 9 are subject to paragraph 3 of Article 127EA and paragraph 6 of Article 127EB.

12 In this Article—

“existing GB distributor under EU REACH” means a person who was, at any time in the 2 year period before IP completion day, a distributor under EU REACH established in Great Britain in relation to a substance on its own, in a mixture or in an article;

“existing GB downstream user under EU REACH” means a person who was, at any time in the 2 year period before IP completion day, a downstream user under EU REACH established in Great Britain in relation to a substance on its own, in a mixture or in an article;

“relevant supplier” has the meaning given in paragraph 2(d)(i);

“GB user or distributor” has the meaning given in paragraph 1(a).

#### *Article 127EA*

#### **Appointment of only representative where Article 127E applies**

1 This Article applies in relation to a protected transitional import of a substance by a GB user or distributor (within the meaning of Article 127E) that is not a protected NI import.

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2 If, or to the extent that, the appointment of an only representative by the manufacturer, formulator or producer relates to the substance as imported, Article 8 has effect as if the following provision were substituted for paragraphs 1 to 3 of that Article—

1 A person established outside Great Britain who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into Great Britain may by mutual agreement appoint a person established in Great Britain to fulfil, as his only representative, the obligations on the GB user or distributor under Article 127E.

1A Article 36 applies to the representative.

2 The representative must have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, must keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

3 If a representative is appointed in accordance with paragraphs 1 and 2, the non-Great British manufacturer shall inform the GB user or distributor of the appointment..

3 If the GB user or distributor is informed of the appointment of the only representative in accordance with paragraph 3 of Article 8 (as set out above), paragraphs 7, 8 and 9 of Article 127E cease to apply to the GB user or distributor as respects any protected transitional import where the manufacturer, formulator or producer is the person who appointed the representative.

#### *Article 127EB*

#### **Import from Northern Ireland where Article 127E applies**

1 This Article applies in relation to a protected transitional import of a substance by a GB user or distributor (within the meaning of Article 127E) that is also a protected NI import.

2 A person established in Northern Ireland who manufactures a substance on its own, in mixtures or in articles, formulates a mixture, or produces an article that is imported into Great Britain may fulfil the obligations on the GB user or distributor under Article 127E (the “NI notifier”).

3 Article 36 applies to the NI notifier.

4 The NI notifier must, without prejudice to Article 36, keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

5 A person who intends to act in accordance with paragraph 2 must inform the GB user or distributor that they intend to do so.

6 If the GB user or distributor is informed of the intention in accordance with paragraph 5, paragraphs 7 to 9 of Article 127E apply to the NI notifier instead of the GB user or distributor as respects any protected transitional import from the NI notifier.

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### Article 127F

#### Existing EU authorisations

1 The holder of an existing EU authorisation which has the relevant connection with Great Britain must, before the end of the 60 day post-IP completion period, supply the Agency with the required technical information relating to the authorisation.

2 An existing EU authorisation which does not have the relevant connection with Great Britain ceases to have effect (as retained EU law) on IP completion day.

3 An existing EU authorisation has the relevant connection with Great Britain if the holder of the authorisation is established in Great Britain.

4 In this Article—

“existing EU authorisation” means an authorisation granted in accordance with Articles 60 to 64 of EU REACH which is subsisting immediately before IP completion day;

“holder”, in relation to an existing EU authorisation, means the person to whom the authorisation has been granted;

“required technical information”, in relation to an existing EU authorisation, means—

- a the information included in the application for the authorisation in accordance with Article 62(4) and (5) of EU REACH,
- b any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinion in relation to the application for the authorisation, and
- c any information required to be submitted or recorded before IP completion day under any condition under which the authorisation is granted.

### Article 127G

#### Existing applications for EU authorisations

1 The Secretary of State must decide an existing application for an EU authorisation (as mentioned in Article 64(8)) if—

- a the application—
  - i is at the final decision stage on IP completion day,
  - ii has the relevant connection with Great Britain; and
- b the person who made the application—
  - i notifies the Secretary of State of the existence of the application,
  - ii provides the Secretary of State with copies of the application, the information included in it under Article 62(4) and (5) of EU REACH, and any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinion in relation to the application for the authorisation, and
  - iii provides the Secretary of State with copies of the final opinions of ECHA referred to in Article 64(5) of EU REACH.

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- 2 An application for an EU authorisation is at the final decision stage if—
- ECHA has adopted the final opinions referred to in Article 64(5) of EU REACH, but
  - the Commission has not made a final decision granting or refusing the application.
- 3 An application for an EU authorisation has the relevant connection with Great Britain if the person making the application is established in Great Britain.
- 4 The period of six months for the Secretary of State to make an authorisation decision in accordance with Article 64(8) of this Regulation begins with the day on which paragraph 1(b) is complied with.
- 5 Where, immediately before IP completion day, a person may place a substance on the market for a use or use it himself in reliance on Article 56(1)(d) of EU REACH, the person may continue to do so on and after IP completion day in reliance on Article 56(1)(d) of this Regulation.
- But this paragraph ceases to apply at the end of the 180 day post-IP completion period if the person does not comply with paragraph 1(b) of this Article before the end of that period.
- 6 In this Article “existing application for an EU authorisation” means an application made before IP completion day for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH.

#### *Article 127GA*

##### **Substances of very high concern: sunset dates and latest application dates**

- 1 Paragraphs 2 and 3 apply where—
- immediately before IP completion day, a substance is included in Annex 14 to EU REACH;
  - the EU latest application date fell before or during the relevant pre-IP completion period;
  - the EU sunset date fell during the relevant pre-IP completion period;
  - before the EU latest application date, an application had been made for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH in relation to the substance (the “authorisation application”); and
  - immediately before IP completion day, the authorisation application was still under consideration (see paragraph 11).
- 2 Where, immediately before IP completion day, a person established in Great Britain may place the substance on the market or use it himself in reliance on Article 56(1)(d) of EU REACH by virtue of the authorisation application having been made, this Regulation has effect subject to the modifications set out in paragraph 3.
- 3 As respects that person placing the substance on the market or using it himself on and after IP completion day—
- the GB latest application date, and
  - the GB sunset date,
- both fall on the transitional cut-off date (rather than on the dates specified in Annex 14 for that substance).
- 4 Paragraphs 5 and 6 apply where—

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- a immediately before IP completion day, a substance is included in Annex 14 to EU REACH;
- b the EU latest application date fell during the relevant pre-IP completion period;
- c the EU sunset date falls after the end of that period;
- d before the EU latest application date, an application had been made for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH in relation to the substance (the “authorisation application”); and
- e immediately before IP completion day, the authorisation application was still under consideration (see paragraph 11).

5 Where, on and after the GB sunset date, a person established in Great Britain would be able to place the substance on the market or use it himself in reliance on Article 56(1)(d) of this Regulation had the authorisation application been made under this Regulation, this Regulation has effect subject to the modifications set out in paragraph 6.

6 As respects that person placing the substance on the market or using it himself on and after IP completion day—

- a the GB latest application date, and
- b the GB sunset date,

both fall on the transitional cut-off date (rather than on the dates specified in Annex 14 for that substance).

The effect of this paragraph is to be ignored in reading the reference to the GB sunset date in paragraph 5.

7 Paragraph 8 applies where—

- a immediately before IP completion day, a substance is included in Annex 14 to EU REACH; and
- b the GB latest application date falls during the 18 month post-IP completion period.

8 As respects a person established in Great Britain placing the substance on the market or using it himself on and after IP completion day, the GB latest application date falls on the transitional cut-off date (rather than on the date specified in Annex 14 for that substance).

9 Where paragraph 3, 6 or 8 modifies this Regulation, Article 56(1) has effect with the following provision substituted for point (d)—

- d the GB sunset date (within the meaning of Article 127GA) has been reached and he made an application before the GB latest application date (within the meaning of Article 127GA) but a decision on the application for authorisation has not yet been taken; or.

10 Where paragraph 3 or 6 modifies the date that is the GB sunset date, any reference in this Regulation to the date of the kind referred to in Article 58(1)(c)(i) has effect subject to the modification made by paragraph 3 or 6.

11 For the purposes of paragraph 1(e) or 4(e), the authorisation application is “still under consideration” unless—

- a the Commission has made a final decision granting or refusing the authorisation application, or
- b the authorisation application—
  - i has the relevant connection with Great Britain (within the meaning of Article 127G), and
  - ii is at the final decision stage (within the meaning of Article 127G).

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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12 In this Article—

“EU latest application date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(ii) of EU REACH that is specified in Annex 14 to EU REACH in relation to the substance;

“EU sunset date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(i) of EU REACH that is specified in Annex 14 to EU REACH in relation to the substance;

“relevant pre-IP completion period” means the period that—

a begins with 29 March 2017, and

b ends immediately before IP completion day;

“transitional cut-off date” means the last day of the 18 month post-IP completion period;

“GB latest application date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(ii) of this Regulation that is specified in Annex 14 to this Regulation in relation to the substance;

“GB sunset date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(i) of this Regulation that is specified in Annex 14 to this Regulation in relation to the substance;

“18 month post-IP completion period” means the period of 18 months beginning with the day after that on which IP completion day falls.

*Article 127H*

**Existing authorised downstream users under EU law**

1 On and after IP completion day, a person who—

a is established in Great Britain, and

b is an existing authorised downstream user under EU law in relation to a substance,

is authorised to use that substance in accordance with Article 56(2).

2 Where Article 56(2) applies to the use of a substance by virtue of paragraph 1, a reference in Article 56(2) to an authorisation granted to a person up a supply chain is a reference to an existing EU authorisation relating to that use of the substance.

3 Accordingly, paragraph 1 ceases to apply to a person if the existing EU authorisation relating to that use of the substance ceases to have effect.

4 A person to whom paragraph 1 applies must, before the end of the 60 day post-IP completion period—

a confirm to the Agency that they are an existing authorised downstream user under EU law in relation to the substance, and

b notify the Agency of—

i the existing EU authorisation;

ii any conditions set out in the existing EU authorisation (as referred to in Article 56(2) of EU REACH);

iii the identity of the supplier of the substance to the person.

5 Article 66(1) does not apply to the use of a substance in accordance with Article 56(2) by virtue of this Article.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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6 In this Article—

“existing authorised downstream user under EU law” means a person who, immediately before IP completion day, is authorised to use a substance in accordance with Article 56(2) of EU REACH;

“existing EU authorisation” means an authorisation granted to a person up a supply chain (as referred to in Article 56(2) of EU REACH) which is subsisting immediately before IP completion day, as it has effect in EU law;

*Article 127I*

**Existing examinations of testing proposals**

1 On and after IP completion day, an existing EU decision on a testing proposal which has the relevant connection with Great Britain has effect as a decision by the Agency under Article 40(3) of this Regulation.

2 An existing EU decision on a testing proposal has the relevant connection with Great Britain if the registrant, or downstream user, concerned is established in Great Britain.

3 The Agency may extend any deadline specified in an existing EU decision on a testing proposal.

4 In this Article, “existing EU decision on a testing proposal” means a decision taken by ECHA—

- a in accordance with Article 40(3)(a), (b), (c) or (e) of EU REACH, if the requirements of the decision have not been fulfilled, or
- b in accordance with Article 40(3)(d) of EU REACH.

*Article 127J*

**Existing Article 7(2) notifications**

1 This Article applies if—

- a before IP completion day, a producer of articles established in Great Britain, or an importer of articles established in Great Britain, has given ECHA a notification under Article 7(2) of EU REACH in relation to a substance, and
- b immediately before IP completion day, that person is not a registrant in relation to the substance concerned.

2 The person that gave the notification to ECHA must submit to the Agency, within the 60 day post-IP completion period, the information notified to ECHA in accordance with Article 7(2) and (4) of EU REACH.

*Article 127K*

**Existing Article 9 exemptions**

1 This Article applies if—

- a a five year exemption under Article 9(1) of EU REACH, or
- b an extended exemption under Article 9(7) of EU REACH,



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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applies in relation to a substance immediately before IP completion day where the research and development concerned takes place in Great Britain.

2 On and after IP completion day—

- a a five year exemption under Article 9(1) of this Regulation, or,
- b an extended exemption under Article 9(7) of this Regulation,

(as the case may be) applies in relation to the substance, subject to the same conditions (if any) imposed by ECHA under Article 9(4) in relation to the corresponding exemption under EU REACH.

3 That exemption under Article 9(1) or (7) of this Regulation is to end on the same date that the corresponding exemption under EU REACH would have ended.

4 Where an exemption under Article 9(1) or (7) of this Regulation applies to a substance by virtue of this Article, the following duties must be complied with in relation to the exemption of the substance within the 120 day post-IP completion period—

- a Article 9(2) must be complied with by the manufacturer or importer or producer, as the case may be (the “notifier”);
- b the notifier must also notify the Agency of the number and notification date assigned by ECHA under Article 9(3) of EU REACH;
- c the notifier must give the Agency copies of any additional necessary information given to ECHA under Article 9(4) of EU REACH.

Where the notifier complies with Article 9(2) in accordance with this paragraph, no fee is payable under Article 9(2).

#### *Article 127L*

### **Existing Article 17 registrations**

1 This Article applies if a registration with ECHA under Article 17 of EU REACH which relates to an on-site isolated intermediate that is manufactured in Great Britain is—

- a subsisting immediately before IP completion day, and
- b either—
  - i has a current connection with Great Britain, or
  - ii has a relevant past connection with Great Britain (but does not have a current connection with Great Britain).

2 On and after IP completion day, the registration has effect as a registration with the Agency under Article 17 of this Regulation.

3 Where paragraph 2 operates on a registration the manufacturer concerned must give the Agency—

- a the information referred to in Article 17(2)(a), (b), (e) and (f) and the confirmation referred to in Article 17(3), within the 120 day post-IP completion period, and
- b the information referred to in Article 17(2)(c) and (d) within the relevant post-IP completion period.

4 Article 19(1) does not apply to the giving of information in accordance with paragraph 3 of this Article.

5 The manufacturer concerned must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-IP completion period.

6 Where paragraph 2 operates on a registration, the other Titles of this Regulation apply to that registration as they would apply to the registration if it had been submitted to the Agency under Article 17 on IP completion day, but with the modifications set out in the following provisions of this Article.

7 No fee is payable under Article 17(2).

8 Article 20 has effect with the following provision substituted for paragraphs 1 to 3—

1 The Agency must assign a submission date to each registration which has effect under Article 127L, which must be the date on which the registrant complies with paragraph 3(a) or (b) of Article 127L.

2 The Agency may undertake a completeness check of each registration in order to ascertain that all the elements required under Article 17 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.

3 Once the registrant has complied with paragraph 3(a) of Article 127L, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration..

9 Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

1 A registrant may continue the manufacture of a substance from IP completion day, subject to any indication to the contrary from the Agency in accordance with Article 20(2)..

#### *Article 127M*

### **Existing Article 18 registrations**

1 This Article applies if a registration with ECHA under Article 18 of EU REACH which relates to a transported isolated intermediate that is manufactured in or imported into Great Britain is—

- a subsisting immediately before IP completion day, and
- b either—
  - i has a current connection with Great Britain, or
  - ii has a relevant past connection with Great Britain (but does not have a current connection with Great Britain).

2 On and after IP completion day, the registration has effect as a registration with the Agency under Article 18 of this Regulation.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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3 Where paragraph 2 operates on a registration, the manufacturer or importer concerned must give the Agency—

- a the information referred to in Article 18(2)(a), (b), (e) and (f) and the confirmation referred to in Article 18(4), within the 120 day post-IP completion period, and
- b the information referred to in Article 18(2)(c) and (d) and 18(3) within the relevant post-IP completion period.

4 Article 19(1) does not apply to the giving of information in accordance with paragraph 3 of this Article.

5 The manufacturer or importer concerned must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-IP completion period.

6 Where paragraph 2 operates on a registration, the other Titles of this Regulation apply to that registration as they would apply to the registration if it had been submitted to the Agency under Article 18 on IP completion day, but with the modifications set out in the following provisions of this Article.

7 No fee is payable under Article 18(2).

8 Article 20 has effect with the following provision substituted for paragraphs 1 to 3—

1 The Agency must assign a submission date to each registration which has effect under Article 127M, which must be the date on which the registrant complies with paragraph 3(a) or (b) of Article 127M.

2 The Agency may undertake a completeness check of each registration in order to ascertain that all the elements required under Article 18 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.

3 Once the registrant has complied with paragraph 3(a) of Article 127M, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration..

9 Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

1 A registrant may continue the manufacture or import of a substance from IP completion day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).

#### *Article 127N*

#### **Registrations under Article 127L and Article 127M**

1 Articles 127L and 127M are to be read in accordance with paragraphs 2 to 5.

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*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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2 A registration under Article 17 or 18 of EU REACH (as the case may be) has a current connection with Great Britain if—

- a the registrant immediately before IP completion day is a person established in Great Britain (a “current GB registrant”), and
- b a registration of the substance concerned by the current GB registrant is a registration of a kind that could be submitted on IP completion day under Article 17 or 18 (as the case may be) of this Regulation.

3 A registration under Article 17 or 18 of EU REACH (as the case may be) has a relevant past connection with Great Britain if—

- a the registrant at any time in the period beginning with 29 March 2017 and ending immediately before IP completion day was a person established in Great Britain (a “former GB registrant”), and
- b a registration of the substance concerned by the former GB registrant is a registration of a kind that could be submitted on IP completion day—
  - i under Article 17 of this Regulation if the former GB registrant was the manufacturer of the on-site intermediate concerned on IP completion day, or
  - ii under Article 18 of this Regulation if the former GB registrant was the manufacturer or importer of the transported isolated intermediate concerned on IP completion day.

4 Where a registration that has a current connection with Great Britain has effect as a registration with the Agency by virtue of Article 127L or 127M, the current GB registrant becomes the registrant in relation to the registration with the Agency on IP completion day.

5 Where a registration that has a relevant past connection with Great Britain has effect as a registration with the Agency by virtue of Article 127L or 127M, the former GB registrant becomes the registrant in relation to the registration with the Agency on IP completion day.

If two or more persons have been former GB registrants at different times in the period beginning with 29 March 2017 and ending immediately before IP completion day, only the person who was the former GB registrant most recently before IP completion day is to become the registrant in relation to the registration with the Agency by virtue of this paragraph.

#### *Article 127O*

### **Obligation to keep information**

1 This Article applies to a person established in Great Britain who, immediately before IP completion day, is, as respects any information, bound by the obligation imposed by Article 36(1) of EU REACH.

2 On and after IP completion day, the person is, as respects the information concerned, bound by the obligation imposed by Article 36(1) of this Regulation.

3 Where paragraph 2 applies to a person, the person is not bound by the obligation imposed by Article 36(1) of this Regulation after the end of a 10 year period under Article 36(1) of EU REACH that was running at IP completion day (and the reference to the 10 year period in Article 36(1) of this Regulation is accordingly to be read as a reference to the remainder of the 10 year period under EU REACH that falls after IP completion day).

## Article 127P

### Post-IP completion periods used in this Title

In this Title—

1 “60 day post-IP completion period” means the period of 60 days beginning with the day after that on which IP completion day falls;

2 “90 day post-IP completion period” means the period of 90 days beginning with the day after that on which IP completion day falls;

3 “120 day post-IP completion period” means the period of 120 days beginning with the day after that on which IP completion day falls;

4 “180 day post-IP completion period” means the period of 180 days beginning with the day after that on which IP completion day falls;

4A “300 day post-IP completion period” means the period of 300 days beginning with the day after that on which IP completion day falls;

4B “relevant post-IP completion period” means the period beginning with the day after that on which IP completion day falls and ending [<sup>F329</sup>with]—

a [<sup>F330</sup>27 October 2026] in respect of—

i substances included on the candidate list by virtue of Article 59(1A) [<sup>F331</sup>or added to the candidate list referred to in Article 59(1) on or before 31 December 2023],

ii substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008 and manufactured in Great Britain or imported, in quantities reaching one tonne or more per year per manufacturer or importer, at least once after IP completion day,

iii substances classified as aquatic chronic category 1 (very toxic to aquatic life with long lasting effects) or aquatic acute category 1 (very toxic to aquatic life) in accordance with Regulation (EC) No 1272/2008 and manufactured in Great Britain or imported, in quantities reaching 100 tonnes or more per year per manufacturer or importer, at least once after IP completion day,

iv substances manufactured in Great Britain or imported, in quantities reaching 1,000 tonnes or more per year per manufacturer or importer, at least once after IP completion day,

b [<sup>F332</sup>27 October 2028] in respect of—

i substances added to the candidate list referred to in Article 59(1), other than by virtue of Article 59(1A), [<sup>F333</sup>during the period beginning with 1 January 2024 and ending with 27 October 2026],

ii substances manufactured in Great Britain or imported, in quantities reaching 100 tonnes or more per year per manufacturer or importer, at least once after IP completion day,

c [<sup>F334</sup>27 October 2030] in respect of substances manufactured in Great Britain or imported, in quantities reaching 1 tonne or more per year per manufacturer or importer, at least once after IP completion day.]

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

#### Textual Amendments

- F329** Word in Art. 127P(4B) inserted (19.7.2023) by [The REACH \(Amendment\) Regulations 2023](#) (S.I. 2023/722), regs. 1(2), **4(2)(a)**
- F330** Words in Art. 127P(4B)(a) substituted (19.7.2023) by [The REACH \(Amendment\) Regulations 2023](#) (S.I. 2023/722), regs. 1(2), **4(2)(b)(i)**
- F331** Words in Art. 127P(4B)(a)(i) inserted (19.7.2023) by [The REACH \(Amendment\) Regulations 2023](#) (S.I. 2023/722), regs. 1(2), **4(2)(b)(ii)**
- F332** Words in Art. 127P(4B)(b) substituted (19.7.2023) by [The REACH \(Amendment\) Regulations 2023](#) (S.I. 2023/722), regs. 1(2), **4(2)(c)(i)**
- F333** Words in Art. 127P(4B)(b)(i) substituted (19.7.2023) by [The REACH \(Amendment\) Regulations 2023](#) (S.I. 2023/722), regs. 1(2), **4(2)(c)(ii)**
- F334** Words in Art. 127P(4B)(c) substituted (19.7.2023) by [The REACH \(Amendment\) Regulations 2023](#) (S.I. 2023/722), regs. 1(2), **4(2)(d)**

#### Textual Amendments

- F328** Title 14A inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), **Sch. 2** (as amended by S.I. 2019/858, regs. 1, **4** (as amended by S.I. 2020/1577, regs. 1(1)(a), **12(2)**); S.I. 2019/1144, regs. 1, **4** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); S.I. 2020/1313, regs. 1(3), **6**; S.I. 2020/1577, regs. 1(1)(b), **5**; 2020 c. 1, Sch. 5 para. 1(1)

## TITLE XV

### <sup>F335</sup> ... FINAL PROVISIONS

#### <sup>F336</sup> Article 128

#### Free movement

#### Textual Amendments

- F336** Art. 128 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 88**; 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F337</sup> Article 129

#### Safeguard clause

1 An appropriate authority may impose an appropriate provisional restriction in respect of a substance if that authority—

- a has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of the substance, on its own, in a mixture or in an article, even if satisfying the requirements of this Regulation, and
- b has competence to impose the provisional restriction.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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2 If an appropriate authority imposes a provisional restriction in accordance with paragraph 1, it must—

- a immediately inform the Agency and the other appropriate authorities, giving reasons for its decision and submitting the scientific or technical information on which the provisional restriction is based, and
- b within three months of its decision, request the Agency to initiate the procedure under Article 69.

3 When a decision has been reached under Article 73 (as part of the procedure under Article 69) the appropriate authority must revoke the provisional measure.

4 In this Article “restriction” means a restriction on the placing on the market or use of a substance.

5 The Secretary of State has competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction—

- a relates to England;
- b relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);
- c relates to Wales and is not within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

6 The Scottish Ministers have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

7 The Welsh Ministers have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006.)

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#### Textual Amendments

**F337** Art. 129 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), [Sch. 1 para. 89\(1\)](#) (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), [4\(24\)](#)); 2020 c. 1, Sch. 5 para. 1(1)

### Article 130

#### Statement of reasons for decisions

The [<sup>F338</sup>appropriate authorities and] the Agency <sup>F339</sup>... shall state the reasons for all decisions they take under this Regulation.

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#### Textual Amendments

**F338** Words in Art. 130 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), [Sch. 1 para. 90\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

**F339** Words in Art. 130 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), [Sch. 1 para. 90\(b\)](#); 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### *¶<sup>F340</sup> Article 131*

#### **Amendments to the Annexes**

1 The Secretary of State may, by regulations, make such amendments of the Annexes as the Secretary of State considers appropriate.

The Secretary of State must consider any request made by any of the other appropriate authorities for amendments of the Annexes to be made.

2 Regulations under this Article are to be made by statutory instrument; and a statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.]

#### **Textual Amendments**

**F340** Art. 131 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 91**; 2020 c. 1, Sch. 5 para. 1(1)

### *¶<sup>F341</sup> Article 132*

#### **Implementing legislation**

1 The Secretary of State may, by regulations, make such provision as the Secretary of State considers appropriate for putting the provisions of this Regulation efficiently into effect.

The Secretary of State must consider any request made by any of the other appropriate authorities for such provision to be made.

2 Regulations under this Article are to be made by statutory instrument; and a statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.]

#### **Textual Amendments**

**F341** Art. 132 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 92**; 2020 c. 1, Sch. 5 para. 1(1)

### *¶<sup>F342</sup> Article 132A*

#### **Regulations under this Regulation**

Any power to make regulations under this Regulation includes power to make supplementary, incidental, consequential, transitional, transitory or saving provision.]



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

**Textual Amendments**

**F342** Art. 132A inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

*F343* Article 133

**Committee procedure**

**Textual Amendments**

**F343** Arts. 133-137 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 94**; 2020 c. 1, Sch. 5 para. 1(1)

*F343* Article 134

**Preparation of establishment of the Agency**

**Textual Amendments**

**F343** Arts. 133-137 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 94**; 2020 c. 1, Sch. 5 para. 1(1)

*F343* Article 135

**Transitional measures regarding notified substances**

**Textual Amendments**

**F343** Arts. 133-137 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 94**; 2020 c. 1, Sch. 5 para. 1(1)

*F343* Article 136

**Transitional measures regarding existing substances**

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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#### Textual Amendments

**F343** Arts. 133-137 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 94**; 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F343</sup> Article 137

#### Transitional measures regarding restrictions

#### Textual Amendments

**F343** Arts. 133-137 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 1 para. 94**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 138

#### Review

1 <sup>F344</sup>Within 18 months of IP completion day], the <sup>F345</sup>Secretary of State] shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. <sup>F346</sup>... When carrying out the review the <sup>F345</sup>Secretary of State] shall take into account all relevant factors, including:

- a the costs for manufacturers and importers of drawing up the chemical safety reports;
- b the distribution of costs between actors in the supply chain and the downstream user;
- c the benefits for human health and the environment;
- <sup>F347</sup>d the views of any appropriate authority.]

On the basis of these reviews, the <sup>F345</sup>Secretary of State] may, if appropriate, <sup>F348</sup>formulate] proposals to extend this obligation.

2 The <sup>F345</sup>Secretary of State] may <sup>F349</sup>formulate] proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:

- a the risks posed by polymers in comparison with other substances;
- b the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.

3 The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at one tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the <sup>F345</sup>Secretary of State] may <sup>F350</sup>formulate] proposals to modify the information requirements for substances manufactured or imported in quantities of one tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

F351	4	.....
F351	5	.....
F351	6	.....
F351	7	.....

8 [F352 Within 18 months of IP completion day], the [F345 Secretary of State] shall carry out a review to assess whether or not to extend the scope of Article 33 to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of that review, the [F345 Secretary of State] may, if appropriate, [F353 formulate] proposals to extend that obligation.

9 In accordance with the objective of promoting non-animal testing and the replacement, reduction or refinement of animal testing required under this Regulation, the [F345 Secretary of State] shall review the testing requirements of Section 8.7 of Annex VIII by [F354 within 18 months of IP completion day].

[F355 The Secretary of State may, by regulations, amend Annex 8 if the Secretary of State considers that it is appropriate to do so on the basis of this review, while ensuring a high level of protection of health and the environment.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.]

#### Textual Amendments

- F344** Words in Art. 138(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(3)(a)** (as amended by S.I. 2019/1144, regs. 1, **3(6)(a)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**) and S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, Sch. 5 para. 1(1))
- F345** Words in Art. 138 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(2)**; 2020 c. 1, Sch. 5 para. 1(1))
- F346** Words in Art. 138(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1))
- F347** Art. 138(1)(d) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1))
- F348** Word in Art. 138(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(3)(d)**; 2020 c. 1, Sch. 5 para. 1(1))
- F349** Word in Art. 138(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(4)**; 2020 c. 1, Sch. 5 para. 1(1))
- F350** Word in Art. 138(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(4)**; 2020 c. 1, Sch. 5 para. 1(1))
- F351** Art. 138(4)-(7) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(5)**; 2020 c. 1, Sch. 5 para. 1(1))
- F352** Words in Art. 138(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(6)(a)** (as amended by S.I. 2019/1144, regs. 1, **3(6)(b)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**) and S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, Sch. 5 para. 1(1))

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- F353** Word in Art. 138(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F354** Words in Art. 138(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(7)(a)** (as amended by S.I. 2019/1144, regs. 1, **3(6)(c)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**) and S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, Sch. 5 para. 1(1))
- F355** Words in Art. 138(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 95(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 139

#### Repeals

Directive 91/155/EEC shall be repealed.

Directives 93/105/EC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) No 1488/94 shall be repealed with effect from 1 June 2008 .

Directive 93/67/EEC shall be repealed with effect from 1 August 2008 .

Directive 76/769/EEC shall be repealed with effect from 1 June 2009 .

References to the repealed acts shall be construed as references to this Regulation.

### <sup>F356</sup> Article 140

#### Amendment of Directive 1999/45/EC

##### Textual Amendments

- F356** Art. 140 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 96**; 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F357</sup> Article 141

#### Entry into force and application

##### Textual Amendments

- F357** Art. 141 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 96**; 2020 c. 1, Sch. 5 para. 1(1)

##### Textual Amendments

- F335** Words in Title 15 heading omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 87**; 2020 c. 1, **Sch. 5 para. 1(1)**

[<sup>F358</sup>TITLE 15A**IMPORTS FROM NORTHERN IRELAND***Article 139A***Protected NI imports**

- 1 This Article applies in a case where there is a protected NI import of a substance.
- 2 There is a protected NI import of a substance if—
  - a a substance—
    - i has a relevant connection to Northern Ireland, and
    - ii is imported on its own, in a mixture or in an article,
  - b the substance, mixture or article is a qualifying Northern Ireland good, and
  - c the person who supplies the substance, mixture or article for the import is a registrant or a downstream user under EU REACH as respects the substance as it is imported.
- 3 A substance has a relevant connection to Northern Ireland if—
  - a it is—
    - i manufactured in Northern Ireland,
    - ii in a mixture that is manufactured or formulated in Northern Ireland, or
    - iii in an article that is manufactured or produced in Northern Ireland, and
  - b it is imported from a supplier established in Northern Ireland.
- 4 The importer of the substance (the “GB importer”) is to be treated for the purposes of this Regulation as a downstream user as respects any protected NI imports of the substance by them.
- 5 The provisions of this Regulation that apply to importers do not apply to the GB importer in relation to the protected NI import of the substance by the GB importer.
- 6 If the GB importer imports the substance in quantities of 1 to 10 tonnes per year they must, before they make a protected NI import—
  - a notify the Agency of their intention to make the protected NI import,
  - b supply the Agency with the information referred to in point (a)(i) of Article 10,
  - c supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB importer,
  - d supply the Agency with the information referred to in points (a) to (d) of Article 32(1) and otherwise comply with Article 32,
  - e supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB importer,
  - f supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (d) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB importer imports into Great Britain by protected NI imports).
- 7 If the GB importer imports the substance in quantities of 10 tonnes or more per year they must, before they make a protected NI import—
  - a notify the Agency of their intention to make the protected NI import,
  - b supply the Agency with the information referred to in point (a)(i) of Article 10,

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- c supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB importer,
  - d supply the Agency with the information referred to in—
    - i Article 14(6) to the extent that information is available to the GB importer,
    - ii Article 31, and
    - iii Article 32(1)(a) to (d),
  - e otherwise comply with Articles 14(6), 31 and 32,
  - f supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB importer,
  - g supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (d) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB importer imports into Great Britain by protected NI imports).
- 8 The GB importer must update the information provided to the Agency under paragraph 6 or 7 with any relevant new information and submit it to the Agency.
- 1 9. Paragraphs 6, 7 and 8 are subject to paragraph 6 of Article 139B.

#### *Article 139B*

#### **Notification by Northern Irish supplier where Article 139A applies**

- 1 This Article applies in relation to a protected NI import of a substance.
- 2 A person established in Northern Ireland who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into Great Britain may fulfil the obligations on the GB importer under Article 139A (the “NI notifier”).
- 3 Article 36 applies to the NI notifier.
- 4 The NI notifier must, without prejudice to Article 36, keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
- 5 A person who intends to act in accordance with paragraph 2 must inform the GB importer that they intend to do so.
- 6 If the GB importer is informed of the intention in accordance with paragraph 5, then paragraphs 6 to 8 of Article 139A apply to the NI notifier instead of the GB importer as respects any protected NI import from the NI notifier.

#### *Article 139C*

#### **Authorisations and imports from Northern Ireland**

Subject to Articles 139D and 139E, Title 7 applies to and in respect of substances imported from Northern Ireland as it applies to and in respect of other substances.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### Article 139D

#### Authorisations and qualifying Northern Ireland goods

1 This Article applies to a person (“P”) that is established in Northern Ireland that is a manufacturer, importer or downstream user of a substance under EU REACH.

2 P may apply for an authorisation in respect of that substance under Article 62 if the substance is a qualifying Northern Ireland good (“QNIG”).

3 A substance is a QNIG if it is a QNIG on its own, or contained in a mixture or article that is a QNIG.

4 This Regulation applies to P in respect of the application, and to the authorisation if it is granted, as if P was an only representative of P appointed in accordance with Article 8.

### Article 139E

#### Application of Article 127G to qualifying Northern Ireland goods

1 This Article applies to a person established in Northern Ireland that made an existing application for an EU authorisation within the meaning of Article 127G(6) (the “existing NI applicant”) that satisfies the condition in paragraph 2.

2 The condition is that the substance in respect of which the application was made is a qualifying Northern Ireland good (“QNIG”).

3 The condition in paragraph (2) is satisfied if the application was in respect of a substance that is a QNIG on its own, or a substance contained in a mixture or article that is a QNIG.

4 Paragraphs 1 to 4 and 6 of Article 127G apply to the existing NI applicant as if the references to “Great Britain” were to “the United Kingdom”.

5 If the authorisation is granted—

- a it has no effect in Northern Ireland,
- b this Regulation applies to the existing NI applicant in respect of the authorisation as if the existing NI applicant was an only representative of the existing NI applicant appointed in accordance with Article 8.]

#### Textual Amendments

**F358** Title 15A inserted (31.12.2020) by S.I. 2019/758, reg. 1(1), **Sch. 2A** (as inserted by **The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020** (S.I. 2020/1577), regs. 1(1)(b), **6**; 2020 c. 1, **Sch. 5 para. 1(1)**)

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## ANNEX I

### GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

#### 0. INTRODUCTION

- [<sup>F359</sup>0.1. The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks. The chemical safety report shall also describe whether and which different nanoforms of substances as characterised in Annex VI are manufactured and imported, including an adequate justification for each information requirement describing when and how information on one form is used to demonstrate safety of other forms. The requirements specific of the following hazard classes or categories setcific to nanoforms of a substance in this Annex apply to all nanoforms covered by the registration and without prejudice to requirements applicable to other forms of that substance. This Annex shall also apply adapted as necessary to producers and importers of articles required to make a chemical safety assessment as part of a registration.]

#### Textual Amendments

**F359** Substituted by [Commission Regulation \(EU\) 2018/1881 of 3 December 2018 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances \(Text with EEA relevance\).](#)

- 0.2. The chemical safety assessment shall be prepared by one or more competent person(s) who have appropriate experience and received appropriate training, including refresher training.
- [<sup>F359</sup>0.3. The chemical safety assessment of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives), in a mixture and in an article, as defined by the identified uses. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The assessment shall address all nanoforms that are covered by the registration. The justifications and conclusions drawn from the assessment shall be relevant to these nanoforms. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.]
- [<sup>F359</sup>0.4. Substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or ‘ category ’ of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or ‘ category ’ of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or ‘ category ’ of substances. The manufacturer or importer shall provide a justification for this. Where



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any of the substances exists in one or more nanoforms and data from one form are used in demonstration of the safe use of other forms, in accordance with the general rules set out in Annex XI, a scientific justification shall be given on how, applying the rules for grouping and read-across, the data from a specific test or other information (e.g. methods, results or conclusions) can be used for the other forms of the substance. Similar considerations apply to exposure scenarios and risk management measures.]

- 0.5. The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Manufacturers or importers submitting a proposal for testing in accordance with Annexes IX and X shall record this under the relevant heading of the chemical safety report. Available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment carried out under [F360 domestic or European Union] legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessments shall be justified.

Thus the information to be considered includes information related to the hazards of the substance, the exposure arising from the manufacture or import, the identified uses of the substance, operational conditions and risk management measures applied or recommended to downstream users to be taken into account.

In accordance with section 3 of Annex XI in some cases, it may not be necessary to generate missing information, because risk management measures and operational conditions which are necessary to control a well-characterised risk may also be sufficient to control other potential risks, which will not therefore need to be characterised precisely.

[F359 If the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex IX or X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the chemical safety report under the appropriate heading. Where considered necessary, the proposal for a testing strategy may concern several studies addressing respectively different forms of the same substance for the same information requirement. While waiting for results of further testing, he shall record in his chemical safety report, and include in the exposure scenario developed, the interim risk management measures that he has put in place and those he recommends to downstream users intended to manage the risks being explored. The exposure scenarios and interim risk management measures recommended shall address all nanoforms that are covered by the registration.]

#### Textual Amendments

**F360** Words in Annex 1 point 0.5 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 1(2)** (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), 7(2)); 2020 c. 1, **Sch. 5 para. 1(1)**

[F361]0.6. Steps of a chemical safety assessment

- 0.6.1. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps 1 to 4 in accordance with the respective sections of this Annex:

1. Human health hazard assessment.

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2. Human health hazard assessment of physicochemical properties.
3. Environmental hazard assessment.
4. PBT and vPvB assessment.
- 0.6.2. In the cases referred to in point 0.6.3 the chemical safety assessment shall also include the following steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:
  5. Exposure assessment.
    - 5.1. The generation of exposure scenario(s) (or the identification of relevant use and exposure categories, if appropriate).
    - 5.2. Exposure estimation.
  6. Risk characterisation.
- [<sup>F359</sup>0.6.3. Where as a result of steps 1 to 4 the manufacturer or importer concludes that the substance or, when applicable, nanoforms thereof fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB, the chemical safety assessment shall also include steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:
  - (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F;
  - (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9, and 3.10;
  - (c) hazard class 4.1;
  - (d) hazard class 5.1.]
- 0.6.4. A summary of all the relevant information used in addressing the points above shall be presented under the relevant heading of the Chemical Safety Report (Section 7).]

#### Textual Amendments

**F361** Substituted by [Commission Regulation \(EU\) No 252/2011 of 15 March 2011 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annex I \(Text with EEA relevance\).](#)

- 0.7. The main element of the exposure part of the chemical safety report is the description of the exposure scenario(s) implemented for the manufacturer's production, the manufacturer or importer's own use, and those recommended by the manufacturer or importer to be implemented for the identified use(s).

An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users.

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If the substance is placed on the market, the relevant exposure scenario(s), including the risk management measures and operational conditions shall be included in an annex to the safety data sheet in accordance with Annex II.

- 0.8. The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous properties and the amount of information available to the manufacturer or importer. Exposure scenarios may describe the appropriate risk management measures for several individual processes or uses of a substance. An exposure scenario may thereby cover a large range of processes or uses. Exposure scenarios covering a wide range of processes or uses may be referred to as Exposure Categories. Further mention of Exposure Scenario in this Annex and Annex II includes Exposure Categories if they are developed.
- 0.9. Where information is not necessary in accordance with Annex XI, this fact shall be stated under the appropriate heading of the chemical safety report and a reference shall be made to the justification in the technical dossier. The fact that no information is required shall also be stated in the safety data sheet.
- 0.10. In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and summarised in the safety data sheet.
- 0.11. When assessing the risk of the use of one or more substances incorporated into a special [<sup>F1</sup>mixture] (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.
- <sup>F362</sup>0.11. When nanoforms are covered by the chemical safety assessment, an appropriate metric for the assessment and presentation of the results in steps 1-6 of the chemical safety assessment under 0.6.1 and 0.6.2 shall be considered, with the justification included in the chemical safety report and summarised in the safety data sheet. A multiple metric presentation, including mass metric information, is preferable. When possible, a method for reciprocal conversion shall be indicated.]

#### Textual Amendments

**F362** Inserted by [Commission Regulation \(EU\) 2018/1881 of 3 December 2018 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances \(Text with EEA relevance\)](#).

- 0.12. Where the methodology described in this Annex is not appropriate, details of alternative methodology used shall be explained and justified in the chemical safety report.
- 0.13. Part A of the chemical safety report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those exposure scenarios for the identified uses are communicated to distributors and downstream users in the safety data sheet(s).
1. HUMAN HEALTH HAZARD ASSESSMENT

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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## 1.0. Introduction

[<sup>F361</sup>1.0.1. The objectives of the human health hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008; and to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).]

[<sup>F361</sup>1.0.2. The human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance and the following groups of effects:

- (1) acute effects such as acute toxicity, irritation and corrosivity;
- (2) sensitisation;
- (3) repeated dose toxicity; and
- (4) CMR effects (carcinogenicity, germ cell mutagenicity and toxicity for reproduction).

Based on all the available information, other effects shall be considered when necessary.]

1.0.3. The hazard assessment shall comprise the following four steps:

- |        |  |
|--------|--|
| Step 1 | : Evaluation of non-human information. |
| Step 2 | : Evaluation of human information.     |
| Step 3 | : Classification and Labelling.        |
| Step 4 | : Derivation of DNELs.                 |

[<sup>F362</sup>The assessment shall address all nanofoms that are covered by the registration.]

1.0.4. The first three steps shall be undertaken for every effect for which information is available and shall be recorded under the relevant section of the Chemical Safety Report and where required and in accordance with Article 31, summarised in the Safety Data Sheet under headings 2 and 11.

1.0.5. For any effect for which no relevant information is available, the relevant section shall contain the sentence: ‘ This information is not available ’. The justification, including reference to any literature search carried out, shall be included in the technical dossier.

1.0.6. Step 4 of the human health hazard assessment shall be undertaken by integrating the results from the first three steps and shall be included under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under heading 8.1.

1.1. Step 1: Evaluation of non-human information

1.1.1. The evaluation of non-human information shall comprise:

- the hazard identification for the effect based on all available non-human information,
- the establishment of the quantitative dose (concentration)-response (effect) relationship.

1.1.2. When it is not possible to establish the quantitative dose (concentration)-response (effect) relationship, then this should be justified and a semi-quantitative or qualitative analysis shall be included. For instance, for acute effects it is usually not possible to establish the quantitative dose (concentration)-response (effect) relationship on the basis of the results of a test conducted in accordance with [<sup>F363</sup>Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to REACH].

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In such cases it suffices to determine whether and to which degree the substance has an inherent capacity to cause the effect.

#### Textual Amendments

**F363** Words in Annex 1 point 1.1.2 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 3 para. 1(3); 2020 c. 1, Sch. 5 para. 1(1)

[<sup>F361</sup>1.1.3. All non-human information used to assess a particular effect on humans and to establish the dose (concentration) – response (effect) relationship, shall be briefly presented, if possible in the form of a table or tables, distinguishing between *in vitro*, *in vivo* and other information. The relevant test results (e.g. ATE, LD50, NO(A)EL or LO(A)EL) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.]

1.1.4. If one study is available then a robust study summary should be prepared for that study. If there are several studies addressing the same effect, then, having taken into account possible variables (e.g. conduct, adequacy, relevance of test species, quality of results, etc.), normally the study or studies giving rise to the highest concern shall be used to establish the DNELs and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies demonstrating a higher concern than the study being used. It is important irrespective of whether hazards have been identified or not that the validity of the study be considered.

1.2. Step 2: Evaluation of human information

If no human information is available, this part shall contain the statement: ‘ No human information is available ’. However, if human information is available, it shall be presented, if possible in the form of a table.

1.3. Step 3: Classification and Labelling

[<sup>F361</sup>1.3.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Where applicable, Specific Concentration limits resulting from the application of Article 10 of Regulation (EC) No 1272/2008 <sup>F364</sup>... shall be presented and, if they are not included in [<sup>F365</sup>the GB mandatory classification and labelling list], justified.

[<sup>F359</sup>The assessment should always include a statement as to whether the substance or, when applicable, nanoforms thereof fulfils or does not fulfil the criteria given in Regulation (EC) No 1272/2008 for classification in the hazard class carcinogenicity category 1A or 1B, in the hazard class germ cell mutagenicity category 1A or 1B or in the hazard class reproductive toxicity category 1A or 1B.]

#### Textual Amendments

**F364** Words in Annex 1 point 1.3.1 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 3 para. 1(4); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

**F365** Words in Annex 1 point 1.3.1 substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), [Sch. 2 para. 5\(a\)](#) (as amended by [S.I. 2020/1567](#), reg. 1(2), [Sch. 2 para. 2\(d\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

[<sup>F359</sup>1.3.2. If the information is inadequate to decide whether a substance or, when applicable, nanoforms thereof should be classified for a particular hazard class or category, the registrants shall indicate and justify the action or decision he has taken as a result.]]

#### 1.4. Step 4: Identification of DNEL(s)

1.4.1. Based on the outcomes of steps 1 and 2, (a) DNEL(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. [<sup>F361</sup>For some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established.] If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, *inter alia*, be taken into account:

- (a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- (b) the nature and severity of the effect;
- (c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies.

1.4.2. If it is not possible to identify a DNEL, then this shall be clearly stated and fully justified.

## 2. PHYSICOCHEMICAL HAZARD ASSESSMENT

[<sup>F361</sup>2.1. The objective of the hazard assessment for physicochemical properties shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008.]

[<sup>F361</sup>2.2. As a minimum, the potential effects to human health shall be assessed for the following physicochemical properties:

- explosivity,
- flammability,
- oxidising potential.

[<sup>F359</sup>If the information is inadequate to decide whether a substance or, when applicable, nanoforms thereof should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.]]

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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2.3. The assessment of each effect shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 31, summarised in the Safety Data Sheet under headings 2 and 9.

2.4. For every physicochemical property, the assessment shall entail an evaluation of the inherent capacity of the substance to cause the effect resulting from the manufacture and identified uses.

[<sup>F361</sup>2.5. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified.]

### 3. ENVIRONMENTAL HAZARD ASSESSMENT

#### 3.0. Introduction

[<sup>F361</sup>3.0.1. The objective of the environmental hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008 and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC).]

3.0.2. The environmental hazard assessment shall consider the potential effects on the environment, comprising the (1) aquatic (including sediment), (2) terrestrial and (3) atmospheric compartments, including the potential effects that may occur (4) via food-chain accumulation. In addition, the potential effects on the (5) microbiological activity of sewage treatment systems shall be considered. The assessment of the effects on each of these five environmental spheres shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 31, summarised in the Safety Data Sheet under headings 2 and 12. [<sup>F362</sup>The assessment shall address all nanoforms that are covered by the registration.]

3.0.3. For any environmental sphere, for which no effect information is available, the relevant section of the chemical safety report shall contain the sentence: ‘ This information is not available ’ . The justification, including reference to any literature research carried out, shall be included in the technical dossier. For any environmental sphere for which information is available, but the manufacturer or importer believes that it is not necessary to conduct the hazard assessment, the manufacturer or importer shall present a justification, with reference to pertinent information, under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 31, summarised in the Safety Data Sheet under heading 12.

3.0.4. The hazard assessment shall comprise the following three steps, which shall be clearly identified as such in the Chemical Safety Report:

Step 1	: Evaluation of information.
Step 2	: Classification and Labelling.
Step 3	: Derivation of the PNEC.

#### 3.1. Step 1: Evaluation of information

3.1.1. The evaluation of all available information shall comprise:

- the hazard identification based on all available information,
- the establishment of the quantitative dose (concentration)-response (effect) relationship.



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- 3.1.2. When it is not possible to establish the quantitative dose (concentration)-response (effect) relationship, then this should be justified and a semi-quantitative or qualitative analysis shall be included.
- 3.1.3. All information used to assess the effects on a specific environmental sphere shall be briefly presented, if possible in the form of a table or tables. The relevant test results (e.g. LC50 or NOEC) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.
- 3.1.4. All information used to assess the environmental fate of the substance shall be briefly presented, if possible in the form of a table or tables. The relevant test results and test conditions and other relevant information shall be presented, in internationally recognised units of measurement for that effect.
- 3.1.5. If one study is available then a robust study summary should be prepared for that study. Where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies reaching a higher concern than the study being used. For substances where all available studies indicate no hazards an overall assessment of the validity of all studies should be performed.

### 3.2. Step 2: Classification and Labelling

- [<sup>F359</sup>3.2.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Any M-factor resulting from the application of Article 10 of Regulation (EC) No 1272/2008 shall be presented and, if it is not included in [<sup>F366</sup>the GB mandatory classification and labelling list], justified.

The presentation and justification is applied to all nanoforms covered by the registration.]

#### Textual Amendments

**F366** Words in Annex 1 point 3.2.1 substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), **Sch. 2 para. 5(b)** (as amended by [S.I. 2020/1567](#), reg. 1(2), **Sch. 2 para. 2(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

- [<sup>F359</sup>3.2.2. If the information is inadequate to decide whether a substance or, when applicable, nanoforms thereof should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.]

### 3.3. Step 3: Identification of the PNEC

- 3.3.1. Based on the available information, the PNEC for each environmental sphere shall be established. The PNEC may be calculated by applying an appropriate assessment factor to the effect values (e.g. LC50 or NOEC). An assessment factor expresses the difference between effects values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere <sup>(31)</sup>.



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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3.3.2. If it is not possible to derive the PNEC, then this shall be clearly stated and fully justified.

#### 4. PBT AND VPVB ASSESSMENT

##### 4.0. Introduction

4.0.1. The objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. A hazard assessment in accordance with Sections 1 and 3 of this Annex addressing all the long-term effects and the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5 (Exposure Assessment), step 2 (Exposure Estimation), cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria in Annex XIII. Therefore, a separate PBT and vPvB assessment is required.

<sup>F359</sup>4.0.2. The PBT and vPvB assessment shall comprise the following two steps, which shall be clearly identified as such in Part B, Section 8 of the Chemical Safety report. The assessment shall address all nanoforms that are covered by the registration:

Step 1	:	Comparison with the Criteria.
Step 2	:	Emission Characterisation.

The assessment shall also be summarised in the Safety Data Sheet under heading 12.]

##### <sup>F361</sup>4.1. **Step 1: Comparison with the criteria**

This part of the PBT and vPvB assessment shall entail the comparison of the available information with the criteria given in Section 1 of Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria. The assessment shall be conducted in accordance with the provisions laid down in the introductory part of Annex XIII as well as Sections 2 and 3 of that Annex.

##### <sup>F359</sup>4.2. **Step 2: Emission Characterisation**

If the substance fulfils the criteria or it is considered as if it is a PBT or vPvB in the registration dossier an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance. The estimation shall address all nanoforms that are covered by the registration.]]

#### 5. EXPOSURE ASSESSMENT

##### 5.0. Introduction

<sup>F359</sup>The objective of the exposure assessment shall be to make a quantitative and qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4. The assessment shall address all nanoforms that are

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covered by the registration. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:]

- Step 1 : Generation of exposure scenario(s) or the generation of relevant use and exposure categories.  
Step 2 : Exposure Estimation.

Where required and in accordance with Article 31, the exposure scenario shall also be included in an annex to the Safety Data Sheet.

#### 5.1. Step 1: Development of exposure scenarios

- 5.1.1. Exposure scenarios as described in Sections 0.7 and 0.8 shall be generated. Exposure scenarios are the core of the process to carry out a chemical safety assessment. The chemical safety assessment process may be iterative. The first assessment will be based on the required minimum and all available hazard information and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario). If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control. The refinement of hazard assessment may require generation of additional hazard information. The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation. The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report and attached to the safety data sheet in accordance with Article 31.

The final exposure scenario shall be presented under the relevant heading of the chemical safety report, and included in an annex to the safety data sheet, using an appropriate short title giving a brief general description of the use, consistent with those given in Section 3.5 of Annex VI. Exposure scenarios shall cover any manufacture in [<sup>F367</sup>Great Britain] and all identified uses.

#### Textual Amendments

**F367** Words in Annex 1 point 5.1.1 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 1(5)** (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), **7(3)(a)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

In particular, an exposure scenario includes, where relevant, a description of:

#### *Operational conditions*

- the processes involved, including the physical form in which the substance is manufactured, processed and/or used,
- the activities of workers related to the processes and the duration and frequency of their exposure to the substance,
- the activities of consumers and the duration and frequency of their exposure to the substance,
- the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment.

#### *Risk management measures*

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- the risk management measures to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance,
  - the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.
- 5.1.2. Where a manufacturer, importer or downstream user applies for an application for an authorisation for a specific use, exposure scenarios need only be developed for that use and the subsequent life-cycle steps.
- 5.2. Step 2: Exposure Estimation
- 5.2.1. The exposure shall be estimated for each exposure scenario developed and shall be presented under the relevant heading of the Chemical Safety Report and where required and in accordance with Article 31, summarised in an annex to the safety data sheet. The exposure estimation entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels.
- 5.2.2. The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented. [F362When nanoforms are covered by the registration, the emission estimation for these shall, where relevant, take account of situations when the conditions outlined in Annex XI section 3.2 point (c) are fulfilled.]
- [F3595.2.3. A characterisation of possible degradation, transformation, or reaction processes, and an estimation of environmental distribution and fate shall be performed.
- When nanoforms are covered by the registration, a characterisation of the dissolution rate, the particle aggregation, the agglomeration and of the particle surface chemistry changes shall be included.]
- 5.2.4. An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern. In particular, the exposure estimation shall take account of:
- adequately measured, representative exposure data,
  - any major impurities and additives in the substance,
  - the quantity in which the substance is produced and/or imported,
  - the quantity for each identified use,
  - implemented or recommended risk management, including the degree of containment,
  - duration and frequency of exposure according to the operational conditions,
  - the activities of workers related to the processes and the duration and frequency of their exposure to the substance,
  - the activities of consumers and the duration and frequency of their exposure to the substance,

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- the duration and frequency of emissions of the substance to the different environmental compartments and the dilution in the receiving environmental compartment,
- the physicochemical properties of the substance,
- transformation and/or degradation products,
- the likely routes of exposure of and potential for absorption in humans,
- the likely pathways to the environment and environmental distribution and degradation and/or transformation (see also Section 3 Step 1),
- scale (geographical) of exposure,
- matrix dependent release/migration of the substance.

5.2.5. Where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered.

## 6. RISK CHARACTERISATION

6.1. The risk characterisation shall be carried out for each exposure scenario and shall be presented under the relevant heading of the Chemical Safety Report.

6.2. The risk characterisation shall consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described in the exposure scenarios in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

6.3. The risk characterisation consists of:

- a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL,
- a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs, and
- an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

6.4. For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

- the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and,
- the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in Section 2 is negligible.

6.5. For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.

For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions

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to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

## 7. CHEMICAL SAFETY REPORT FORMAT

The Chemical Safety Report shall include the following headings:  
CHEMICAL SAFETY REPORT FORMAT

### PART A 1. SUMMARY OF RISK MANAGEMENT MEASURES

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

### PART B 1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

2. MANUFACTURE AND USES

2.1. Manufacture

2.2. Identified uses

2.3. Uses advised against

3. CLASSIFICATION AND LABELLING

4. ENVIRONMENTAL FATE PROPERTIES

4.1. Degradation

4.2. Environmental distribution

4.3. Bioaccumulation

4.4. Secondary poisoning

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.2. Acute toxicity

5.3. Irritation

<sup>F368</sup>5.3.1. ....

#### Textual Amendments

**F368** Deleted by [Commission Regulation \(EU\) No 252/2011 of 15 March 2011 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annex I \(Text with EEA relevance\).](#)

<sup>F368</sup>5.3.2. ....

<sup>F368</sup>5.3.3. ....

5.4. Corrosivity

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- 5.5. Sensitisation
  - <sup>F368</sup>5.5.1. ....
  - <sup>F368</sup>5.5.2. ....
- 5.6. Repeated dose toxicity
- [<sup>F361</sup>5.7. Germ cell mutagenicity]
- 5.8. Carcinogenicity
- 5.9. Toxicity for reproduction
  - <sup>F368</sup>5.9.1. ....
  - <sup>F368</sup>5.9.2. ....
- 5.10. Other effects
- 5.11. Derivation of DNEL(s)
- 6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES
  - 6.1. Explosivity
  - 6.2. Flammability
  - 6.3. Oxidising potential
- 7. ENVIRONMENTAL HAZARD ASSESSMENT
  - 7.1. Aquatic compartment (including sediment)
  - 7.2. Terrestrial compartment
  - 7.3. Atmospheric compartment
  - 7.4. Microbiological activity in sewage treatment systems
- 8. PBT AND VPVB ASSESSMENT
- 9. EXPOSURE ASSESSMENT
  - 9.1. (Title of exposure scenario 1)
    - 9.1.1. Exposure scenario
    - 9.1.2. Exposure estimation
  - 9.2. (Title of exposure scenario 2)
    - 9.2.1. Exposure scenario
    - 9.2.2. Exposure estimation
  - (etc.)
- 10. RISK CHARACTERISATION

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- 10.1. (Title of exposure scenario 1)
  - 10.1.1. Human health
    - 10.1.1.1. Workers
    - 10.1.1.2. Consumers
    - 10.1.1.3. Indirect exposure to humans via the environment
  - 10.1.2. Environment
    - 10.1.2.1. Aquatic compartment (including sediment)
    - 10.1.2.2. Terrestrial compartment
    - 10.1.2.3. Atmospheric compartment
    - 10.1.2.4. Microbiological activity in sewage treatment systems
- 10.2. (Title of exposure scenario 2)
  - 10.2.1. Human health
    - 10.2.1.1. Workers
    - 10.2.1.2. Consumers
    - 10.2.1.3. Indirect exposure to humans via the environment
  - 10.2.2. Environment
    - 10.2.2.1. Aquatic compartment (including sediment)
    - 10.2.2.2. Terrestrial compartment
    - 10.2.2.3. Atmospheric compartment
    - 10.2.2.4. Microbiological activity in sewage treatment systems
- (etc.)
- 10.x. Overall exposure (combined for all relevant emission/release sources)
  - 10.x.1. Human health (combined for all exposure routes)
    - 10.x.1.1.
  - 10.x.2. Environment (combined for all emission sources)
    - 10.x.2.1.

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

## [<sup>F369</sup>ANNEX II

### REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS

#### Textual Amendments

**F369** Substituted by [Commission Regulation \(EU\) 2015/830 of 28 May 2015 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) \(Text with EEA relevance\).](#)

#### PART A

##### 0.1. Introduction

- 0.1.1. This Annex sets out the requirements that the supplier shall fulfil for the compilation of a safety data sheet that is provided for a substance or a mixture in accordance with Article 31.
- 0.1.2. The information provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been completed, the relevant exposure scenario(s) shall be placed in an annex to the safety data sheet.

##### 0.2. General requirements for compiling a safety data sheet

- 0.2.1. The safety data sheet shall enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment. The writer of the safety data sheet shall take into account that a safety data sheet must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture.
- 0.2.2. The information provided by safety data sheets shall also meet the requirements set out in [<sup>F370</sup>retained EU law that transposed] Directive 98/24/EC. In particular, the safety data sheet shall enable employers to determine whether any hazardous chemical agents are present in the workplace and to assess any risk to the health and safety of workers arising from their use.

#### Textual Amendments

**F370** Words in Annex 2 point 0.2.2 inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(2)**; 2020 c. 1, Sch. 5 para. 1(1)

- 0.2.3. The information in the safety data sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known. Suppliers of substances and mixtures shall ensure that such competent persons have received appropriate training, including refresher training.
- 0.2.4. The language used in the safety data sheet shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Statements such as ‘ may be dangerous ’, ‘ no health effects ’, ‘ safe under most conditions of use ’ or ‘ harmless ’ or any other statements indicating that the substance or mixture is not hazardous or any other



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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statements that are inconsistent with the classification of that substance or mixture shall not be used.

0.2.5. The date of compilation of the safety data sheet shall be given on the first page. When a safety data sheet has been revised and the new, revised version is provided to recipients, the changes shall be brought to the attention of the recipients in Section 16 of the safety data sheet, unless the changes have been indicated elsewhere. For the revised safety data sheets, the date of compilation, identified as ‘ Revision: (date) ’, as well as a version number, revision number, supersedes date or some other indication of what version is replaced shall appear on the first page.

### 0.3. **Safety data sheet format**

0.3.1. A safety data sheet is not a fixed length document. The length of the safety data sheet shall be commensurate with the hazard of the substance or mixture and the information available.

0.3.2. All pages of a safety data sheet, including any annexes, shall be numbered and shall bear either an indication of the length of the safety data sheet (such as ‘ page 1 of 3 ’) or an indication whether there is a page following (such as ‘ Continued on next page ’ or ‘ End of safety data sheet ’).

### 0.4. **Safety data sheet content**

The information required by this Annex shall be included in the safety data sheet, where applicable and available, in the relevant subsections set out in Part B. The safety data sheet shall not contain blank subsections.

### 0.5. **Other information requirements**

The inclusion of additional relevant and available information in the relevant subsections may be necessary in some cases in view of the wide range of properties of substances and mixtures.

Additional safety and environmental information is required to address the needs of seafarers and other transport workers in the bulk transport of dangerous goods in seagoing or inland navigation bulk carriers or tank-vessels subject to International Maritime Organisation (IMO) or national regulations. Subsection 14.7 recommends the inclusion of basic classification information when such cargoes are transported in bulk according to Annex II of the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (Marpol) <sup>(32)</sup> and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code) (the IBC Code) <sup>(33)</sup>. In addition, ships carrying oil or oil fuel, as defined in Annex I of Marpol, in bulk or bunkering oil fuel are required, before loading, to be provided with a ‘material safety data sheet’ in accordance with the IMO's Maritime Safety Committee (MSC) resolution ‘Recommendations for Material Safety Data Sheets (MSDS) for Marpol Annex I Oil Cargo and Oil Fuel’ (MSC.286(86)). Therefore, in order to have one harmonised safety data sheet for maritime and non-maritime use, the additional provisions of Resolution MSC.286(86) may be included in the safety data sheets, where appropriate, for marine transport of Marpol Annex I cargoes and marine fuel oils.

### 0.6. **Units**

The units of measurement as set out in Council Directive 80/181/EEC <sup>(34)</sup> shall be used.

### 0.7. **Special cases**

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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Safety data sheets shall also be required for the special cases listed in paragraph 1.3 of Annex I to Regulation (EC) No 1272/2008 for which there are labelling derogations.

1. **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

This section of the safety data sheet shall prescribe how the substance or mixture shall be identified and how the identified relevant uses, the name of the supplier of the substance or mixture and the contact detail information of the supplier of the substance or mixture, including an emergency contact, shall be provided in the safety data sheet.

1.1. **Product identifier**

The product identifier shall be provided in accordance with Article 18(2) of Regulation (EC) No 1272/2008 in the case of a substance and in accordance with Article 18(3)(a) of Regulation (EC) No 1272/2008 in the case of a mixture, and as provided on the label in [<sup>F371</sup>English].

**Textual Amendments**

**F371** Word in Annex 2 point 1.1 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

For substances subject to registration, the product identifier shall be consistent with that provided in the registration and the registration number assigned under Article 20(3) of this Regulation shall also be indicated.

Without affecting the obligations of downstream users laid down in Article 39 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by a supplier who is a distributor or a downstream user provided that:

- (a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and
- (b) this supplier provides the full registration number to the <sup>F372</sup>... authority responsible for enforcement (the enforcement authority) within 7 days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within 7 days upon request and at the same time inform the enforcement authority thereof.

**Textual Amendments**

**F372** Words in Annex 2 point 1.1 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

A single safety data sheet may be provided to cover more than one substance or mixture where the information in that safety data sheet fulfils the requirements of this Annex for each of those substances or mixtures.

*Other means of identification*

Other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers may be provided.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## 1.2. Relevant identified uses of the substance or mixture and uses advised against

At least the identified uses relevant for the recipient(s) of the substance or mixture shall be indicated. This shall be a brief description of what the substance or mixture is intended to do, such as ‘ flame retardant ’ , ‘ antioxidant ’ .

The uses which the supplier advises against and the reasons why shall, where applicable, be stated. This need not be an exhaustive list.

Where a chemical safety report is required, the information in this subsection of the safety data sheet shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

## 1.3. Details of the supplier of the safety data sheet

The supplier, whether it is the manufacturer, importer, only representative, downstream user or distributor, shall be identified. The full address and telephone number of the supplier shall be given as well as an e-mail address for a competent person responsible for the safety data sheet.

F373

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### Textual Amendments

**F373** Words in Annex 2 point 1.3 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

Where an only representative has been appointed, details of the [<sup>F374</sup>non-Great British] manufacturer or formulator may also be provided.

### Textual Amendments

**F374** Words in Annex 2 point 1.3 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(4)(b)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **7(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

## 1.4. Emergency telephone number

References to emergency information services shall be provided. If an official advisory body exists <sup>F375</sup>... (this may be the body responsible for receiving information relating to health referred to in Article 45 of Regulation (EC) No 1272/2008), its telephone number shall be given and can suffice. If availability of such services is limited for any reasons, such as hours of operation, or if there are limits on specific types of information provided, this shall be clearly stated.

### Textual Amendments

**F375** Words in Annex 2 point 1.4 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(5)**; 2020 c. 1, Sch. 5 para. 1(1)

## 2. SECTION 2: Hazards identification

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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This section of the safety data sheet shall describe the hazards of the substance or mixture and the appropriate warning information associated with those hazards.

### 2.1. Classification of the substance or mixture

The classification of the substance or the mixture which results from the application of the classification criteria in Regulation (EC) No 1272/2008 shall be given. Where the supplier has notified information regarding the substance<sup>F376</sup>... in accordance with Article 40 of Regulation (EC) No 1272/2008, the classification given in the safety data sheet shall be the same as the classification provided in that notification.

#### Textual Amendments

**F376** Words in Annex 2 point 2.1 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 2\(6\)](#); 2020 c. 1, Sch. 5 para. 1(1)

If the mixture does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008, this shall be clearly stated.

Information on the substances in the mixture is provided under subsection 3.2.

If the classification, including the hazard statements, is not written out in full, reference shall be made to Section 16 where the full text of each classification, including each hazard statement, shall be given.

The most important adverse physical, human health and environmental effects shall be listed in accordance with Sections 9 to 12 of the safety data sheet, in such a way as to allow non-experts to identify the hazards of the substance or mixture.

### 2.2. Label elements

Based on the classification, at least the following elements appearing on the label in accordance with Regulation (EC) No 1272/2008 shall be provided: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s). A graphical reproduction of the full hazard pictogram in black and white or a graphical reproduction of the symbol only may be substituted for the colour pictogram provided in Regulation (EC) No 1272/2008.

The applicable label elements in accordance with Article 25 and Article 32(6) of Regulation (EC) No 1272/2008 shall be provided.

### 2.3. Other hazards

Information on whether the substance or mixture meets the criteria for PBT or vPvB in accordance with Annex XIII shall be provided.

Information shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture, such as formation of air contaminants during hardening or processing, dustiness, explosive properties which do not fulfil the classification criteria of part 2 Section 2.1 of Annex I to Regulation (EC) No 1272/2008, dust explosion hazards, cross-sensitisation, suffocation, freezing, high potency for odour or taste, or environmental effects like hazards to soil-dwelling organisms, or photochemical ozone creation potential. The statement ‘ May form explosible dust-air mixture if dispersed ’ is appropriate in the case of a dust explosion hazard.

## 3. SECTION 3: Composition/information on ingredients

This section of the safety data sheet shall describe the chemical identity of the ingredient(s) of the substance or mixture, including impurities and stabilising additives as set out below. Appropriate and available safety information on surface chemistry shall be indicated.

### 3.1. Substances

The chemical identity of the main constituent of the substance shall be provided by providing at least the product identifier or one of the other means of identification given in subsection 1.1.

The chemical identity of any impurity, stabilising additive, or individual constituent other than the main constituent, which is itself classified and which contributes to the classification of the substance shall be provided as follows:

- (a) the product identifier in accordance with Article 18(2) of Regulation (EC) No 1272/2008;
- (b) if the product identifier is not available, one of the other names (usual name, trade name, abbreviation) or identification numbers.

Suppliers of substances may choose to list in addition all constituents including non-classified ones.

This subsection may also be used to provide information on multi-constituent substances.

### 3.2. Mixtures

The product identifier, the concentration or concentration ranges and the classifications shall be provided for at least all substances referred to in points 3.2.1 or 3.2.2. Suppliers of mixtures may choose to list in addition all substances in the mixture, including substances not meeting the criteria for classification. This information shall enable the recipient to identify readily the hazards of the substances in the mixture. The hazards of the mixture itself shall be given in Section 2.

The concentrations of the substances in a mixture shall be described as either of the following:

- (a) exact percentages in descending order by mass or volume, if technically possible;
- (b) ranges of percentages in descending order by mass or volume, if technically possible.

When using a range of percentages, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

If the effects of the mixture as a whole are available, this information shall be included under Section 2.

Where the use of an alternative chemical name is permitted in accordance with Article 24 of Regulation (EC) No 1272/2008, that name can be used.

3.2.1. For a mixture meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008, the following substances shall be indicated, together with their concentration or concentration range in the mixture:

- (a) substances presenting a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008, if those substances are present in concentrations equal to or greater than the lowest of any of the following:
  - (ia) the generic cut-off values set out in Table 1.1 of Annex I to Regulation (EC) No 1272/2008;

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- (ib) the generic concentration limits given in parts 3 to 5 of Annex I to Regulation (EC) No 1272/2008, taking into account the concentrations specified in the notes to certain tables in part 3 in relation to the obligation to make available a safety data sheet for the mixture upon request, and for aspiration hazard (Section 3.10 of Annex I to Regulation (EC) No 1272/2008)  $\geq 10\%$ ;

**LIST OF HAZARD CLASSES, HAZARD CATEGORIES AND CONCENTRATION LIMITS FOR WHICH A SUBSTANCE SHALL BE LISTED AS A SUBSTANCE IN A MIXTURE IN SUBSECTION 3.2**

<b>1.1. Hazard class and category</b>	<b>Concentration limit (%)</b>
Acute toxicity, category 1, 2 and 3	$\geq 0,1$
Acute toxicity, category 4	$\geq 1$
Skin corrosion/irritation, category 1, sub-categories 1A, 1B, 1C and category 2	$\geq 1$
Serious damage to eyes/eye irritation, category 1 and 2	$\geq 1$
Respiratory/skin sensitisation	$\geq 0,1$
Germ cell mutagenicity category 1A and 1B	$\geq 0,1$
Germ cell mutagenicity category 2	$\geq 1$
Carcinogenicity category 1A, 1B and 2	$\geq 0,1$
Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation	$\geq 0,1$
Specific target organ toxicity (STOT) — single exposure, category 1 and 2	$\geq 1$
Specific target organ toxicity (STOT) — repeated exposure, category 1 and 2	$\geq 1$
Aspiration hazard	$\geq 10$
Hazardous to the aquatic environment — Acute, category 1	$\geq 0,1$
Hazardous to the aquatic environment — Chronic, category 1	$\geq 0,1$
Hazardous to the aquatic environment — Chronic, category 2, 3 and 4	$\geq 1$
Hazardous for the ozone layer	$\geq 0,1$

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- (ii) the specific concentration limits given in [<sup>F377</sup>the GB mandatory classification and labelling list];
  - (iii) if an M-factor has been given in [<sup>F378</sup>the GB mandatory classification and labelling list], the generic cut-off value in Table 1.1 of Annex I to that Regulation, adjusted using the calculation set out in Section 4.1 of Annex I to that Regulation;
  - (iv) the specific concentration limits provided to the [<sup>F379</sup>GB notification database] established under Regulation (EC) No 1272/2008;
  - (v) the concentration limits set out in Annex II to Regulation (EC) No 1272/2008;
  - (vi) if an M-factor has been provided to the [<sup>F380</sup>GB notification database] established under Regulation (EC) No 1272/2008, the generic cut-off value in Table 1.1 of Annex I to that Regulation, adjusted using the calculation set out in Section 4.1 of Annex I to that Regulation.
- (b) substances for which there are Union workplace exposure limits which are not already included under point (a);
- (c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or substances included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a), if the concentration of an individual substance is equal to or greater than 0,1 %.

#### Textual Amendments

- F377** Words in Annex 2 point 3.2.1(a)(ii) substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), [Sch. 2 para. 6\(a\)](#) (as amended by [S.I. 2020/1567](#), reg. 1(2), [Sch. 2 para. 2\(e\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F378** Words in Annex 2 point 3.2.1(a)(iii) substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), [Sch. 2 para. 6\(a\)](#) (as amended by [S.I. 2020/1567](#), reg. 1(2), [Sch. 2 para. 2\(e\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F379** Words in Annex 2 point 3.2.1(a)(iv) substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), [Sch. 2 para. 6\(b\)](#) (as amended by [S.I. 2020/1567](#), reg. 1(2), [Sch. 2 para. 2\(e\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F380** Words in Annex 2 point 3.2.1(a)(vi) substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), [Sch. 2 para. 6\(b\)](#) (as amended by [S.I. 2020/1567](#), reg. 1(2), [Sch. 2 para. 2\(e\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

3.2.2. For a mixture not meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008, substances present in an individual concentration equal to or greater than the following concentrations shall be indicated, together with their concentration or concentration range:

- (a) 1 % by weight in non-gaseous mixtures and 0,2 % by volume in gaseous mixtures for:

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- (i) substances which present a health or environmental hazard within the meaning of Regulation (EC) No 1272/2008; or
  - (ii) substances for which <sup>F381</sup>... workplace exposure limits have been assigned;
- (b) 0,1 % by weight for substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII, very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or included in the list established in accordance with Article 59(1) for reasons other than the hazards referred to in point (a).

#### Textual Amendments

**F381** Word in Annex 2 point 3.2.2(a)(ii) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(7)**; 2020 c. 1, Sch. 5 para. 1(1)

- 3.2.3. For the substances indicated in subsection 3.2, the classification of the substance according to Regulation (EC) No 1272/2008, including the hazard class(es) and category code(s) as provided in Table 1.1 of Annex VI to that Regulation as well as the hazard statements which are assigned in accordance with their physical, human health and environmental hazards, shall be provided. The hazard statements do not need to be written out in full in this section; their codes shall be sufficient. In cases where they are not written out in full, reference shall be made to Section 16, where the full text of each relevant hazard statement shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in subsection 3.2 shall be described, such as ‘ non-classified vPvB substance ’ or ‘ substance with a <sup>F382</sup>... workplace exposure limit ’ .

#### Textual Amendments

**F382** Word in Annex 2 point 3.2.3 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(8)**; 2020 c. 1, Sch. 5 para. 1(1)

- 3.2.4. For the substances indicated in subsection 3.2 the name and, if available, the registration number, as assigned under Article 20(3) of this Regulation, shall be given.

Without affecting the obligations of downstream users laid down in Article 39 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by the supplier of the mixture provided that:

- (a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and
- (b) this supplier provides the full registration number to the <sup>F383</sup>... authority responsible for enforcement (hereinafter referred to as the enforcement authority) within seven days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within seven days upon request and at the same time inform the enforcement authority thereof.



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F383** Words in Annex 2 point 3.2.4 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(9)**; 2020 c. 1, Sch. 5 para. 1(1)

The EC number, if available, shall be given in accordance with Regulation (EC) No 1272/2008. The CAS number, if available, and the IUPAC name, if available, may also be given.

For substances indicated in this subsection by means of an alternative chemical name in accordance with Article 24 of Regulation (EC) No 1272/2008, the registration number, EC number and other precise chemical identifiers are not necessary.

#### 4. **SECTION 4: First aid measures**

This section of the safety data sheet shall describe the initial care in such a way that an untrained responder can understand and provide it without the use of sophisticated equipment and without the availability of a wide selection of medications. If medical attention is required, the instructions shall state this, including its urgency.

##### 4.1. **Description of first aid measures**

4.1.1. First aid instructions shall be provided by relevant routes of exposure. Subdivisions shall be used to indicate the procedure for each route, such as inhalation, skin, eye and ingestion.

4.1.2. Advice shall be provided as to whether:

- (a) immediate medical attention is required and if delayed effects can be expected after exposure;
- (b) movement of the exposed individual from the area to fresh air is recommended;
- (c) removal and handling of clothing and shoes from the individual is recommended; and
- (d) personal protective equipment for first aid responders is recommended.

##### 4.2. **Most important symptoms and effects, both acute and delayed**

Briefly summarised information shall be provided on the most important symptoms and effects, both acute and delayed, from exposure.

##### 4.3. **Indication of any immediate medical attention and special treatment needed**

Where appropriate, information shall be provided on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications.

For some substances or mixtures, it may be important to emphasise that special means to provide specific and immediate treatment shall be available at the workplace.

#### 5. **SECTION 5: Firefighting measures**

This section of the safety data sheet shall describe the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

##### 5.1. **Extinguishing media**

Suitable extinguishing media:

Information shall be provided on the appropriate extinguishing media.

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Unsuitable extinguishing media:

Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture (e.g. avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture).

#### 5.2. **Special hazards arising from the substance or mixture**

Information shall be provided on hazards that may arise from the substance or mixture, like hazardous combustion products that form when the substance or mixture burns, such as ‘ may produce toxic fumes of carbon monoxide if burning ’ or ‘ produces oxides of sulphur and nitrogen on combustion ’ .

#### 5.3. **Advice for firefighters**

Advice shall be provided on any protective actions to be taken during firefighting, such as ‘ keep containers cool with water spray ’ , and on special protective equipment for firefighters, such as boots, overalls, gloves, eye and face protection and breathing apparatus.

### 6. **SECTION 6: Accidental release measures**

This section of the safety data sheet shall recommend the appropriate response to spills, leaks, or releases, to prevent or minimise the adverse effects on persons, property and the environment. It shall distinguish between responses to large and small spills, in cases where the spill volume has a significant impact on the hazard. If the procedures for containment and recovery indicate that different practices are required, these shall be indicated in the safety data sheet.

#### 6.1. **Personal precautions, protective equipment and emergency procedures**

##### 6.1.1. *For non-emergency personnel*

Advice shall be provided related to accidental spills and release of the substance or mixture such as:

- (a) the wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing;
- (b) removal of ignition sources, provision of sufficient ventilation, control of dust; and
- (c) emergency procedures such as the need to evacuate the danger area or to consult an expert.

##### 6.1.2. *For emergency responders*

Advice shall be provided related to suitable fabric for personal protective clothing (such as ‘ appropriate: Butylene ’ ; ‘ not appropriate: PVC ’ ).

#### 6.2. **Environmental precautions**

Advice shall be provided on any environmental precautions to be taken related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water.

#### 6.3. **Methods and material for containment and cleaning up**

- 6.3.1. Appropriate advice shall be provided on how to contain a spill. Appropriate containment techniques may include any of the following:

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- (a) bunding, covering of drains;
  - (b) capping procedures.
- 6.3.2. Appropriate advice shall be provided on how to clean-up a spill. Appropriate clean-up procedures may include any of the following:
- (a) neutralisation techniques;
  - (b) decontamination techniques;
  - (c) adsorbent materials;
  - (d) cleaning techniques;
  - (e) vacuuming techniques;
  - (f) equipment required for containment/clean-up (include the use of non-sparking tools and equipment where applicable).
- 6.3.3. Any other information shall be provided relating to spills and releases, including advice on inappropriate containment or clean-up techniques, such as by indications like ‘ never use ... ’.

#### 6.4. Reference to other sections

If appropriate Sections 8 and 13 shall be referred to.

### 7. SECTION 7: Handling and storage

This section of the safety data sheet shall provide advice on safe handling practices. It shall emphasise precautions that are appropriate to the identified uses referred to under subsection 1.2 and to the unique properties of the substance or mixture.

Information in this section of the safety data sheet shall relate to the protection of human health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to [F384 retained EU law that transposed] Article 5 of Directive 98/24/EC and Article 5 of Directive 2004/37/EC.

#### Textual Amendments

**F384** Words in Annex 2 point 7 inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 2\(10\)](#); 2020 c. 1, Sch. 5 para. 1(1)

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

In addition to information given in this section, relevant information may also be found in Section 8.

#### 7.1. Precautions for safe handling

7.1.1. Recommendations shall be specified to:

- (a) allow safe handling of the substance or mixture, such as containment and measures to prevent fire as well as aerosol and dust generation;

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- (b) prevent handling of incompatible substances or mixtures;
- (c) draw attention to operations and conditions which create new risks by altering the properties of the substance or mixture, and to appropriate countermeasures; and
- (d) reduce the release of the substance or mixture to the environment, such as avoiding spills or keeping away from drains.

7.1.2. Advice on general occupational hygiene shall be provided, such as:

- (a) not to eat, drink and smoke in work areas;
- (b) to wash hands after use; and
- (c) to remove contaminated clothing and protective equipment before entering eating areas.

## 7.2. **Conditions for safe storage, including any incompatibilities**

The advice provided shall be consistent with the physical and chemical properties described in Section 9 of the safety data sheet. If relevant, advice shall be provided on specific storage requirements including:

- (a) how to manage risks associated with:
  - (i) explosive atmospheres;
  - (ii) corrosive conditions;
  - (iii) flammability hazards;
  - (iv) incompatible substances or mixtures;
  - (v) evaporative conditions; and
  - (vi) potential ignition sources (including electrical equipment);
- (b) how to control the effects of:
  - (i) weather conditions;
  - (ii) ambient pressure;
  - (iii) temperature;
  - (iv) sunlight;
  - (v) humidity; and
  - (vi) vibration;
- (c) how to maintain the integrity of the substance or mixture by the use of:
  - (i) stabilisers; and
  - (ii) antioxidants;
- (d) other advice including:
  - (i) ventilation requirements;

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- (ii) specific designs for storage rooms or vessels (including retention walls and ventilation);
- (iii) quantity limits under storage conditions (if relevant); and
- (iv) packaging compatibilities.

### 7.3. Specific end use(s)

For substances and mixtures designed for specific end use(s), recommendations shall relate to the identified use(s) referred to in subsection 1.2 and be detailed and operational. If an exposure scenario is attached, reference to it may be made or the information as required in subsections 7.1 and 7.2 shall be provided. If an actor in the supply chain has carried out a chemical safety assessment for the mixture, it is sufficient that the safety data sheet and the exposure scenarios are consistent with the chemical safety report for the mixture, rather than with the chemical safety reports for each substance in the mixture. If industry- or sector-specific guidance is available, detailed reference to it (including source and issuing date) may be made.

## 8. SECTION 8: Exposure controls/personal protection

This section of the safety data sheet shall describe the applicable occupational exposure limits and necessary risk management measures.

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

### 8.1. Control parameters

- 8.1.1. Where available, the following national limit values, including the legal basis of each of them, which are currently applicable <sup>F385</sup>... shall be listed for the substance or for each of the substances in the mixture. When listing occupational exposure limit values, the chemical identity as specified in Section 3 shall be used:

#### Textual Amendments

**F385** Words in Annex 2 point 8.1.1 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(11)**; 2020 c. 1, **Sch. 5 para. 1(1)**

- 8.1.1.1. [<sup>F386</sup>the workplace exposure limit within the meaning of the Control of Substances Hazardous to Health Regulations 2002 ([S.I. 2002/2677](#));
- 8.1.1.2. the occupational exposure limit within the meaning of the Control of Lead at Work Regulations 2002 ([S.I. 2002/2676](#)).]

#### Textual Amendments

**F386** Annex 2 points 8.1.1.1, 8.1.1.2 substituted for points 8.1.1.1-8.1.1.5 (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(12)** (as amended by [S.I. 2020/1577](#), regs. 1(1)(b), 7(5)); 2020 c. 1, **Sch. 5 para. 1(1)**

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- 8.1.2. Information on currently recommended monitoring procedures shall be provided at least for the most relevant substances.
- 8.1.3. If air contaminants are formed when using the substance or mixture as intended, applicable occupational exposure limit values and/or biological limit values for these shall also be listed.
- 8.1.4. Where a chemical safety report is required or where a DNEL as referred to in Section 1.4 of Annex I or a PNEC as referred to in Section 3.3 of Annex I is available, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.
- 8.1.5. Where a control banding approach is used to decide on risk management measures in relation to specific uses, sufficient detail shall be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation shall be made clear.

## 8.2. Exposure controls

The information required in the present subsection shall be provided, unless an exposure scenario containing that information is attached to the safety data sheet.

Where the supplier has waived a test under Section 3 of Annex XI, he shall indicate the specific conditions of use relied on to justify the waiving.

Where a substance has been registered as an isolated intermediate (on-site or transported), the supplier shall indicate that this safety data sheet is consistent with the specific conditions relied on to justify the registration in accordance with Article 17 or 18.

### 8.2.1. *Appropriate engineering controls*

The description of appropriate exposure control measures shall relate to the identified use(s) of the substance or mixture as referred to in subsection 1.2. This information shall be sufficient to enable the employer to carry out an assessment of risk to the safety and health of workers arising from the presence of the substance or mixture in accordance with [F387 the retained EU law that transposed] Articles 4 to 6 of Directive 98/24/EC and Articles 3 to 5 of Directive 2004/37/EC, where appropriate.

#### **Textual Amendments**

**F387** Words in Annex 2 point 8.2.1 inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 2\(13\)](#); 2020 c. 1, Sch. 5 para. 1(1)

This information shall complement that already given under Section 7.

### 8.2.2. *Individual protection measures, such as personal protective equipment*

8.2.2.1. The information on use of personal protective equipment shall be consistent with good occupational hygiene practices and in conjunction with other control measures, including engineering controls, ventilation and isolation. Where appropriate, Section 5 shall be referred to for specific fire/chemical personal protective equipment advice.

8.2.2.2. Taking into account [F388 Regulation (EU) 2016/425] and referring to the appropriate CEN standards, detailed specifications shall be given on which equipment will provide adequate and suitable protection, including:

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F388** Words in Annex 2 point 8.2.2.2 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(14)**; 2020 c. 1, Sch. 5 para. 1(1)

(a) Eye/face protection

The type of eye/face protection equipment required shall be specified based on the hazard of the substance or mixture and potential for contact, such as safety glasses, safety goggles, face-shield.

(b) Skin protection

(i) *Hand protection*

The type of gloves to be worn when handling the substance or mixture shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

- the type of material and its thickness,
- the typical or minimum breakthrough times of the glove material,

If necessary, any additional hand protection measures shall be indicated.

(ii) *Other*

If it is necessary to protect a part of the body other than the hands, the type and quality of protection equipment required shall be specified, such as gauntlets, boots, bodysuit based on the hazards associated with the substance or mixture and the potential for contact.

If necessary, any additional skin protection measures and specific hygiene measures shall be indicated.

(c) Respiratory protection

For gases, vapours, mist or dust, the type of protective equipment to be used shall be specified based on the hazard and potential for exposure, including air-purifying respirators, specifying the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or self-contained breathing apparatus.

(d) Thermal hazards

When specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration shall be given to the construction of the personal protective equipment.

### 8.2.3. *Environmental exposure controls*

The information required by the employer to fulfil his commitments under <sup>F389</sup>... environmental protection legislation shall be specified.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F389** Word in Annex 2 point 8.2.3 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(15)**; 2020 c. 1, Sch. 5 para. 1(1)

Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of the environment to the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

## 9. SECTION 9: Physical and chemical properties

This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant. Article 8(2) of Regulation (EC) No 1272/2008 shall apply. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

### 9.1. Information on basic physical and chemical properties

The following properties shall be clearly identified including, where appropriate, a reference to the test methods used and specification of appropriate units of measurement and/or reference conditions. If relevant for the interpretation of the numerical value, the method of determination shall also be provided (for example, the method for flash point, the open-cup/closed-cup method):

(a) Appearance:

The physical state (solid (including appropriate and available safety information on granulometry and specific surface area if not already specified elsewhere in this safety data sheet), liquid, gas) and the colour of the substance or mixture as supplied shall be indicated;

(b) Odour:

If odour is perceptible, a brief description of it shall be given;

(c) Odour threshold;

(d) pH:

The pH of the substance or mixture as supplied or of an aqueous solution shall be indicated; in the case of an aqueous solution, the concentration shall also be indicated;

(e) Melting point/freezing point;

(f) Initial boiling point and boiling range;

(g) Flash point;

(h) Evaporation rate;

(i) Flammability (solid, gas);

(j) Upper/lower flammability or explosive limits;

(k) Vapour pressure;

(l) Vapour density;

(m) Relative density;



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (n) Solubility(ies);
- (o) Partition coefficient: n-octanol/water;
- (p) Auto-ignition temperature;
- (q) Decomposition temperature;
- (r) Viscosity;
- (s) Explosive properties;
- (t) Oxidising properties.

If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided. The information in this section shall be consistent with the information provided in a registration where one is required.

In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.

## 9.2. Other information

Other physical and chemical parameters shall be indicated as necessary, such as miscibility, fat solubility (solvent — oil to be specified), conductivity, or gas group. Appropriate and available safety information on redox potential, radical formation potential and photocatalytic properties shall be indicated.

## 10. SECTION 10: Stability and reactivity

This section of the safety data sheet shall describe the stability of the substance or mixture and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, including, where appropriate, a reference to the test methods used. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

### 10.1. Reactivity

10.1.1. The reactivity hazards of the substance or mixture shall be described. Specific test data shall be provided for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of substance or mixture if such data adequately represent the anticipated hazard of the substance or mixture.

10.1.2. If data for mixtures are not available, data on substances in the mixture shall be provided. In determining incompatibility, the substances, containers and contaminants that the substance or mixture might be exposed to during transportation, storage and use shall be considered.

### 10.2. Chemical stability

It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Any stabilisers which are, or may need to be, used to maintain the chemical stability of the substance or mixture shall be described. The safety significance of any change in the physical appearance of the substance or mixture shall be indicated.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### 10.3. Possibility of hazardous reactions

If relevant, it shall be stated if the substance or mixture will react or polymerise, releasing excess pressure or heat, or creating other hazardous conditions. The conditions under which the hazardous reactions may occur shall be described.

### 10.4. Conditions to avoid

Conditions such as temperature, pressure, light, shock, static discharge, vibrations or other physical stresses that might result in a hazardous situation shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

### 10.5. Incompatible materials

Families of substances or mixtures or specific substances, such as water, air, acids, bases, oxidising agents, with which the substance or mixture could react to produce a hazardous situation (like an explosion, a release of toxic or flammable materials, or a liberation of excessive heat), shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

### 10.6. Hazardous decomposition products

Known and reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating shall be listed. Hazardous combustion products shall be included in Section 5 of the safety data sheet.

## 11. SECTION 11: Toxicological information

This section of the safety data sheet is meant for use primarily by medical professionals, occupational health and safety professionals and toxicologists. A concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects shall be provided, including where appropriate information on toxicokinetics, metabolism and distribution. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

### 11.1. Information on toxicological effects

The relevant hazard classes, for which information shall be provided, are:

- (a) acute toxicity;
- (b) skin corrosion/irritation;
- (c) serious eye damage/irritation;
- (d) respiratory or skin sensitisation;
- (e) germ cell mutagenicity;
- (f) carcinogenicity;
- (g) reproductive toxicity;
- (h) STOT-single exposure;
- (i) STOT-repeated exposure;

(j) aspiration hazard.

These hazards shall always be listed on the safety data sheet.

For substances subject to registration, brief summaries of the information derived from the application of Annexes VII to XI shall be given, including, where appropriate, a reference to the test methods used. For substances subject to registration, the information shall also include the result of the comparison of the available data with the criteria given in Regulation (EC) No 1272/2008 for CMR, categories 1A and 1B, following point 1.3.1 of Annex I to this Regulation.

11.1.1. Information shall be provided for each hazard class or differentiation. If it is stated that the substance or mixture is not classified for a particular hazard class or differentiation, the safety data sheet shall clearly state whether this is due to lack of data, technical impossibility to obtain the data, inconclusive data or data which are conclusive although insufficient for classification; in the latter case the safety data sheet shall specify ‘ based on available data, the classification criteria are not met ’ .

11.1.2. The data included in this subsection shall apply to the substance or mixture as placed on the market. In the case of a mixture, the data should describe the toxicological properties of the mixture as a whole, except if Article 6(3) of Regulation (EC) No 1272/2008 applies. If available, the relevant toxicological properties of the hazardous substances in a mixture shall also be provided, such as the LD50, acute toxicity estimates or LC50.

11.1.3. Where there is a substantial amount of test data on the substance or mixture, it may be necessary to summarise results of the critical studies used, for example, by route of exposure.

11.1.4. Where the classification criteria for a particular hazard class are not met, information supporting this conclusion shall be provided.

11.1.5. *Information on likely routes of exposure*

Information shall be provided on likely routes of exposure and the effects of the substance or mixture via each possible route of exposure, that is, through ingestion (swallowing), inhalation or skin/eye exposure. If health effects are not known, this shall be stated.

11.1.6. *Symptoms related to the physical, chemical and toxicological characteristics*

Potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products shall be described. Available information shall be provided on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture following exposure. The first symptoms at low exposures through to the consequences of severe exposure shall be described, such as ‘ headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death ’ .

11.1.7. *Delayed and immediate effects as well as chronic effects from short and long-term exposure*

Information shall be provided on whether delayed or immediate effects can be expected after short- or long-term exposure. Information on acute and chronic health effects relating to human exposure to the substance or mixture shall also be provided. Where human data are not available, animal data shall be summarised and the species clearly identified. It shall be indicated whether toxicological data is based on human or animal data.

11.1.8. *Interactive effects*

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Information on interactions shall be included if relevant and available.

#### 11.1.9. *Absence of specific data*

It may not always be possible to obtain information on the hazards of a substance or mixture. In cases where data on the specific substance or mixture are not available, data on similar substances or mixtures, if appropriate, may be used, provided the relevant similar substance or mixture is identified. Where specific data are not used, or where data are not available, this shall be clearly stated.

#### 11.1.10. *Mixtures*

For a given health effect, if a mixture has not been tested for its health effects as a whole, relevant information on relevant substances listed under Section 3 shall be provided.

#### 11.1.11. *Mixture versus substance information*

11.1.11.1. The substances in a mixture may interact with each other in the body, resulting in different rates of absorption, metabolism and excretion. As a result, the toxic actions may be altered and the overall toxicity of the mixture may be different from that of the substances in it. This shall be taken into account when providing toxicological information in this section of the safety data sheet.

11.1.11.2. It is necessary to consider whether the concentration of each substance is sufficient to contribute to the overall health effects of the mixture. The information on toxic effects shall be presented for each substance, except for the following cases:

- (a) if the information is duplicated, it shall be listed only once for the mixture overall, such as when two substances both cause vomiting and diarrhoea;
- (b) if it is unlikely that these effects will occur at the concentrations present, such as when a mild irritant is diluted to below a certain concentration in a non-irritant solution;
- (c) where information on interactions between substances in a mixture is not available, assumptions shall not be made and instead the health effects of each substance shall be listed separately.

#### 11.1.12. *Other information*

Other relevant information on adverse health effects shall be included even when not required by the classification criteria.

## 12. **SECTION 12: Ecological information**

This section of the safety data sheet shall provide information to enable evaluation of the environmental impact of the substance or mixture where it is released to the environment. Subsections 12.1 to 12.6 of the safety data sheet shall provide a short summary of the data including, where available, relevant test data and clearly indicating species, media, units, test duration and test conditions. This information may assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures and transport. If it is stated that a particular property does not apply (because the available data shows that the substance or mixture does not meet the criteria for classification) or if information on a particular property is not available, the reasons shall be indicated. Additionally, if a substance or mixture is not classified for other reasons (for example, due to the technical impossibility of obtaining the data or to inconclusive data) this should be clearly stated on the safety data sheet.

Some properties are substance specific, i.e. bioaccumulation, persistence and degradability, and that information shall be given, where available and appropriate, for each relevant substance in

the mixture (i.e. those which are required to be listed in Section 3 of the safety data sheet and are hazardous to the environment or PBT/vPvB substances). Information shall also be provided for hazardous transformation products arising from the degradation of substances and mixtures.

The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

#### 12.1. **Toxicity**

Information on toxicity using data from tests performed on aquatic and/or terrestrial organisms shall be provided when available. This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro- and macroorganisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or mixture has inhibitory effects on the activity of microorganisms, the possible impact on sewage treatment plants shall be mentioned.

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of this Regulation shall be included.

#### 12.2. **Persistence and degradability**

Persistence and degradability is the potential for the substance or the appropriate substances in a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. Test results relevant to assess persistence and degradability shall be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralisation or to primary degradation. The potential of the substance or certain substances in a mixture to degrade in sewage treatment plants shall also be mentioned.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

#### 12.3. **Bioaccumulative potential**

Bioaccumulative potential is the potential of the substance or certain substances in a mixture to accumulate in biota and, eventually, to pass through the food chain. Test results relevant to assess the bioaccumulative potential shall be given. This shall include reference to the octanol-water partition coefficient (K<sub>ow</sub>) and bioconcentration factor (BCF), if available.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

#### 12.4. **Mobility in soil**

Mobility in soil is the potential of the substance or the components of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release. The potential for mobility in soil shall be given where available. Information on mobility in soil can be determined from relevant mobility data such as adsorption studies or leaching studies, known or predicted distribution to environmental compartments, or surface tension. For example, K<sub>oc</sub> values can be predicted from octanol/water partition coefficients (K<sub>ow</sub>). Leaching and mobility can be predicted from models.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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Where experimental data is available, that data shall, in general, take precedence over models and predictions.

#### 12.5. Results of PBT and vPvB assessment

Where a chemical safety report is required, the results of the PBT and vPvB assessment as set out in the chemical safety report shall be given.

#### 12.6. Other adverse effects

Information on any other adverse effects on the environment shall be included where available, such as environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential, endocrine-disrupting potential and/or global warming potential.

### 13. SECTION 13: Disposal considerations

This section of the safety data sheet shall provide information for proper waste management of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of [F390 the retained EU law that transposed] Directive 2008/98/EC of the European Parliament and of the Council <sup>(35)F391</sup>.... Information relevant for the safety of persons conducting waste management activities shall complement the information given in Section 8.

#### Textual Amendments

**F390** Words in Annex 2 point 13 inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 2\(16\)\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

**F391** Words in Annex 2 point 13 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 2\(16\)\(b\)](#); 2020 c. 1, Sch. 5 para. 1(1)

Where a chemical safety report is required and where a waste stage analysis has been performed, the information on the waste management measures shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

#### 13.1. Waste treatment methods

This subsection of the safety data sheet shall:

- (a) specify waste treatment containers and methods including the appropriate methods of waste treatment of both the substance or mixture and any contaminated packaging (for example, incineration, recycling, landfilling);
- (b) specify the physical/chemical properties that may affect waste treatment options;
- (c) discourage sewage disposal;
- (d) Identify, where appropriate, any special precautions for any recommended waste treatment option.

Any relevant [F392 legislation relating to waste] shall be referred to.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

#### Textual Amendments

**F392** Words in Annex 2 point 13.1 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(17)**; 2020 c. 1, Sch. 5 para. 1(1)

### 14. **SECTION 14: Transport information**

This section of the safety data sheet shall provide basic classification information for the transport/shipment of substances or mixtures mentioned in Section 1 by road, rail, sea, inland waterways or air. Where such information is not available or relevant this shall be stated.

Where relevant, this section shall provide information on the transport classification for each of the UN Model Regulations: the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)<sup>(36)</sup>, the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)<sup>(37)</sup> and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)<sup>(38)F393</sup> ..., as well as the International Maritime Dangerous Goods (IMDG) Code<sup>(39)</sup> (sea) and the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO)<sup>(40)</sup> (air).

#### Textual Amendments

**F393** Words in Annex 2 point 14 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(18)**; 2020 c. 1, Sch. 5 para. 1(1)

#### 14.1. **UN number**

The UN number (i.e. the four-figure identification number of the substance, mixture or article preceded by the letters ' UN ' ) from the UN Model Regulations shall be provided.

#### 14.2. **UN proper shipping name**

The UN proper shipping name from the UN Model Regulations shall be provided, unless it was used as the product identifier in subsection 1.1.

#### 14.3. **Transport hazard class(es)**

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures on the basis of the predominant hazard that they present according to the UN Model Regulations shall be provided.

#### 14.4. **Packing group**

The packing group number from the UN Model Regulations shall be provided, if applicable. The packing group number is assigned to certain substances in accordance with their degree of hazard.

#### 14.5. **Environmental hazards**

It shall be indicated whether the substance or mixture is environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID and ADN) and/or a marine pollutant according to the IMDG Code. If the substance or mixture is authorised or intended for carriage by inland waterways in tank-vessels, it shall be indicated whether the substance or mixture is environmentally hazardous in tank-vessels only according to the ADN.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

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#### 14.6. Special precautions for user

Information shall be provided on any special precautions which a user should or must take or be aware of in connection with transport or conveyance either within or outside his premises.

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

This subsection only applies when cargoes are intended to be carried in bulk according to the following IMO instruments: Annex II of Marpol and the IBC Code.

The product name shall be provided (if different from that given in subsection 1.1) as required by the shipment document and in accordance with the name used in the lists of product names given in chapters 17 or 18 of the IBC Code or the latest edition of the IMO's Maritime Environment Protection Committee (MEPC).2/Circular <sup>(41)</sup>. Ship type required and pollution category shall be indicated.

### 15. SECTION 15: Regulatory information

This section of the safety data sheet shall describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet (such as whether the substance or mixture is subject to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer <sup>(42)</sup>, Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC <sup>(43)</sup> or Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals <sup>(44)</sup>).

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Information shall be provided regarding relevant <sup>F394</sup>... safety, health and environmental provisions ([<sup>F395</sup>including relevant EU provisions transposed through retained EU law, such as the] Seveso category/named substances in Annex I to [<sup>F396</sup>Directive 2012/18/EU]) or regarding the national regulatory status of the substance or mixture (including the substances in the mixture), including advice on action that should be taken by the recipient as a result of these provisions. Where relevant the national laws of the relevant Member States which implement these provisions and any other national measures that may be relevant shall be mentioned.

#### Textual Amendments

**F394** Word in Annex 2 point 15.1 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(19)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F395** Words in Annex 2 point 15.1 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(19)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

**F396** Words in Annex 2 point 15.1 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 2(19)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F397** Words in Annex 2 point 15.1 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 2\(19\)\(d\)](#); 2020 c. 1, Sch. 5 para. 1(1)

## 15.2. Chemical safety assessment

This subsection of the safety data sheet shall indicate whether the supplier has carried out a chemical safety assessment for the substance or the mixture.

## 16. SECTION 16: Other information

This section of the safety data sheet shall contain other information that is not included in Sections 1 to 15, including information on the revision of the safety data sheet such as:

- (a) in the case of a revised safety data sheet, a clear indication of where changes have been made to the previous version of the safety data sheet, unless such indication is given elsewhere in the safety data sheet, with an explanation of the changes, if appropriate. A supplier of a substance or mixture shall be able to provide an explanation of the changes upon request;
- (b) a key or legend to abbreviations and acronyms used in the safety data sheet;
- (c) key literature references and sources for data;
- (d) in the case of mixtures, an indication of which of the methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 was used for the purpose of classification;
- (e) a list of relevant hazard statements and/or precautionary statements. Write out the full text of any statements which are not written out in full under Sections 2 to 15;
- (f) advice on any training appropriate for workers to ensure protection of human health and the environment.

**PART B** The safety data sheet shall include the following 16 headings in accordance with Article 31(6) and in addition the subheadings also listed except Section 3, where only subsections 3.1 or 3.2 need to be included as appropriate:]

## [<sup>F359</sup>ANNEX III

### CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES

Criteria for substances and, when applicable, for nanoforms thereof, registered between 1 and 10 tonnes, with reference to Article 12(1)(a) and (b):

- (a) substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII;
- (b) substances:

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- (i) with dispersive or diffuse use(s) particularly where such substances are used in consumer mixtures or incorporated into consumer articles; and
- (ii) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under Regulation (EC) No 1272/2008 or for substances with nanoforms, unless those nanoforms are soluble in biological and environmental media.]

### [<sup>F398</sup>ANNEX IV

#### Textual Amendments

**F398** Substituted by Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V (Text with EEA relevance).

#### EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(A)

Einecs No	Name/Group	CAS No
200-061-5	D-glucitol C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	50-70-4
200-066-2	Ascorbic acid C <sub>6</sub> H <sub>8</sub> O <sub>6</sub>	50-81-7
200-075-1	Glucose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	50-99-7
200-233-3	Fructose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	57-48-7
200-294-2	L-lysine C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub>	56-87-1
200-334-9	Sucrose, pure C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>	57-50-1
200-405-4	α-tocopheryl acetate C <sub>31</sub> H <sub>52</sub> O <sub>3</sub>	58-95-7
200-416-4	Galactose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	59-23-4
200-432-1	DL-methionine C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S	59-51-8
200-559-2	Lactose C <sub>12</sub> H <sub>22</sub> O <sub>11</sub>	63-42-3
200-711-8	D-mannitol C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	69-65-8
201-771-8	L-sorbose C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	87-79-6
204-664-4	Glycerol stearate, pure C <sub>21</sub> H <sub>42</sub> O <sub>4</sub>	123-94-4
204-696-9	Carbon dioxide CO <sub>2</sub>	124-38-9
205-278-9	Calcium pantothenate, D-form C <sub>9</sub> H <sub>17</sub> NO <sub>5.1/2</sub> Ca	137-08-6

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

205-756-7	DL-phenylalanine C <sub>9</sub> H <sub>11</sub> NO <sub>2</sub>	150-30-1
208-407-7	Sodium gluconate C <sub>6</sub> H <sub>12</sub> O <sub>7</sub> .Na	527-07-1
215-665-4	Sorbitan oleate C <sub>24</sub> H <sub>44</sub> O <sub>6</sub>	1338-43-8
231-098-5	Krypton Kr	7439-90-9
231-110-9	Neon Ne	7440-01-9
231-147-0	Argon Ar	7440-37-1
231-168-5	Helium He	7440-59-7
231-172-7	Xenon Xe	7440-63-3
231-783-9	Nitrogen N <sub>2</sub>	7727-37-9
231-791-2	Water, distilled, conductivity or of similar purity H <sub>2</sub> O	7732-18-5
232-307-2	Lecithins The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid	8002-43-5
232-436-4	Syrups, hydrolyzed starch A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins	8029-43-4
232-442-7	Tallow, hydrogenated	8030-12-4
232-675-4	Dextrin	9004-53-9
232-679-6	Starch High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water	9005-25-8
232-940-4	Maltodextrin	9050-36-6
238-976-7	Sodium D-gluconate C <sub>6</sub> H <sub>12</sub> O <sub>7</sub> .xNa	14906-97-9
248-027-9	D-glucitol monostearate C <sub>24</sub> H <sub>48</sub> O <sub>7</sub>	26836-47-5

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

262-988-1	Fatty acids, coco, Me esters	61788-59-8
265-995-8	Cellulose pulp	65996-61-4
266-948-4	Glycerides, C <sub>16-18</sub> and C <sub>18</sub> -unsaturated. This substance is identified by SDA Substance Name: C <sub>16</sub> -C <sub>18</sub> and C <sub>18</sub> unsaturated trialkyl glyceride and SDA Reporting Number: 11-001-00	67701-30-8
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-658-6	Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3
270-312-1	Glycerides, C <sub>16-18</sub> and C <sub>18</sub> -unsaturated, mono- and di- This substance is identified by SDA Substance Name: C <sub>16</sub> -C <sub>18</sub> and C <sub>18</sub> unsaturated alkyl and C <sub>16</sub> -C <sub>18</sub> and C <sub>18</sub> unsaturated dialkyl glyceride and SDA Reporting Number: 11-002-00	68424-61-3
288-123-8	Glycerides, C <sub>10-18</sub>	85665-33-4]

### [<sup>F398</sup> ANNEX V

#### EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.
2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, [<sup>F1</sup>mixture] or article.
3. Substances which result from a chemical reaction occurring upon end use of other substances, [<sup>F1</sup>mixtures] or articles and which are not themselves manufactured, imported or placed on the market.
4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
  - (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant,

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
- (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
5. By-products, unless they are imported or placed on the market themselves.
6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
7. The following substances which occur in nature, if they are not chemically modified:  
Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.
8. Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as <sup>F399</sup>[<sup>F1</sup>hazardous] according to [<sup>F1</sup>Regulation (EC) No 1272/2008] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

#### Textual Amendments

**F399** Word in Annex 5 para. 8 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), Sch. 3 para. 3; 2020 c. 1, Sch. 5 para. 1(1)

9. The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C<sub>6</sub> to C<sub>24</sub> and their potassium, sodium, calcium and magnesium salts; glycerol.

10. The following substances if they are not chemically modified:

Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.

11. The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the lifecycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.

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*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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[<sup>F400</sup>12. Compost, biogas and digestate.]

**Textual Amendments**

**F400** Substituted by [Commission Regulation \(EU\) 2019/1691 of 9 October 2019 amending Annex V to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) \(Text with EEA relevance\)](#).

13. Hydrogen and oxygen.]

## ANNEX VI

### INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

[<sup>F359</sup>NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use, and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

A substance is defined in accordance with Article 3(1) and identified in accordance with section 2 in this Annex. A substance is always manufactured or imported in at least one form. A substance can also occur in more than one form.

For all nanoforms covered by the registration certain specific information items shall be provided. Nanoforms shall be characterised as provided for in this Annex. The registrant shall justify why the information provided in the joint registration, covering the information requirements for the registered substances with nanoforms, is adequate for assessing the nanoforms. Information relevant to cover information requirements for such a substance can also be submitted separately by individual registrants, where justified in accordance with Article 11(3).

More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties relevant for the hazard, exposure and risk assessment and management of nanoforms. The information shall be reported in such a manner that it is clear which information in the joint submission pertains to which nanoform of the substance.

Where technically and scientifically justified, the methodologies set out in Annex XI.1.5 shall be used within a registration dossier when two or more forms of a substance are 'grouped' for the purposes of one, more or possibly all the information requirements.

The requirements specific to nanoforms apply without prejudice to requirements applicable to other forms of a substance.

Definition of a nanoform and a set of similar nanoforms:

On the basis of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial<sup>(45)</sup>, a nanoform is a form of a natural or manufactured substance

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

For this purpose, ‘particle’ means a minute piece of matter with defined physical boundaries; ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components and ‘aggregate’ means a particle comprising of strongly bound or fused particles.

A nanoform shall be characterised in accordance with section 2.4 below. A substance may have one or more different nanoforms, based on differences in the parameters in points 2.4.2 to 2.4.5.

A ‘set of similar nanoforms’ is a group of nanoforms characterised in accordance with section 2.4 where the clearly defined boundaries in the parameters in the points 2.4.2 to 2.4.5 of the individual nanoforms within the set still allow to conclude that the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly. A justification shall be provided to demonstrate that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set. A nanoform can only belong to one set of similar nanoforms

The term ‘nanoform’, when it is referred to in the other Annexes, shall refer to a nanoform or a set of similar nanoforms, when one has been defined, as defined in this Annex.]

#### [<sup>F359</sup>STEP 1 — GATHER AND SHARE EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance.

Wherever practicable, registrations should be submitted jointly, in accordance with Articles 11 or 19. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance including on all nanoforms of the substance that are covered by the registration, regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other substances, *in vivo* and *in vitro* testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests.

In addition, information on exposure, use and risk management measures in accordance with article 10 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information.]

#### STEP 2 — CONSIDER INFORMATION NEEDS

The registrant shall identify what information is required for the registration. First, the relevant Annex or Annexes to be followed shall be identified, according to tonnage. These Annexes set out the standard information requirements, but shall be considered in conjunction with Annex XI, which allows variation from the standard approach, where it can be justified. In particular, information on exposure, use and risk management measures shall be considered at this stage in order to determine the information needs for the substance.

#### [<sup>F359</sup>STEP 3 — IDENTIFY INFORMATION GAPS

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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The registrant shall then compare the information needs for the substance with the information already available and the extent to which currently available information can be applied to all nanoforms covered by the registration and identify where there are gaps.

It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.]

[<sup>F359</sup>STEP 4 — GENERATE NEW DATA/PROPOSE TESTING STRATEGY

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes VII and VIII), or a testing strategy shall be proposed (Annexes IX and X), depending on the tonnage. New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.

The above approach shall also apply if there is a gap of available information for one or more nanoforms of the substance included in the jointly submitted registration dossier.

In some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.

NOTES

Note 1: If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions.

Note 2: The registrant may wish to declare that certain information submitted in the registration dossier is commercially sensitive and its disclosure might harm him commercially. If this is the case, he shall list the items and provide a justification.]

INFORMATION REFERRED TO IN ARTICLE 10(a) (i) TO (v)

1. GENERAL REGISTRANT INFORMATION

1.1. Registrant

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

1.2. Joint submission of data

Articles 11 or 19 foresee that parts of the registration may be submitted by a lead registrant on behalf of other registrants.

In this case, the lead registrant shall identify the other registrants specifying:

- their name, address, telephone number, fax number and e-mail address,
- parts of the present registration which apply to other registrants.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

Any other registrant shall identify the lead registrant submitting on his behalf specifying:

- his name, address, telephone number, fax number and e-mail address,
- parts of the registration which are submitted by the lead registrant.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

1.3 Third party appointed under Article 4



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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1.3.1. Name, address, telephone number, fax number and e-mail address

1.3.2. Contact person

## 2. IDENTIFICATION OF THE SUBSTANCE

[<sup>F359</sup>For each substance, the information given in this section shall be sufficient to enable each substance to be identified and the different nanoforms to be characterised. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.]

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCS number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including SMILES notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

[<sup>F359</sup>2.3. Composition of each substance. Where a registration covers one or more nanoforms, these nanoforms shall be characterised pursuant to section 2.4 of this Annex.

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (e.g. ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced

2.4. Characterisation of nanoforms of a substance: For each of the characterisation parameters, the information provided may be applicable to either an individual nanoform or a set of similar nanoforms provided that the boundaries of the set are clearly specified.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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The information in points 2.4.2 – 2.4.5 shall be clearly assigned to the different nanoforms or sets of similar nanoforms identified in point 2.4.1

- 2.4.1. Names or other identifiers of the nanoforms or sets of similar nanoforms of the substance
- 2.4.2. Number based particle size distribution with indication of the number fraction of constituent particles in the size range within 1 nm – 100 nm
- 2.4.3. Description of surface functionalisation or treatment and identification of each agent including IUPAC name and CAS or EC number
- 2.4.4. Shape, aspect ratio and other morphological characterisation: crystallinity, information on assembly structure including e.g. shell like structures or hollow structures, if appropriate
- 2.4.5. Surface area (specific surface area by volume, specific surface area by mass or both)
- 2.4.6. Description of the analytical methods or the appropriate bibliographical references for the information elements in this sub-section. This information shall be sufficient to allow the methods to be reproduced.]

### 3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)

[<sup>F362</sup>Where a substance being registered is manufactured or imported in one or several nanoforms, the information on manufacture and use under 3.1-3.7 shall include separate information on the different nanoforms or sets of similar nanoforms as characterised in subsection 2.4.]

- 3.1. Overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year in:

the calendar year of the registration (estimated quantity)

- 3.2. In the case of a manufacturer or producer of articles: brief description of the technological process used in manufacture or production of articles.

Precise details of the process, particularly those of a commercially sensitive nature, are not required.

- 3.3. An indication of the tonnage used for his own use(s)
- 3.4. Form (substance, [<sup>F1</sup>mixture] or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in [<sup>F1</sup>mixtures] made available to downstream users and quantities of the substance in articles made available to downstream users.
- 3.5. Brief general description of the identified use(s)
- 3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses
- 3.7. Uses advised against [<sup>F401</sup>(see Section 1 of the safety data sheet)]

Where applicable, an indication of the uses which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

### Textual Amendments

**F401** Substituted by [Commission Regulation \(EU\) No 453/2010 of 20 May 2010 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) \(Text with EEA relevance\)](#).

## 4. CLASSIFICATION AND LABELLING

[<sup>F1</sup>4.1 The hazard classification of the substance(s), resulting from the application of Title I and II of Regulation (EC) No 1272/2008 for all hazard classes and categories in that Regulation,

In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification),

4.2 The resulting hazard label for the substance(s), resulting from the application of Title III of Regulation (EC) No 1272/2008,

[<sup>F1</sup>4.3 Specific concentration limits, where applicable, resulting from the application of Article 10 of Regulation (EC) No 1272/2008.]]

## 5. GUIDANCE ON SAFE USE CONCERNING:

[<sup>F359</sup>This information shall be consistent with that in the Safety Data Sheet where such a Safety Data Sheet is required according to Article 31.

Where a substance being registered is also manufactured or imported in one or several nanoforms, the information pursuant to this Section shall address the different nanoforms or sets of similar nanoforms as characterised in subsection 2.4 where relevant.]

- 5.1. First-aid measures (Safety Data Sheet heading 4)
- 5.2. Fire-fighting measures (Safety Data Sheet heading 5)
- 5.3. Accidental release measures (Safety Data Sheet heading 6)
- 5.4. Handling and storage (Safety Data Sheet heading 7)
- 5.5. Transport information (Safety Data Sheet heading 14)

Where a Chemical Safety Report is not required, the following additional information is required:

- 5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)
- 5.7. Stability and reactivity (Safety Data Sheet heading 10)
- 5.8. Disposal considerations
  - 5.8.1. Disposal considerations (Safety Data Sheet heading 13)
  - 5.8.2. Information on recycling and methods of disposal for industry
  - 5.8.3. Information on recycling and methods of disposal for the public.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## 6. INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES PER YEAR PER MANUFACTURER OR IMPORTER

[<sup>F362</sup>Where a substance being registered is manufactured or imported in one or several nanoforms, the information pursuant to this Section shall address the different nanoforms or sets of similar nanoforms as characterised in subsection 2.4 separately.]

### 6.1. Main use category:

#### 6.1.1.

- (a) industrial use; and/or
- (b) professional use; and/or
- (c) consumer use.

#### 6.1.2. Specification for industrial and professional use:

- (a) used in closed system; and/or
- (b) use resulting in inclusion into or onto matrix; and/or
- (c) non-dispersive use; and/or
- (d) dispersive use.

### 6.2. Significant route(s) of exposure:

#### 6.2.1. Human exposure:

- (a) oral; and/or
- (b) dermal; and/or
- (c) inhalatory.

#### 6.2.2. Environmental exposure:

- (a) water; and/or
- (b) air; and/or
- (c) solid waste; and/or
- (d) soil.

### 6.3. Pattern of exposure:

- (a) accidental/infrequent; and/or
- (b) occasional; and/or
- (c) continuous/frequent.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## ANNEX VII

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE <sup>(46)</sup>

Column 1 of this Annex establishes the standard information required for:

- (a) non-phase-in substances manufactured or imported in quantities of 1 to 10 tonnes;
- (b) phase-in substances manufactured or imported in quantities of 1 to 10 tonnes and meeting the criteria in Annex III in accordance with Article 12(1)(a) and (b); and
- (c) substances manufactured or imported in quantities of 10 tonnes or more.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. For substances not meeting the criteria in Annex III only the physicochemical requirements as set out in section 7 of this Annex are required.

Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

[<sup>F362</sup>Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.]

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI with the exception of Section 3 on substance-tailored exposure waiving. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI <sup>(47)</sup>.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

#### 7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.1. State of the substance at 20 °C and 101,3 kPa	

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

7.2. Melting/freezing point	7.2. The study does not need to be conducted below a lower limit of -20 °C.
7.3. Boiling point	7.3. The study does not need to be conducted: — for gases, or — for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured, or — for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
7.4. Relative density	7.4. The study does not need to be conducted if: — the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient, or — the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.
7.5. Vapour pressure	7.5. The study does not need to be conducted if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
7.6. Surface tension	7.6. The study need only be conducted if: — based on structure, surface activity is expected or can be predicted, or — surface activity is a desired property of the material. If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.
F <sup>359</sup> 7.7. Water solubility For nanoforms, in addition the testing of dissolution rate in water as well as in relevant	7.7. The study does not need to be conducted if:

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biological and environmental media shall be considered.	<ul style="list-style-type: none"> <li>— the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours), or</li> <li>— the substance is readily oxidisable in water.</li> </ul> <p>If the substance appears ‘ insoluble ’ in water, a limit test up to the detection limit of the analytical method shall be performed. For nanoforms the potential confounding effect of dispersion shall be assessed when conducting the study.]</p>
[ <sup>F359</sup> 7.8. Partition coefficient n-octanol/water	<p>7.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.</p> <p>For nanoforms the potential confounding effect of dispersion in octanol and water shall be assessed when conducting the study. For nanoforms, whether of inorganic or organic substances, for which the partition coefficient n-octanol/water is not applicable the study of dispersion stability shall be considered instead.]</p>
7.9. Flash-point	<p>7.9. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is inorganic, or</li> <li>— the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions, or</li> <li>— the estimated flash-point is above 200 °C, or</li> <li>— the flash-point can be accurately predicted by interpolation from existing characterised materials.</li> </ul>
7.10. Flammability	<p>7.10. The study does not need to be conducted:</p> <ul style="list-style-type: none"> <li>— if the substance is a solid which possesses explosive or pyrophoric properties. These properties should</li> </ul>

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	<ul style="list-style-type: none"> <li>— always be considered before considering flammability, or</li> <li>— for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit, or</li> <li>— for substances which spontaneously ignite when in contact with air.</li> </ul>
7.11. Explosive properties	<p>7.11. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— there are no chemical groups associated with explosive properties present in the molecule, or</li> <li>— the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200, or</li> <li>— the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C, or</li> <li>— for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: <ul style="list-style-type: none"> <li>— less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard),</li> <li>— less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard).</li> </ul> </li> </ul> <p><i>Note</i> : Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.</p>
7.12. Self-ignition temperature	<p>7.12. The study does not need to be conducted:</p> <ul style="list-style-type: none"> <li>— if the substance is explosive or ignites spontaneously with air at room temperature, or</li> </ul>



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	<ul style="list-style-type: none"> <li>— for liquids non flammable in air, e.g. no flash point up to 200 °C, or</li> <li>— for gases having no flammable range, or</li> <li>— for solids, if the substance has a melting point <math>\leq</math> 160 °C, or if preliminary results exclude self-heating of the substance up to 400 °C.</li> </ul>
7.13. Oxidising properties	<p>7.13. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is explosive, or</li> <li>— the substance is highly flammable, or</li> <li>— the substance is an organic peroxide, or</li> <li>— the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms).</li> </ul> <p>The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties.</p> <p>Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.</p>
7.14. Granulometry	7.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.
[ <sup>F362</sup> 7.14 Dustiness <i>bis.</i> For nanoforms	7.14 <i>bis.</i> The study does not need to be conducted if exposure to granular form of the substance during its life-cycle can be excluded.]

## 8. TOXICOLOGICAL INFORMATION

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
<p>[<sup>F402</sup>8.1. Skin corrosion/irritation</p>	<p>8.1. The study/ies do(es) not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as skin corrosion (Category 1), or</li> <li>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or</li> <li>— the substance is classified as acute toxicity by the dermal route (Category 1), or</li> <li>— an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level ( 2 000 mg/kg body weight).</li> </ul> <p>If results from one of the two studies under point 8.1.1 or 8.1.2 already allow a conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study need not be conducted.</p>
<p>8.1.1. Skin corrosion, <i>in vitro</i></p>	
<p>8.1.2. Skin irritation, <i>in vitro</i></p>	
<p>8.2. Serious eye damage/eye irritation</p>	<p>8.2. The study/ies do(es) not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1), or</li> <li>— the substance is classified as skin irritation and the available information indicates that it should be classified as eye irritation (Category 2), or</li> <li>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as serious eye damage (Category 1), or</li> <li>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.</li> </ul>

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<p>8.2.1. Serious eye damage/eye irritation, <i>in vitro</i></p>	<p>8.2.1. If results from a first <i>in vitro</i> study do not allow a conclusive decision on the classification of a substance or on the absence of eye irritation potential, (an)other <i>in vitro</i> study(ies) for this endpoint shall be considered.]</p>
<p>[<sup>X2</sup>8.3. Skin sensitisation Information allowing: — a conclusion whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and — risk assessment, where required.</p>	<p>The study(ies) under point 8.3.1 and 8.3.2 do not need to be conducted if: — the substance is classified as skin corrosion (Category 1), or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.</p>
<p>8.3.1. Skin sensitisation, <i>in vitro/in chemico</i> Information from <i>in vitro/in chemico</i> test method(s) recognised according to Article 13(3), addressing each of the following key events of skin sensitisation: (a) molecular interaction with skin proteins; (b) inflammatory response in keratinocytes; (c) activation of dendritic cells.</p>	<p>The(se) test(s) do not need to be conducted if: — an <i>in vivo</i> study according to point 8.3.2 is available, or — the available <i>in vitro/in chemico</i> test methods are not applicable for the substance or are not adequate for classification and risk assessment according to point 8.3. If information from test method(s) addressing one or two of the key events in column 1 already allows classification and risk assessment according to point 8.3, studies addressing the other key event(s) need not be conducted.</p>
<p>8.3.2. Skin sensitisation, <i>in vivo</i></p>	<p>An <i>in vivo</i> study shall be conducted only if <i>in vitro/in chemico</i> test methods described under point 8.3.1 are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment according to point 8.3. The murine local lymph node assay (LLNA) is the first-choice method for <i>in vivo</i> testing. Only in exceptional circumstances should another test be used. Justification for the use of another <i>in vivo</i> test shall be provided. <i>In vivo</i> skin sensitisation studies that were carried out or initiated before 10 May 2017, and that meet the requirements set out in Article 13(3), first subparagraph, and Article 13(4) shall be considered appropriate to address this standard information requirement.]</p>

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8.4. Mutagenicity	8.4. Further mutagenicity studies shall be considered in case of a positive result.
[ <sup>F359</sup> 8.4.1 <i>In vitro</i> gene mutation study in bacteria	8.4.1. The study does not need to be conducted for nanoforms where it is not appropriate. In this case other studies involving one or more <i>in vitro</i> mutagenicity study(ies) in mammalian cells (Annex VIII, sections 8.4.2. and 8.4.3 or other internationally recognised <i>in vitro</i> methods) shall be provided.]
8.5. Acute toxicity	8.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin.
[ <sup>F359</sup> 8.5.1 By oral route	8.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available. For nanoforms, a study by the oral route shall be replaced by a study by the inhalation route (8.5.2), unless exposure of humans via inhalation is unlikely, taking into account the possibility of exposure to aerosols, particles or droplets of an inhalable size.]

## 9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1. Aquatic toxicity	
[ <sup>F359</sup> 9.1.1 Short-term toxicity testing on invertebrates (preferred species <i>Daphnia</i> ) The registrant may consider long-term toxicity testing instead of short-term.	9.1.1. The study does not need to be conducted if: — there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, — a long-term aquatic toxicity study on invertebrates is available, or — adequate information for environmental classification and labelling is available.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	For nanoforms, the study may not be waived on the basis of high insolubility in water alone. The long-term aquatic toxicity study on <i>Daphnia</i> (Annex IX, section 9.1.5.) shall be considered if the substance is poorly water soluble, or for nanoforms if they have low dissolution rate in the relevant test media.]
[ <sup>F359</sup> 9.1.2. Growth inhibition study aquatic plants (algae preferred)	9.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.]
9.2. Degradation	
9.2.1. Biotic	
9.2.1.1. Ready biodegradability	9.2.1.1. The study does not need to be conducted if the substance is inorganic.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

## ANNEX VIII

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE<sup>(48)</sup>

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 10 tonnes or more in accordance with Article 12(1) (c). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annex VII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

[<sup>F362</sup>Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation

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of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.]

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI<sup>(49)</sup>.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

#### [<sup>F362</sup>7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

7.14ter. Further information on physicochemical properties Only for nanoforms	Further testing for nanoforms covered by the registration shall be considered by the registrant or may be required by the Agency in accordance with Article 41, if there is an indication that specific additional particle properties significantly influence the hazard of or the exposure to those nanoforms.]
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### 8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
[ <sup>F402</sup> 8.1. Skin corrosion/irritation	8.1. An <i>in vivo</i> study for skin corrosion/irritation shall be considered only if the <i>in vitro</i> studies under points 8.1.1 and 8.1.2 in Annex VII are not applicable, or the results of these studies are not adequate for classification and risk assessment. The study does not need to be conducted if: — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or — the substance is classified as acute toxicity by the dermal route (Category 1), or

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	—	an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).
8.2. Serious eye damage/eye irritation	8.2.	<p>An <i>in vivo</i> study for eye corrosion/irritation shall be considered only if the <i>in vitro</i> study(ies) under point 8.2.1 in Annex VII are not applicable, or the results obtained from these study(ies) are not adequate for classification and risk assessment.</p> <p>The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is classified as skin corrosion, or</li> <li>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or</li> <li>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.]</li> </ul>
<b>8.4.Mutagenicity</b>		
8.4.2. <i>In vitro</i> cytogenicity study in mammalian cells or <i>in vitro</i> micronucleus study	8.4.2.	<p>The study does not usually need to be conducted</p> <ul style="list-style-type: none"> <li>— if adequate data from an <i>in vivo</i> cytogenicity test are available, or</li> <li>— [F1 the substance is known to be carcinogenic category 1A or 1B or germ cell mutagenic category 1A, 1B or 2.]</li> </ul>
8.4.3. <i>In vitro</i> gene mutation study in mammalian cells, if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2.	8.4.3.	The study does not usually need to be conducted if adequate data from a reliable <i>in vivo</i> mammalian gene mutation test are available.
	8.4.	Appropriate <i>in vivo</i> mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII.
[F402][F359] Acute toxicity	8.5.	<p>The study/ies do(es) not generally need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is classified as corrosive to the skin.</li> </ul> <p>In addition to the oral route (8.5.1.) or to the inhalation route (8.5.2) for nanoforms, for substances other than gases, the information mentioned under 8.5.1. to 8.5.3. shall be</p>

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	provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route needs to be provided.]
8.5.2. By inhalation	8.5.2. Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.
8.5.3. By dermal route	8.5.3. Testing by the dermal route is appropriate if: <ol style="list-style-type: none"> <li>(1) inhalation of the substance is unlikely; and</li> <li>(2) skin contact in production and/or use is likely; and</li> <li>(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.</li> </ol> Testing by the dermal route does not need to be conducted if: <ul style="list-style-type: none"> <li>— the substance does not meet the criteria for classification as acute toxicity or STOT SE by the oral route and</li> <li>— no systemic effects have been observed in <i>in vivo</i> studies with dermal exposure (e.g. skin irritation, skin sensitisation) or, in the absence of an <i>in vivo</i> study by the oral route, no systemic effects after dermal exposure are predicted on the basis of non-testing approaches (e.g. read across, QSAR studies).]</li></ul>
<b>8.6.Repeated dose toxicity</b>	
[ <sup>F359</sup> 8.6.1.Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	8.6.1. The short-term toxicity study (28 days) does not need to be conducted if: <ul style="list-style-type: none"> <li>— a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used, or</li> </ul>



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- where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products, or
- relevant human exposure can be excluded in accordance with Annex XI Section 3.

The appropriate route shall be chosen on the following basis:

Testing by the dermal route is appropriate if:

- inhalation of the substance is unlikely, and
- skin contact in production and/or use is likely, and
- the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.

Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

For nanoforms toxicokinetics shall be considered including recovery period and, where relevant, lung clearance.

The sub-chronic toxicity study (90 days) (Annex IX, Section 8.6.2) shall be proposed by the registrant if: the frequency and duration of human exposure indicates that a longer term study is appropriate;

and one of the following conditions is met:

- other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or
- appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.

Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case of:

- failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a

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	<p>NOAEL is absence of adverse toxic effects, or</p> <ul style="list-style-type: none"> <li>— toxicity of particular concern (e.g. serious/severe effects), or</li> <li>— indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, and in particular for nanoforms indirect genotoxicity), or</li> <li>— the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made, or</li> <li>— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected), or</li> <li>— effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 or the 90 days study.]</li> </ul>
<b>8.7.Reproductive toxicity</b>	
<p>8.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from <i>in vitro</i> methods that the substance may be a developmental toxicant</p>	<p>[<sup>F403</sup>8.7.1.This study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or</li> <li>— the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or</li> <li>— relevant human exposure can be excluded in accordance with Annex XI section 3, or</li> <li>— a pre-natal developmental toxicity study (Annex IX, 8.7.2) or, either an Extended One-Generation Reproductive Toxicity Study (B.56, OECD TG 443) (Annex IX,</li> </ul>

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	<p>section 8.7.3) or a two-generation study (B.35, OECD TG 416), is available.</p> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>In cases where there are serious concerns about the potential for adverse effects on fertility or development, either an Extended One-Generation Reproductive Toxicity Study (Annex IX, section 8.7.3) or a pre-natal developmental toxicity study (Annex IX, section 8.7.2) may, as appropriate, be proposed by the registrant instead of the screening study.]</p>
[ <sup>F359</sup> 8.8. Toxicokinetics	
8.8.1. Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information.	<p>For nanoforms without high dissolution rate in biological media a toxicokinetics study shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case such an assessment cannot be performed on the basis of relevant available information, including from the study conducted in accordance with 8.6.1. The choice of the study will depend on the remaining information gaps and the results of the chemical safety assessment.]</p>

## 9. ECOTOXICOLOGICAL INFORMATION

<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
[ <sup>F359</sup> 9.1.3. Short-term toxicity testing on fish: the registrant may consider long-	9.1.3. The study does not need to be conducted if:

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

<p>term toxicity testing instead of short-term.</p>	<ul style="list-style-type: none"> <li>— there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or</li> <li>— a long-term aquatic toxicity study on fish is available.</li> </ul> <p>For nanoforms, the study may not be waived on the basis of high insolubility in water alone.</p> <p>Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.</p> <p>The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble, or for nanoforms if they have low dissolution rate in the relevant test media.]</p>
<p>[<sup>F359</sup>9.1.4. Activated sludge respiration inhibition testing</p>	<p>9.1.4. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— there is no emission to a sewage treatment plant, or</li> <li>— there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or</li> <li>— the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.</li> </ul> <p>For nanoforms, the study may not be waived on the basis of high insolubility in water alone.</p> <p>The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.]</p>
<p>[<sup>F359</sup>9.2. Degradation</p>	<p>9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I</p>

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	<p>indicates the need to investigate further the degradation of the substance.</p> <p>For nanoforms that are not soluble, nor have high dissolution rate, such test(s) shall consider morphological transformation (e.g. irreversible changes in particle size, shape and surface properties, loss of coating), chemical transformation (e.g. oxidation, reduction) and other abiotic degradation (e.g. photolysis).</p> <p>The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.]</p>
<p>[<sup>F359</sup>9.2.2.Abiotic</p> <p>9.2.2.1. Hydrolysis as a function of pH.</p>	<p>9.2.2.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is readily biodegradable, or</li> <li>— the substance is highly insoluble in water.</li> </ul> <p>For nanoforms, the study may not be waived on the basis of high insolubility in water alone.]</p>
<p><b>9.3.Fate and behaviour in the environment</b></p>	
<p>[<sup>F359</sup>9.3.1.Adsorption/desorption screening</p>	<p>9.3.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient), or</li> <li>— the substance and its relevant degradation products decompose rapidly.</li> </ul> <p>For nanoforms, use of any physicochemical property (e.g. octanol-water partition coefficient) as a reason for waiving the study shall include adequate justification of its relevance to low potential for adsorption.]</p>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## ANNEX IX

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE <sup>(50)</sup>

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 12(1)(d).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more in accordance with Article 12(1)(d). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII and VIII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

[<sup>F362</sup>Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.]

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI <sup>(51)</sup>.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

#### 7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.	7.15. The study does not need to be conducted if the substance is inorganic.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

7.16. Dissociation constant	7.16. The study does not need to be conducted if: <ul style="list-style-type: none"> <li>— the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water, or</li> <li>— it is scientifically not possible to perform the test for instance if the analytical method is not sensitive enough.</li> </ul>
7.17. Viscosity	

## 8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<p>8.4. If there is a positive result in any of the <i>in vitro</i> genotoxicity studies in Annex VII or VIII and there are no results available from an <i>in vivo</i> study already, an appropriate <i>in vivo</i> somatic cell genotoxicity study shall be proposed by the registrant.</p> <p>If there is a positive result from an <i>in vivo</i> somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.</p>
<b>8.6. Repeated dose toxicity</b>	
8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VIII requirements or if tests according to Section 8.6.2 of this Annex is proposed. In this case, Section 3 of Annex XI shall not apply.	
[ <sup>F359</sup> 8.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of	8.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if:

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- administration, having regard to the likely route of human exposure.
- a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or
  - a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or
  - a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake), or
  - the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day ‘ limit test ’ , particularly if such a pattern is coupled with limited human exposure.
- The appropriate route shall be chosen on the following basis:
- Testing by the dermal route is appropriate if:
- (1) skin contact in production and/or use is likely; and
  - (2) the physicochemical properties suggest a significant rate of absorption through the skin; and
  - (3) one of the following conditions is met:
    - toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or
    - systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or
    - *in vitro* tests indicate significant dermal absorption, or
    - significant dermal toxicity or dermal penetration is recognised for structurally-related substances.



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	<p>Testing by the inhalation route is appropriate if:</p> <ul style="list-style-type: none"> <li>— exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.</li> </ul> <p>For nanoforms toxicokinetics shall be considered including recovery period and, where relevant, lung clearance.</p> <p>Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 in case of:</p> <ul style="list-style-type: none"> <li>— failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or</li> <li>— toxicity of particular concern (e.g. serious/severe effects), or</li> <li>— indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, and in particular for nanoforms indirect genotoxicity), or</li> <li>— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).]</li> </ul>
8.7. Reproductive toxicity	<p>8.7. The studies do not need to be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or</li> <li>— the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or</li> <li>— the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven</li> </ul>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	<p>from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.</p> <p>[<sup>F1</sup>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.]</p>
<p>8.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods [<sup>F404</sup>made under] Article 13(3) or OECD 414).</p>	<p>8.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.</p>
<p>[<sup>F403</sup>8.7.3. Extended One-Generation Reproductive Toxicity Study (B.56 of the Commission Regulation on test methods [<sup>F405</sup>made under] Article 13(3) or OECD 443), basic test design (cohorts 1A and 1B without extension to include a F2 generation), one species, most appropriate route of administration, having regard to the likely route of human exposure, if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD 421 or 422 screening</p>	<p>8.7.3. An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41, if:</p> <p>(a) the substance has uses leading to significant exposure of consumers or professionals, taking into account, inter alia, consumer exposure from articles, and</p> <p>(b) any of the following conditions are met:</p>

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studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

- the substance displays genotoxic effects in somatic cell mutagenicity tests *in vivo* which could lead to classifying it as Mutagen Category 2, or
- there are indications that the internal dose for the substance and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure, or
- there are indications of one or more relevant modes of action related to endocrine disruption from available *in vivo* studies or non-animal approaches.

An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41, in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:

- existing information on the substance itself derived from relevant available *in vivo* or non-animal approaches (e.g. abnormalities of the CNS, evidence of adverse effects on the nervous or immune system in studies on adult animals or animals exposed prenatally), or
- specific mechanisms/modes of action of the substance with an association to (developmental) neurotoxicity and/or (developmental) immunotoxicity (e.g. cholinesterase inhibition or relevant changes in thyroidal hormone levels associated to adverse effects), or
- existing information on effects caused by substances structurally analogous to the substance being studied, suggesting such effects or mechanisms/modes of action.

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Other studies on developmental neurotoxicity and/or developmental immunotoxicity instead of cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) of the Extended One-Generation Reproductive Toxicity Study may be proposed by the registrant in order to clarify the concern on developmental toxicity.

Two-generation reproductive toxicity studies (B.35, OECD TG 416) that were initiated before 13 March 2015 shall be considered appropriate to address this standard information requirement.

The study shall be performed on one species. The need to perform a study at this tonnage level or the next on a second strain or a second species may be considered and a decision should be based on the outcome of the first test and all other relevant available data.]

## 9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1. Aquatic toxicity	9.1. Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
9.1.5. Long-term toxicity testing on invertebrates (preferred species <i>Daphnia</i> ), (unless already provided as part of Annex VII requirements)	
9.1.6. Long-term toxicity testing on fish, (unless already provided as part of Annex VIII requirements) The information shall be provided for one of the Sections 9.1.6.1, 9.1.6.2 or 9.1.6.3.	
9.1.6.1. Fish early-life stage (FELS) toxicity test	

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

9.1.6.2.	Fish short-term toxicity test on embryo and sac-fry stages	
9.1.6.3.	Fish, juvenile growth test	
9.2.	Degradation	9.2. Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
9.2.1.	Biotic	
[ <sup>F359</sup> 9.2.1.]	Simulation testing on ultimate degradation in surface water	9.2.1.2. The study need not be conducted if: the substance is highly insoluble in water, or the substance is readily biodegradable. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.]
9.2.1.3.	Soil simulation testing (for substances with a high potential for adsorption to soil)	9.2.1.3. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of soil is unlikely.
9.2.1.4.	Sediment simulation testing (for substances with a high potential for adsorption to sediment)	9.2.1.4. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely.
9.2.3.	Identification of degradation products	9.2.3. Unless the substance is readily biodegradable
[ <sup>F359</sup> 9.3.]	Fate and behaviour in the environment	
9.3.2.	Bioaccumulation in aquatic species, preferably fish	9.3.2. The study need not be conducted if: the substance has a low potential for bioaccumulation (for instance a

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	<p>log <math>K_{ow} \leq 3</math>) and/or a low potential to cross biological membranes, or direct and indirect exposure of the aquatic compartment is unlikely.</p> <p>For nanoforms, use of any physicochemical property (e.g. octanol water partition coefficient, dissolution rate, dispersion stability) as a reason for waiving the study shall include adequate justification of its relevance to low potential for bioaccumulation or unlikely direct and indirect exposure of the aquatic compartment.</p>
9.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VIII	<p>9.3.3. The study need not be conducted if: based on the physicochemical properties, the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or the substance and its degradation products decompose rapidly.</p> <p>For nanoforms, use of any physicochemical property (e.g. octanol water partition coefficient, dissolution rate, dispersion stability) as a reason for waiving the study shall include adequate justification of its relevance to low potential for adsorption.]</p>
[ <sup>F359</sup> 9.4. Effects on terrestrial organisms	<p>9.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.</p> <p>In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. Where the equilibrium partitioning method is applied to nanoforms, this shall be scientifically justified.</p> <p>The choice of the appropriate tests depends on the outcome of the chemical safety assessment.</p> <p>In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.]</p>
9.4.1. Short-term toxicity to invertebrates	
9.4.2. Effects on soil micro-organisms	

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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#### 9.4.3. Short-term toxicity to plants

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### 10. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

## ANNEX X

### STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE <sup>(52)</sup>

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 12(1)(e).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 1 000 tonnes or more in accordance with Article 12(1)(e). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII, VIII and IX. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

[<sup>F362</sup>Without prejudice to the information submitted for other forms, any relevant physicochemical, toxicological and ecotoxicological information shall include characterisation of the nanoform tested and test conditions. A justification shall be provided where QSARs are used or evidence is obtained by means other than testing, as well as a description of the range of the characteristics/properties of the nanoforms to which the evidence can be applied.]

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI <sup>(53)</sup>.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

### 8. TOXICOLOGICAL INFORMATION

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<p>8.4. If there is a positive result in any of the <i>in vitro</i> genotoxicity studies in Annexes VII or VIII, a second <i>in vivo</i> somatic cell test may be necessary, depending on the quality and relevance of all the available data.</p> <p>If there is a positive result from an <i>in vivo</i> somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.</p>
	<p>[<sup>F359</sup> 8.6.3. A long-term repeated toxicity study (<math>\geq 12</math> months) may be proposed by the registrant or required by the Agency in accordance with Articles 40 or 41 if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met:</p> <ul style="list-style-type: none"> <li>— serious or severe toxicity effects of particular concern were observed in the 28-day or 90-day study for which the available evidence is inadequate for toxicological evaluation or risk characterisation, or</li> <li>— effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28-day or 90-day study, or</li> <li>— the substance may have a dangerous property that cannot be detected in a 90-day study.</li> </ul> <p>If nanoforms are covered by the registration, physicochemical characteristics, in particular particle size, shape and other morphological parameters, surface functionalisation and surface area, as well as molecular structure shall be taken into consideration when determining if one of the conditions above are met.]</p>



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	<p>8.6.4. Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 in case of:</p> <ul style="list-style-type: none"> <li>— toxicity of particular concern (e.g. serious/severe effects), or</li> <li>— indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or</li> <li>— particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).</li> </ul>
<p>8.7. Reproductive toxicity</p>	<p>8.7. The studies need not be conducted if:</p> <ul style="list-style-type: none"> <li>— the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or</li> <li>— the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or</li> <li>— the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.</li> </ul> <p>[<sup>F1</sup>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary.</p>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	<p>However, testing for developmental toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.]</p>
<p>8.7.2. Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (OECD 414).</p>	
<p>[<sup>F403</sup>8.7.3. Extended One-Generation Reproductive Toxicity Study (B.56 of the Commission Regulation on test methods [<sup>F406</sup>made under] Article 13(3) or OECD 443), basic test design (cohorts 1A and 1B without extension to include a F2 generation), one species, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex IX requirements.</p>	<p>8.7.3. An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41, if:</p> <p>(a) the substance has uses leading to significant exposure of consumers or professionals, taking into account, inter alia, consumer exposure from articles, and</p> <p>(b) any of the following conditions are met:</p> <ul style="list-style-type: none"> <li>— the substance displays genotoxic effects in somatic cell mutagenicity tests <i>in vivo</i> which could lead to classifying it as Mutagen Category 2, or</li> <li>— there are indications that the internal dose for the substance and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure, or</li> <li>— there are indications of one or more relevant modes of action related to endocrine disruption from available <i>in vivo</i> studies or non-animal approaches.</li> </ul>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	<p>An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41, in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:</p> <ul style="list-style-type: none"> <li>— existing information on the substance itself derived from relevant available <i>in vivo</i> or non-animal approaches (e.g. abnormalities of the CNS, evidence of adverse effects on the nervous or immune system in studies on adult animals or animals exposed prenatally), or</li> <li>— specific mechanisms/modes of action of the substance with an association to (developmental) neurotoxicity and/or (developmental) immunotoxicity (e.g. cholinesterase inhibition or relevant changes in thyroidal hormone levels associated to adverse effects), or</li> <li>— existing information on effects caused by substances structurally analogous to the substance being studied, suggesting such effects or mechanisms/modes of action.</li> </ul> <p>Other studies on developmental neurotoxicity and/or developmental immunotoxicity instead of cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) of the Extended One-Generation Reproductive Toxicity Study may be proposed by the registrant in order to clarify the concern on developmental toxicity.</p> <p>Two-generation reproductive toxicity studies (B.35, OECD TG 416) that were initiated before 13 March 2015 shall be considered appropriate to address this standard information requirement.]</p>
8.9.1. Carcinogenicity study	8.9.1. A carcinogenicity study may be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 if:

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	<ul style="list-style-type: none"> <li>— the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure, and</li> <li>— [<sup>F1</sup>the substance is classified as germ cell mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions.]</li> </ul> <p>[<sup>F1</sup>If the substance is classified as germ cell mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.]</p>
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## 9. ECOTOXICOLOGICAL INFORMATION

<b>COLUMN 1 STANDARD INFORMATION REQUIRED</b>	<b>COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1</b>
9.2. Degradation	9.2. Further biotic degradation testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
9.2.1. Biotic	
<b>9.3. Fate and behaviour in the environment</b>	
9.3.4. Further information on the environmental fate and behaviour of the substance and/or degradation products	9.3.4. Further testing shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 if the chemical safety assessment according to Annex I indicates the need to investigate further the fate and behaviour of the substance. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

9.4. Effects on terrestrial organisms	9.4. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment.  These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.
9.4.4. Long-term toxicity testing on invertebrates, unless already provided as part of Annex IX requirements.	
9.4.6. Long-term toxicity testing on plants, unless already provided as part of Annex IX requirements.	
9.5.1. Long-term toxicity to sediment organisms	9.5.1. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
9.6.1. Long-term or reproductive toxicity to birds	9.6.1. Any need for testing should be carefully considered taking into account the large mammalian dataset that is usually available at this tonnage level.

## 10. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## ANNEX XI

### GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X

Annexes VII to X set out the information requirements for all substances manufactured or imported in quantities of:

- one tonne or more in accordance with Article 12(1)(a),
- 10 tonnes or more in accordance with Article 12(1)(c),
- 100 tonnes or more in accordance with Article 12(1)(d), and
- 1 000 tonnes or more in accordance with Article 12(1)(e).

In addition to the specific rules set out in column 2 of Annexes VII to X, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of this Annex. Under dossier evaluation the Agency may assess these adaptations to the standard testing regime.

[<sup>F362</sup>The requirements specific to nanoforms in this Annex are without prejudice to requirements applicable to other forms of a substance.]

#### 1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

##### 1.1. Use of existing data

##### 1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:

- (1) adequacy for the purpose of classification and labelling and/or risk assessment;
- (2) sufficient documentation is provided to assess the adequacy of the study; and
- (3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

##### 1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:

- (1) adequacy for the purpose of classification and labelling and/or risk assessment;
- (2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
- (3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
- (4) adequate and reliable documentation of the study is provided.

##### [<sup>F359</sup>1.1.3. Historical human data

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data and clinical studies, shall be considered.

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The strength of the data for a specific human health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

- (1) the proper selection and characterisation of the exposed and control groups;
- (2) adequate characterisation of exposure;
- (3) sufficient length of follow-up for disease occurrence;
- (4) valid method for observing an effect;
- (5) proper consideration of bias and confounding factors; and
- (6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

When nanoforms are covered by the registration the above approach shall address the nanoforms separately.]

#### [<sup>F359</sup>1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by <sup>F407</sup>... the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

#### **Textual Amendments**

**F407** Words in Annex 11 point 1.2 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 8(2)**; 2020 c. 1, Sch. 5 para. 1(1)

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

- further testing on vertebrate animals for that property shall be omitted,
- further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

When nanoforms are covered by the registration the above approach shall address the nanoforms separately.]

#### [<sup>F359</sup>1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

The Agency in collaboration with <sup>F408</sup>... interested parties shall develop and provide guidance in assessing which (Q)SARs will meet these conditions and provide examples.

#### Textual Amendments

**F408** Words in Annex 11 point 1.3 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 8(3)**; 2020 c. 1, Sch. 5 para. 1(1)

When nanoforms are covered by the registration the above approach shall address the nanoforms separately.]

#### 1.4. *In vitro* methods

Results obtained from suitable *in vitro* methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, ‘suitable’ means sufficiently well developed according to internationally agreed test development criteria <sup>F409</sup>... for the entry of a test into the prevalidation [<sup>F410</sup>process]. Depending on the potential risk, immediate confirmation requiring testing beyond the information foreseen in Annexes VII or VIII or proposed confirmation requiring testing beyond the information foreseen in Annexes IX or X for the respective tonnage level may be necessary.

#### Textual Amendments

**F409** Words in Annex 11 point 1.4 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 8(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F410** Word in Annex 11 point 1.4 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 8(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

If the results obtained from the use of such *in vitro* methods do not indicate a certain dangerous property, the relevant test shall nevertheless be carried out at the appropriate tonnage level to confirm the negative result, unless testing is not required in accordance with Annexes VII to X or the other rules in this Annex.

[<sup>F359</sup>Such confirmation may be waived if the following conditions are met:

- (1) results are derived from an *in vitro* method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;
- (2) results are adequate for the purpose of classification and labelling and/or risk assessment; and
- (3) adequate and reliable documentation of the applied method is provided.

When nanoforms are covered by the registration the above approach in points (1) to (3) shall address the nanoforms separately.]

#### 1.5. Grouping of substances and read-across approach



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

[<sup>F359</sup>Substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or ‘ category ’ of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances <sup>F411</sup> ....

#### Textual Amendments

**F411** Words in Annex 11 point 1.5 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 8\(5\)](#); 2020 c. 1, Sch. 5 para. 1(1)

When nanoforms are covered by the registration the above approach shall address the nanoforms separately. For grouping different nanoforms of the same substance the molecular structural similarities alone cannot serve as a justification.

If nanoforms covered by a registration are grouped or placed in a ‘ category ’ with other forms, including other nanoforms, of the substance in the same registration the obligations above shall apply in the same manner.]

The similarities may be based on:

- (1) a common functional group;
- (2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
- (3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results should:

- be adequate for the purpose of classification and labelling and/or risk assessment,
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),
- cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and
- adequate and reliable documentation of the applied method shall be provided.

## 2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, shall always be respected.

[<sup>F412</sup>3. SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- 3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.
- 3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I and shall meet any one of the following criteria:
- (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:
- (i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;
  - (ii) a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes <sup>(54)</sup> ;
  - (iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC;
- (b) where the substance is not incorporated in an article the manufacturer or importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply;
- (c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions are fulfilled:
- (i) the substance is not released during its life cycle;
  - (ii) the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and
  - (iii) the substance is handled according to the conditions set out in Article 18(4) (a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.
- 3.3. The specific conditions of use must be communicated through the supply chain in accordance with Article 31 or 32, as the case may be.]

#### Textual Amendments

**F412** Inserted by [Commission Regulation \(EU\) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \('REACH'\) \(Text with EEA relevance\).](#)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## ANNEX XII

### GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS

#### [<sup>F359</sup>INTRODUCTION

The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the Safety Data Sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses further down the supply chain. The assessment shall consider the use of the substance on its own, in a mixture or in an article.

The assessment shall address all nanoforms that are covered by the registration. Justifications and conclusions drawn from the assessment shall be relevant to the nanoforms, from their receipt by the downstream user, for his own uses and for his identified uses further down the supply chain.

In carrying out the chemical safety assessment and producing the Chemical Safety Report, the downstream user shall take account of information received from the supplier of the chemical in accordance with Article 31 and 32 of this Regulation.

When nanoforms of the substance are covered by his own use or his identified uses down the supply chain, an appropriate metric for the assessment and presentation of the results in steps 1- 6 of the chemical safety assessment under 0.6.1 and 0.6.2 shall be considered, with the justification included in the chemical safety report and summarised in the safety data sheet. A multiple metric presentation is preferable, ensuring availability of mass metric information.

Where available and appropriate, an assessment carried out under other legislation, (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the chemical safety assessment and be reflected in the Chemical Safety Report. Deviations from such assessments shall be justified. Assessments carried out under [<sup>F413</sup>other] international and national programmes may also be taken into account.

#### **Textual Amendments**

**F413** Word in Annex 12 substituted (30.9.2021) by virtue of [The REACH etc. \(Amendment\) Regulations 2021 \(S.I. 2021/904\)](#), regs. 1(2), 6

The process which the downstream user goes through in carrying out the chemical safety assessment and in producing his Chemical Safety Report, involves three steps:]

#### STEP 1: DEVELOPMENT OF EXPOSURE SCENARIO(S)

The downstream user shall develop exposure scenarios for uses not covered in a Safety Data Sheet supplied to him in accordance with Section 5 of Annex I.

#### STEP 2: IF NECESSARY, A REFINEMENT OF THE HAZARD ASSESSMENT BY THE SUPPLIER

If the downstream user considers the hazard and PBT assessments reported in the Safety Data Sheet supplied to him to be appropriate, then no further hazard assessment or PBT and vPvB assessment is necessary. In this case he shall use the relevant information reported by the supplier for the risk characterisation. This shall be stated in the Chemical Safety Report.

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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[<sup>F362</sup>When nanoforms of the substance are covered by his own use or his identified uses down the supply chain, the assessment shall cover the hazard, PBT and vPvB assessment of nanoforms(s) as used.]

If the downstream user considers the assessments reported in the Safety Data Sheet supplied to him to be inappropriate, then he shall carry out the relevant assessments in accordance with Sections 1 to 4 of Annex I as appropriate to him.

[<sup>F359</sup>In those cases where the downstream user considers that information, in addition to that provided by the supplier, is necessary for producing his Chemical Safety Report, the downstream user shall gather this information. Where this information can only be obtained by testing on vertebrate animals, he shall submit a proposal for a testing strategy to the Agency in accordance with Article 38. He shall explain why he considers that additional information is necessary. While waiting for results of further testing, he shall record in his chemical safety report the risk management measures intended to manage the risks being explored that he has put in place. The above record taking shall address all nanoforms that are covered by his own uses or his identified uses down the supply chain. Such information shall be relevant to the nanoforms.]

On completion of any additional testing, the downstream user shall revise the Chemical Safety Report, and his Safety Data Sheet if he is required to prepare one, as appropriate.

#### STEP 3: RISK CHARACTERISATION

A risk characterisation shall be carried out for each new exposure scenario as prescribed in Section 6 of Annex I. The risk characterisation shall be presented under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under the relevant heading(s).

When generating an exposure scenario it will be necessary to make initial assumptions about the operating conditions and risk managements measures. If the initial assumptions lead to a risk characterisation indicating inadequate protection of human health and the environment, then it shall be necessary to carry out an iterative process with amendment of one or a number of factors until adequate control can be demonstrated. This may require the generation of additional hazard or exposure information or appropriate alteration of the process, operating conditions or risk management measures. Therefore, iterations may be made between on the one hand developing and revising an (initial) exposure scenario, which includes developing and implementing risk management measures, and on the other hand generating further information to produce the definitive exposure scenario. The purpose of generating further information is to establish a more precise risk characterisation, based on a refined hazard assessment and/or exposure assessment.

The downstream user shall produce a Chemical Safety Report detailing his chemical safety assessment using Part B, Sections 9 and 10, of the format set out in Section 7 of Annex I and the other sections of this format, if appropriate.

Part A of the Chemical Safety Report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios are implemented by the downstream user for his own uses and that the risk management measures outlined in the exposure scenarios for the identified uses are communicated down the supply chain.

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## [<sup>F414</sup> ANNEX XIII

### **CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES**

#### **Textual Amendments**

**F414** Substituted by [Commission Regulation \(EU\) No 253/2011 of 15 March 2011 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annex XIII \(Text with EEA relevance\)](#).

This Annex lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.

For the identification of PBT substances and vPvB substances a weight-of-evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1. This shall be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information.

A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.

The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.

This Annex shall apply to all organic substances, including organo-metals.

#### 1. CRITERIA FOR THE IDENTIFICATION OF PBT AND vPvB SUBSTANCES

##### 1.1. PBT Substances

A substance that fulfils the persistence, bioaccumulation and toxicity criteria of Sections 1.1.1, 1.1.2 and 1.1.3 shall be considered to be a PBT substance.

##### 1.1.1. Persistence

A substance fulfils the persistence criterion (P) in any of the following situations:

- (a) the degradation half-life in marine water is higher than 60 days;
- (b) the degradation half-life in fresh or estuarine water is higher than 40 days;
- (c) the degradation half-life in marine sediment is higher than 180 days;

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;
- (e) the degradation half-life in soil is higher than 120 days.

#### 1.1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2 000.

#### 1.1.3. Toxicity

A substance fulfils the toxicity criterion (T) in any of the following situations:

- (a) the long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms is less than 0,01 mg/l;
- (b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to Regulation EC No 1272/2008;
- (c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008.

#### 1.2. vPvB Substances

A substance that fulfils the persistence and bioaccumulation criteria of Sections 1.2.1 and 1.2.2 shall be considered to be a vPvB substance.

##### 1.2.1. Persistence

A substance fulfils the ‘very persistent’ criterion (vP) in any of the following situations:

- (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;
- (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;
- (c) the degradation half-life in soil is higher than 180 days.

##### 1.2.2. Bioaccumulation

A substance fulfils the ‘very bioaccumulative’ criterion (vB) when the bioconcentration factor in aquatic species is higher than 5 000.

## 2. SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES

### 2.1. Registration

For the identification of PBT and vPvB substances in the registration dossier, the registrant shall consider the information as described in Annex I and in Section 3 of this Annex.

If the technical dossier contains for one or more endpoints only information as required in Annexes VII and VIII, the registrant shall consider information relevant for screening for P, B, or T properties in accordance with Section 3.1 of this Annex. If the result from the screening tests or other information indicate that the substance may have PBT or vPvB properties, the registrant shall generate relevant additional information as set out in Section 3.2 of this Annex. In case the generation of relevant additional information would require information listed in Annexes IX or X, the registrant shall submit a testing proposal. Where the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI

the additional information may be omitted, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier. No additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information.

## 2.2. Authorisation

For dossiers for the purposes of identifying substances referred to in Article 57(d) and Article 57(e), relevant information from the registration dossiers and other available information as described in Section 3 shall be considered.

## 3. INFORMATION RELEVANT FOR THE SCREENING AND ASSESSMENT OF P, vP, B, vB and T PROPERTIES

### 3.1. Screening Information

The following information shall be considered for screening for P, vP, B, vB and T properties in the cases referred to in the second paragraph of Section 2.1 and may be considered for screening for P, vP, B, vB and T properties in the context of Section 2.2.

#### 3.1.1. Indication of P and vP properties

- (a) Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII;
- (b) Results from other screening tests (e.g. enhanced ready test, tests on inherent biodegradability);
- (c) Results obtained from biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI;
- (d) Other information provided that its suitability and reliability can be reasonably demonstrated.

#### 3.1.2. Indication of B and vB properties

- (a) Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII or estimated by (Q)SAR models in accordance with Section 1.3 of Annex XI;
- (b) Other information provided that its suitability and reliability can be reasonably demonstrated.

#### 3.1.3. Indication of T properties

- (a) Short-term aquatic toxicity in accordance with Section 9.1 of Annex VII and Section 9.1.3 of Annex VIII;
- (b) Other information provided that its suitability and reliability can be reasonably demonstrated.

## 3.2. Assessment Information

The following information shall be considered for the assessment of P, vP, B, vB and T properties, using a weight-of-evidence approach.

### 3.2.1. Assessment of P or vP properties

- (a) Results from simulation testing on degradation in surface water;

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- (b) Results from simulation testing on degradation in soil;
  - (c) Results from simulation testing on degradation in sediment;
  - (d) Other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.
- 3.2.2. Assessment of B or vB properties
- (a) Results from a bioconcentration or bioaccumulation study in aquatic species;
  - (b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:
    - Results from a bioaccumulation study in terrestrial species;
    - Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat;
    - Detection of elevated levels in biota, in particular in endangered species or in vulnerable populations, compared to levels in their surrounding environment;
    - Results from a chronic toxicity study on animals;
    - Assessment of the toxicokinetic behaviour of the substance;
  - (c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.
- 3.2.3. Assessment of T properties
- (a) Results from long-term toxicity testing on invertebrates as set out in Section 9.1.5 of Annex IX;
  - (b) Results from long-term toxicity testing on fish as set out in Section 9.1.6 of Annex IX;
  - (c) Results from growth inhibition study on aquatic plants as set out in Section 9.1.2 of Annex VII;
  - (d) The substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard phrases: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard phrase: H340), toxic for reproduction in Category 1A, 1B and/or 2 (assigned hazard phrases: H360, H360F, H360D, H360FD, H360Fd, H360fD, H361, H361f, H361d or H361fd), specific target organ toxic after repeated dose in Category 1 or 2 (assigned hazard phrase: H372 or H373), according to Regulation EC No 1272/2008;
  - (e) Results from long-term or reproductive toxicity testing with birds as set out in Section 9.6.1 of Annex X;
  - (f) Other information provided that its suitability and reliability can be reasonably demonstrated.]



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## ANNEX XIV

## LIST OF SUBSTANCES SUBJECT TO AUTHORISATION

[X3] <sup>F415</sup> Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date <sup>a</sup>	Sunset date <sup>b</sup>		
1.	5-tert-butyl-2,4,6-trinitro-m-xylene ( <b>Musk xylene</b> ) EC201-329-4 No CAS1-15-2 No	vPvB	21 February 2013	21 August 2014	—	—
2.	4,4'-Diaminodiphenylethane ( <b>MDA</b> ) EC202-974-4 No CAS1-77-9 No	Carcinogenic (category 1B)	21 February 2013	21 August 2014	—	—
3.	Hexabromocyclododecane ( <b>HBCDD</b> ) EC221-695-9, No247-148-4, CAS194-55-6 No25637-99-4 alpha-hexabromocyclododecane CAS4237-50-6, No beta-hexabromocyclododecane CAS4237-51-7 No gamma-hexabromocyclododecane CAS4237-52-8 No	PBT	21 February 2014	21 August 2015	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

4.	Bis(2-ethylhexyl) phthalate ( <b>DEHP</b> ) EC204-211-0 No CAS 7-81-7 No	Toxic for reproduction (category 1B)	21 August 2013 <sup>c</sup>	21 February 2015 <sup>d</sup>	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, [ <sup>F418</sup> the Veterinary Medicines Regulations 2013 or the Human Medicines Regulations 2012].
5.	Benzyl butyl phthalate ( <b>BBP</b> ) EC201-622-7 No CAS 5-68-7 No	Toxic for reproduction (category 1B)	21 August 2013 <sup>c</sup>	21 February 2015 <sup>d</sup>	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.
6.	Dibutyl phthalate ( <b>DBP</b> ) EC201-557-4 No CAS 1-74-2 No	Toxic for reproduction (category 1B)	21 August 2013 <sup>c</sup>	21 February 2015 <sup>d</sup>	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

					Directive 2001/83/ EC.	
[ <sup>F419</sup> 7.	Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	Toxic for reproduction (category 1B)	21 August 2013 <sup>c</sup>	21 February 2015 <sup>d</sup>	—	—
8.	Diarsenic trioxide EC No: 215-481-4 CAS No: 1327-53-3	Carcinogenic (category 1A)	21 November 2013	21 May 2015	—	—
9.	Diarsenic pentaoxide EC No: 215-116-9 CAS No: 1303-28-2	Carcinogenic (category 1A)	21 November 2013	21 May 2015	—	—
10.	Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21 November 2013 <sup>c</sup>	21 May 2015 <sup>d</sup>	—	—
11.	Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21 November 2013 <sup>c</sup>	21 May 2015 <sup>d</sup>	—	—
12.	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21 November 2013 <sup>c</sup>	21 May 2015 <sup>d</sup>		

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	CAS No: 12656-85-8					
13.	Tris (2-chloroethyl) phosphate (TCEP) EC No: 204-118-5 CAS No: 115-96-8	Toxic for reproduction (category 1B)	21 February 2014	21 August 2015		
14.	2,4-Dinitrotoluene (2,4-DNT) EC No: 204-450-0 CAS No: 121-14-2	Carcinogenic (category 1B)	21 February 2014 <sup>c</sup>	21 August 2015 <sup>d</sup>		
<sup>F420</sup> 15.	Trichloroethylene EC No: 201-167-4 CAS No: 79-01-6	Carcinogenic (category 1B)	21 October 2014 <sup>c</sup>	21 April 2016 <sup>d</sup>	—	—
16.	Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	Carcinogenic (category 1A) Mutagenic (category 1B)	21 March 2016 <sup>c</sup>	21 September 2017 <sup>d</sup>	—	—
17.	Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid EC No: 231-801-5 CAS No: 7738-94-5 Dichromic acid EC No: 236-881-5	Carcinogenic (category 1B)	21 March 2016 <sup>c</sup>	21 September 2017 <sup>d</sup>	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	CAS No: 13530-68-2 Oligomers of chromic acid and dichromic acid EC No: not yet assigned CAS No: not yet assigned					
18.	Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9		Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 September 2017 <sup>d</sup>	—	—
19.	Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9		Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 September 2017 <sup>d</sup>	—	—
20.	Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5		Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction	21 September 2017 <sup>d</sup>		

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

		(category 1B)				
21.	Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	Carcinogenic (category 1B) Mutagenic (category 1B)	21 March 2016 <sup>c</sup>	21 September 2017 <sup>d</sup>		
22.	Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21 March 2016 <sup>c</sup>	21 September 2017 <sup>d</sup>		
[ <sup>F421</sup> 23.	Formaldehyde oligomeric reaction products with aniline (technical MDA) EC No: 500-036-1 CAS No: 25214-70-4	Carcinogenic (category 1B)	22 February 2016 <sup>c</sup>	22 August 2017 <sup>d</sup>	—	—
24.	Arsenic acid EC No: 231-901-9 CAS No: 7778-39-4	Carcinogenic (category 1A)	22 February 2016	22 August 2017	—	—
25.	Bis(2-methoxyethyl) ether (diglyme) EC No: 203-924-4 CAS No: 111-96-6	Toxic for reproduction (category 1B)	22 February 2016 <sup>c</sup>	22 August 2017 <sup>d</sup>	—	—
26.	1,2-dichloroethane (EDC) EC No: 203-458-1	Carcinogenic (category 1B)	22 May 2016	22 November 2017	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	CAS No: 107-06-2					
27.	2,2'-dichloro-4,4'-methylene dianiline (MOCA) EC No: 202-918-9 CAS No: 101-14-4	Carcinogenic (category 1B)	22 May 2016 <sup>c</sup>	22 November 2017 <sup>d</sup>	—	—
28.	Dichromium tris(chromate) EC No: 246-356-2 CAS No: 24613-89-6	Carcinogenic (category 1B)	22 July 2017 <sup>c</sup>	22 January 2019 <sup>d</sup>	—	—
29.	Strontium chromate EC No: 232-142-6 CAS No: 7789-06-2	Carcinogenic (category 1B)	22 July 2017 <sup>c</sup>	22 January 2019 <sup>d</sup>	—	—
30.	Potassium hydroxyoctaoxodichromate EC No: 234-329-8 CAS No: 11103-86-9	Carcinogenic (category 1A)	22 July 2017 <sup>c</sup>	22 January 2019 <sup>d</sup>	—	—
31.	Pentazine chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	Carcinogenic (category 1A)	22 July 2017 <sup>c</sup>	22 January 2019 <sup>d</sup>	—	—
[ <sup>F422</sup> 32.	1-Bromopropane (n-propyl bromide) EC203-445-0 No CAS06-94-5 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—
33.	Diisopentylphthalate EC210-088-4 No CAS05-50-5 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

34.	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich EC276-158-1 No CAS 1888-89-6 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—
35.	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters EC271-084-6 No CAS 515-42-4 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—
36.	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear EC284-032-2 No CAS 1777-06-0 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—
37.	Bis(2-methoxyethyl)phthalate EC204-212-6 No CAS 17-82-8 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—
38.	Dipentylphthalate EC205-017-9 No CAS 1-18-0 No	Toxic for reproduction (category 1B)	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—
39.	N-pentyl-isopentylphthalate	Toxic for reproduction	4 January 2019 <sup>c</sup>	4 July 2020 <sup>d</sup>	—	—



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	EC — No CAS No	(category 1B) 6297-69-9				
40.	Anthracene oil EC No CAS No	Carcinogenic (category 1B) <sup>e</sup> , PBT, vPvB 292-602-7 90640-80-5	4 April 2019 <sup>e</sup>	4 October 2020 <sup>d</sup>	—	—
41.	Pitch, coal tar, high temp. EC No CAS No	Carcinogenic (category 1B), PBT, vPvB 266-028-2 65996-93-2	4 April 2019 <sup>e</sup>	4 October 2020 <sup>d</sup>	—	—
42.	4-(1,1,3,3- Tetramethyl- butyl)phthalol, ethoxylated (covering well- defined substances and UVCB substances, polymers and homologues) EC — No CAS— No	Endocrine disrupting properties (Article 57(f) — environment)	<sup>F417</sup> a 4 July 2019 <sup>e</sup> ;  b by way of derogation from point (a), 22 June 2022 for uses as follows:  — for the research, development and production of medicinal products falling within the scope of [ <sup>F423</sup> the Human Medicines Regulations 2012]	<sup>F430</sup> a 4 January 2021 <sup>d</sup> ;  b by way of derogation from point (a), 22 December 2023 for uses as follows:  — for the research, development and production of medicinal products falling within the scope of [ <sup>F431</sup> the Human Medicines Regulations	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

				<p>or                  [F424 relevant] or                  medical [F432 relevant]                  devices medical                  or devices                  [F425 relevant] or                  accessories [F433 relevant]                  to accessories                  medical to                  devices medical                  F426 ... devices                  in F434 ...                  view in                  of view                  their of                  use their                  for use                  the for                  diagnosis, the                  treatment diagnosis,                  or treatment                  prevention or                  of prevention                  the of                  coronavirus COVID-19,                  disease —                  (COVID-19),in                  — [F435 relevant]                  in medical                  [F427 relevant] devices                  medical or                  devices [F436 relevant]                  or accessories                  [F428 relevant] to                  accessories medical                  to devices                  medical F437 ...                  devices for                  F429 ... the                  for diagnosis,                  the treatment                  diagnosis, or                  treatment prevention                  or of                  prevention COVID-19.]                  of                  COVID-19.]</p>		
43.	4-Nonylpheno, branched	Endocrine disrupting properties (Article	4 July 2019 <sup>c</sup>	4 January 2021 <sup>d</sup>	—	—]

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	and linear, ethoxylated (substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof)  EC — No CAS— No	57(f) — environment)				
[ <sup>F438</sup> ][ <sup>X4</sup> 44.	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear EC No: 271-093-5 CAS No: 68515-50-4	Toxic for reproduction (category 1B)	27 August 2021 <sup>c</sup>	27 February 2023 <sup>d</sup>	—	—
45.	Dihexyl phthalate EC No: 201-559-5	Toxic for reproduction (category 1B)	27 August 2021 <sup>c</sup>	27 February 2023 <sup>d</sup>	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	CAS No: 84-75-3					
46.	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq$ 0,3 % of dihexyl phthalate (EC No 201-559-5) EC No: 271-094-0; 272-013-1 CAS No: 68515-51-5; 68648-93-1	Toxic for reproduction (category 1B)	27 August 2021 <sup>c</sup>	27 February 2023 <sup>d</sup>	—	—
47.	Trixylyl phosphate EC No: 246-677-8 CAS No: 25155-23-1	Toxic for reproduction (category 1B)	27 November 2021	27 May 2023	—	—
48.	Sodium perborate; perboric acid, sodium salt EC No: 239-172-9; 234-390-0 CAS No: -	Toxic for reproduction (category 1B)	27 November 2021	27 May 2023	—	—
49.	Sodium peroxometaborate EC No: 231-556-4 CAS No: 7632-04-4	Toxic for reproduction (category 1B)	27 November 2021	27 May 2023	—	—
50.	5-sec-butyl-2-(2,4-	vPvB	27 February 2022	27 August 2023	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

	dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] EC No: - CAS No: -					
51.	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) EC No: 247-384-8 CAS No: 25973-55-1	PBT, vPvB	27 May 2022	27 November 2023	—	—
52.	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) EC No: 223-383-8 CAS No: 3864-99-1	vPvB	27 May 2022	27 November 2023	—	—
53.	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) EC No: 253-037-1 CAS No: 36437-37-3	vPvB	27 May 2022	27 November 2023	—	—

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

54.	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) EC No: 223-346-6 CAS No: 3846-71-7	PBT, vPvB	27 May 2022	27 November 2023	—	—]]
a	Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006.					
b	Date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006.					
c	[ <sup>F416</sup> 1 September 2021 for the use of the substance in the production of spare parts as articles or as complex products for the repair of articles or complex products, the production of which ceased or will have ceased before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles or complex products and these cannot function as intended without that spare part and the spare part cannot be produced without that substance, and for the use of the substance (on its own or in a mixture) for the repair of such articles or complex products where that substance on its own or in a mixture was used in the production of those articles or complex products and they cannot be repaired otherwise than by using that substance.					
d	1 March 2023 for the use of the substance in the production of spare parts as articles or as complex products for the repair of articles or complex products the production of which ceased or will have ceased before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles or complex products and these cannot function as intended without those spare parts and the spare part cannot be produced without that substance, and for the use of the substance (on its own or in a mixture) for the repair of such articles or complex products, where that substance on its own or in a mixture was used in the production of those articles or complex products and they cannot be repaired otherwise than by using that substance.					
e	Does not meet the criteria for identification as a carcinogen if it contains < 0,005 % (w/w) benzo[a]pyrene (Einecs No 200-028-5).]					
f	[ <sup>F417</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on <i>in vitro</i> diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).]]]					

### Editorial Information

- X3** Substituted by [Corrigendum to Commission Regulation \(EU\) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \('REACH'\)](#) (Official Journal of the European Union L 44 of 18 February 2011).
- X4** Substituted by [Corrigendum to Commission Regulation \(EU\) 2020/171 of 6 February 2020 amending Annex XIV to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \('REACH'\)](#) (Official Journal of the European Union L 35 of 7 February 2020).

### Textual Amendments

- F415** Substituted by [Commission Regulation \(EU\) 2020/171 of 6 February 2020 amending Annex XIV to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\)](#) (Text with EEA relevance).
- F416** Inserted by [Commission Regulation \(EU\) 2017/999 of 13 June 2017 amending Annex XIV to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\)](#) (Text with EEA relevance).
- F417** Substituted by [Commission Regulation \(EU\) 2020/2160 of 18 December 2020 amending Annex XIV to Regulation \(EU\) No 1907/2006 of the European Parliament and of the Council as regards the](#)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and substances of unknown or variable composition, complex reaction products or biological materials, polymers and homologues) (Text with EEA relevance).
- F418** Words in Annex 14 Table substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 10**; 2020 c. 1, Sch. 5 para. 1(1)
- F419** Inserted by Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F420** Inserted by Commission Regulation (EU) No 895/2014 of 14 August 2014 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F421** Inserted by Commission Regulation (EU) 2020/171 of 6 February 2020 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F422** Inserted by Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') (Text with EEA relevance).
- F423** Words in Annex 14 Table substituted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(a)(i)**
- F424** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(a)(ii)**
- F425** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(a)(iii)**
- F426** Words in Annex 14 Table omitted (30.9.2021) by virtue of The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(a)(iv)**
- F427** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(b)(i)**
- F428** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(b)(ii)**
- F429** Words in Annex 14 Table omitted (30.9.2021) by virtue of The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(2)(b)(iii)**
- F430** Substituted by Commission Regulation (EU) 2020/2160 of 18 December 2020 amending Annex XIV to Regulation (EU) No 1907/2006 of the European Parliament and of the Council as regards the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and substances of unknown or variable composition, complex reaction products or biological materials, polymers and homologues) (Text with EEA relevance).
- F431** Words in Annex 14 Table substituted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(a)(i)**
- F432** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(a)(ii)**
- F433** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(a)(iii)**
- F434** Words in Annex 14 Table omitted (30.9.2021) by virtue of The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(a)(iv)**
- F435** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(b)(i)**
- F436** Word in Annex 14 Table inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(b)(ii)**
- F437** Words in Annex 14 Table omitted (30.9.2021) by virtue of The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **7(3)(b)(iii)**

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

**F438** Inserted by Commission Regulation (EU) 2020/171 of 6 February 2020 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).

## ANNEX XV

### DOSSIERS

#### I. INTRODUCTION AND GENERAL PROVISIONS

This Annex lays down general principles for preparing dossiers to propose and justify:

- <sup>F297</sup> ...
- [<sup>F1</sup>the identification of CMRs, PBTs, vPvBs, or a substance of equivalent concern in accordance with Article 59,]
- restrictions of the manufacture, placing on the market or use of a substance <sup>F439</sup> ... .

#### Textual Amendments

**F439** Words in Annex 15 Pt. 1 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 11(2)**; 2020 c. 1, Sch. 5 para. 1(1)

The relevant parts of Annex I shall be used for the methodology and format of any dossier according to this Annex.

For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier.

#### II. CONTENT OF DOSSIERS

- <sup>F297</sup> 1. Dossier for harmonised classification and labelling for CMRs, respiratory sensitisers and other effects

Proposal

.....  
Justification

.....  
Justification for other effects at Community Level

2. Dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Article 59

Proposal

The proposal shall include the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 57(a), (b) or (c), a PBT according to Article 57(d), a vPvB according to Article 57(e), or a substance of equivalent concern according to Article 57(f).

Justification



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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A comparison of the available information with the criteria in Annex XIII for PBT according to Article 57(d), and vPvBs according to Article 57(e), or an assessment of the hazards and a comparison with Article 57(f), according to the relevant parts of Sections 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B of the Chemical Safety Report in Annex I.

Information on exposures, alternative substances and risks

The available use and exposure information and information on alternative substances and techniques shall be provided.

### 3. Dossiers for restrictions proposal

#### Proposal

The proposal shall include the identity of the substance and the restriction(s) proposed for the manufacture, placing on the market or use(s) and a summary of the justification.

Information on hazard and risk

The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report.

Evidence shall be provided that implemented risk management measures (including those identified in registrations under Articles 10 to 14) are not sufficient.

Information on alternatives

Available information on alternative substances and techniques shall be provided, including:

- information on the risks to human health and the environment related to the manufacture or use of the alternatives,
- availability, including the time scale,
- technical and economical feasibility.

Justification for Restrictions <sup>F440</sup>...

Justification shall be provided that:

- action is required <sup>F441</sup>...
- a restriction is the most appropriate <sup>F442</sup>... measure which shall be assessed using the following criteria:
  - (i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;
  - (ii) practicality: the restriction must be implementable, enforceable and manageable;
  - (iii) monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

#### Textual Amendments

**F441** Words in Annex 15 Pt. 2 point 3 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 11(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

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**F442** Words in Annex 15 Pt. 2 point 3 omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 11(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Socio-economic assessment

The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

#### Information on stakeholder consultation

Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.

## ANNEX XVI

### SOCIO-ECONOMIC ANALYSIS

This Annex outlines the information that may be addressed by those submitting a socio-economic analysis (SEA) with an application for authorisation, as specified in Article 62(5)(a), or in connection with a proposed restriction, as specified in Article 69(6)(b).

The Agency shall prepare guidance for the preparation of SEAs. SEAs, or contributions to them, shall be submitted in the format specified by the Agency in accordance with Article 111.

However, the level of detail and scope of the SEA, or contributions to them, shall be the responsibility of the applicant for authorisation, or, in the case of a proposed restriction, the interested party. The information provided can address the socio-economic impacts at any level.

An SEA may include the following elements:

- impact of a granted or refused authorisation on the applicant(s), or, in the case of a proposed restriction, the impact on industry (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology, etc.) taking into account general trends in the market and technology,
- impacts of a granted or refused authorisation, or a proposed restriction, on consumers. For example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on human health and the environment to the extent that these affect consumers,
- social implications of a granted or refused authorisation, or a proposed restriction. For example job security and employment,
- availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives,
- wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) of a granted or refused authorisation, or a

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- proposed restriction. This may include consideration of local, regional, national or international aspects,
- in the case of a proposed restriction, proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction (this shall take account of existing legislation). This should include an assessment of the effectiveness and the costs linked to alternative risk management measures,
  - in the case of a proposed restriction or refused authorisation, the benefits for human health and the environment as well as the social and economic benefits of the proposed restriction. For example, worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups,
  - an SEA may also address any other issue that is considered to be relevant by the applicant(s) or interested party.

## ANNEX XVII

### [<sup>F443</sup>RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES]

#### Textual Amendments

**F443** Substituted by [Commission Regulation \(EC\) No 552/2009 of 22 June 2009 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annex XVII \(Text with EEA relevance\)](#).

- [<sup>F444</sup>1. In this Annex “competent appropriate authority”, in relation to the exercise of a function under this Annex, means—
- a the Secretary of State if, or to the extent that, the exercise of the function—
    - i relates to England;
    - ii relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);
    - iii relates to Wales and is not within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006);
  - b the Scottish Ministers if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 54 of the Scotland Act 1998);
  - c the Welsh Ministers if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).]

#### Textual Amendments

**F444** Annex 17 para. 1 inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 13** (as amended by S.I. 2020/1577, regs. 1(1)(b), **7(6)(a)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
1. Polychlorinated terphenyls (PCTs)	Shall not be placed on the market, or used: — as substances, — in mixtures, including waste oils, or in equipment, in concentrations greater than 50 mg/kg (0,005 % by weight).
2. Chloroethene (vinyl chloride) CAS No 75-01-4 EC No 200-831-0	Shall not be used as propellant in aerosols for any use. Aerosols dispensers containing the substance as propellant shall not be placed on the market.
<p><sup>F450</sup><sup>F13</sup> 3. Liquid substances or mixtures <sup>F297</sup> which are regarded as dangerous in accordance with Directive 1999/45/EC or are] fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:</p> <p>(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;</p> <p>(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;</p> <p>(c) hazard class 4.1;</p> <p>(d) hazard class 5.1.]</p>	<p>1. Shall not be used in: — ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, — tricks and jokes, — games for one or more participants, or any article intended to be used as such, even with ornamental aspects,</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p> <p>3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they: — can be used as fuel in decorative oil lamps for supply to the general public, and, — present an aspiration hazard and are labelled with R65 or H304,</p> <p>4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the <sup>F451</sup>British Standard Specification on Decorative oil lamps (BS EN 14059) adopted by the British Standards Institute].</p>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>5. Without prejudice to the implementation of other [<sup>F452</sup>legislation] relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:</p> <p>(a) lamp oils, labelled with R65 or H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: ‘ Keep lamps filled with this liquid out of the reach of children ’ ; and, by 1 December 2010 , ‘ Just a sip of lamp oil — or even sucking the wick of lamps — may lead to life-threatening lung damage ’ ;</p> <p>(b) grill lighter fluids, labelled with R65 or H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: ‘ Just a sip of grill lighter may lead to life threatening lung damage ’ ;</p> <p>(c) lamp oils and grill lighters, labelled with R65 or H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010 .</p> <p><sup>F453</sup>6. ....</p> <p>7. Natural or legal persons placing on the market for the first time lamp oils and grill lighter fluids, labelled with R65 or H304, shall by 1 December 2011 , and annually thereafter, provide data on alternatives to lamp oils and grill lighter fluids labelled R65 or H304 to the [<sup>F454</sup>Agency].]</p>
<p>4. Tris (2,3 dibromopropyl) phosphate CAS No 126-72-7</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments</p>

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		and linen, intended to come into contact with the skin.
	2.	Articles not complying with paragraph 1 shall not be placed on the market.
5. Benzene CAS No 71-43-2 EC No 200-753-7	1.	Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy.
	2.	Toys and parts of toys not complying with paragraph 1 shall not be placed on the market.
	3.	Shall not be placed on the market, or used,
	—	as a substance,
	—	as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight.
	4.	However, paragraph 3 shall not apply to:
	(a)	motor fuels which are covered by [ <sup>F455</sup> the Motor Fuel (Composition and Content) Regulations 1999];
	(b)	substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation [ <sup>F456</sup> ;
	(c)	[ <sup>F457</sup> natural gas placed on the market for use by consumers, provided that the concentration of benzene remains below 0,1 % volume/volume.]
6. Asbestos fibres	[ <sup>F458</sup> 1.	The manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally is prohibited.
(a) Crocidolite CAS No 12001-28-4		
(b) Amosite CAS No 12172-73-5		
(c) Anthophyllite CAS No 77536-67-5	<sup>F459</sup> ...	

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

<p>(d) Actinolite CAS No 77536-66-4</p> <p>(e) Tremolite CAS No 77536-68-6</p> <p>(f) Chrysotile CAS No 12001-29-5 CAS No 132207-32-0</p>	<p>F459 ... F459 ...]</p> <p>2. The use of articles containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005 shall continue to be permitted until they are disposed of or reach the end of their service life. However, [<sup>F460</sup>the competent appropriate authority may, after having consulted the other appropriate authorities], for reasons of protection of human health, restrict, prohibit or make subject to specific conditions, the use of such articles before they are disposed of or reach the end of their service life.</p> <p>[<sup>F461</sup>The competent appropriate authority may, after having consulted the other appropriate authorities,] allow placing on the market of articles in their entirety containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005, under specific conditions ensuring a high level of protection of human health. <sup>F462</sup> ...</p> <p>3. Without prejudice to the application of other [<sup>F463</sup>legislation] on the classification, packaging and labelling of substances and mixtures, the placing on the market and use of articles containing these fibres, as permitted according to the preceding derogations, shall be permitted only if suppliers ensure before the placing on the market that articles bear a label in accordance with Appendix 7 to this Annex.</p>
<p>7. Tris(aziridinyl)phosphin oxide CAS No 545-55-1 EC No 208-892-5</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments</p>

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		and linen, intended to come into contact with the skin.
		2. Articles not complying with paragraph 1 shall not be placed on the market.
8.	Polybromobiphenyls; Polybrominatedbiphenyls (PBB) CAS No 59536-65-1	1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
9.	(a) Soap bark powder ( <i>Quillaja saponaria</i> ) and its derivatives containing saponines CAS No 68990-67-0 EC 273-620-4 (b) Powder of the roots of <i>Helleborus viridis</i> and <i>Helleborus niger</i> (c) Powder of the roots of <i>Veratrum album</i> and <i>Veratrum nigrum</i> (d) Benzidine and/or its derivatives CAS No 92-87-5 EC No 202-199-1 (e) o-Nitrobenzaldehyde CAS No 552-89-6 EC No 209-025-3 (f) Wood powder	1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs. 2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market. 3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.
10.	(a) Ammonium sulphide CAS No 12135-76-1 EC No 235-223-4 (b) Ammonium hydrogen sulphide CAS No 12124-99-1 EC No 235-184-3 (c) Ammonium polysulphide CAS No 9080-17-5 EC No 232-989-1	1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs. 2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market. 3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

<p>[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.</p>	
<p>11. Volatile esters of bromoacetic acids:</p> <p>(a) Methyl bromoacetate CAS No 96-32-2 EC No 202-499-2</p> <p>(b) Ethyl bromoacetate CAS No 105-36-2 EC No 203-290-9</p> <p>(c) Propyl bromoacetate CAS No 35223-80-4</p> <p>(d) Butyl bromoacetate CAS No 18991-98-5 EC No 242-729-9</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>
<p>12. 2-Naphthylamine CAS No 91-59-8 EC No 202-080-4 and its salts</p> <p>13. Benzidine CAS No 92-87-5 EC No 202-199-1 and its salts</p> <p>14. 4-Nitrobiphenyl CAS No 92-93-3 Einecs EC No 202-204-7</p> <p>15. 4-Aminobiphenyl xenylamine CAS No 92-67-1 Einecs EC No 202-177-1 and its salts</p>	<p>The following shall apply to entries 12 to 15: Shall not be placed on the market, or used, as substances or in mixtures in concentrations greater than 0,1 % by weight.</p>
<p>16. Lead carbonates:</p> <p>(a) Neutral anhydrous carbonate (PbCO<sub>3</sub>) CAS No 598-63-0 EC No 209-943-4</p> <p>(b) Trilead-bis(carbonate)-dihydroxide 2Pb CO<sub>3</sub> -Pb(OH)<sub>2</sub> CAS No 1319-46-6 EC No 215-290-6</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>[<sup>F464</sup>However, [<sup>F465</sup>the competent appropriate authority may, after having consulted the other appropriate authorities], in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use <sup>F466</sup>... of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. <sup>F467</sup>...]</p>
<p>17. Lead sulphates:</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures, where the</p>

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<p>[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.</p>	
<p>(a) PbSO<sub>4</sub> CAS No 7446-14-2 EC No 231-198-9</p> <p>(b) Pb<sub>x</sub>SO<sub>4</sub> CAS No 15739-80-7 EC No 239-831-0</p>	<p>substance or mixture is intended for use as paint.</p> <p>[<sup>F464</sup>However, [<sup>F468</sup>the competent appropriate authority may, after having consulted the other appropriate authorities], in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use <sup>F469</sup>... of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. <sup>F470</sup>...]</p>
<p>18. Mercury compounds</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use:</p> <p>(a) to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> <li>— the hulls of boats,</li> <li>— cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,</li> <li>— any totally or partly submerged appliances or equipment;</li> </ul> <p>(b) in the preservation of wood;</p> <p>(c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture;</p> <p>(d) in the treatment of industrial waters, irrespective of their use.</p>
<p>18a. Mercury CAS No 7439-97-6 EC No 231-106-7</p>	<p>1. Shall not be placed on the market:</p> <p>(a) in fever thermometers;</p> <p>(b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers).</p> <p>2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However [<sup>F471</sup>the competent appropriate</p>

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

authority may, after having consulted the other appropriate authorities,] restrict or prohibit the placing on the market of such measuring devices.

3. The restriction in paragraph 1(b) shall not apply to:
- (a) measuring devices more than 50 years old on 3 October 2007 ;
  - (b) barometers (except barometers within point (a)) until 3 October 2009 .

<sup>F472</sup>4. ....

- [<sup>F473</sup>5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014 :
- (a) barometers;
  - (b) hygrometers;
  - (c) manometers;
  - (d) sphygmomanometers;
  - (e) strain gauges to be used with plethysmographs;
  - (f) tensiometers;
  - (g) thermometers and other non-electrical thermometric applications.

The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury.

6. The restriction in paragraph 5 shall not apply to:
- (a) sphygmomanometers to be used:
    - (i) in epidemiological studies which are ongoing on 10 October 2012 ;
    - (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers;
  - (b) thermometers exclusively intended to perform tests according to

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		standards that require the use of mercury thermometers until 10 October 2017 ; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers.
		7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014 : (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point.
		8. The restrictions in paragraphs 5 and 7 shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007 ; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.]
19.	Arsenic compounds	1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment. 2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use. 3. Shall not be used in the preservation of wood. Furthermore,

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>wood so treated shall not be placed on the market.</p> <p>4. By way of derogation from paragraph 3:</p> <p>(a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorised in accordance with [<sup>F474</sup>Articles 19 or 26 of Regulation (EU) No 528/2012]. Wood so treated shall not be placed on the market before fixation of the preservative is completed.</p> <p>(b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:</p> <ul style="list-style-type: none"> <li>— as structural timber in public and agricultural buildings, office buildings, and industrial premises,</li> <li>— in bridges and bridgework,</li> <li>— as constructional timber in freshwater areas and brackish waters, for example jetties and bridges,</li> <li>— as noise barriers,</li> <li>— in avalanche control,</li> <li>— in highway safety fencing and barriers,</li> <li>— as debarked round conifer livestock fence posts,</li> </ul>
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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<ul style="list-style-type: none"> <li>— in earth retaining structures,</li> <li>— as electric power transmission and telecommunications poles,</li> <li>— as underground railway sleepers.</li> </ul> <p>(c) Without prejudice to the application of other [<sup>F475</sup>legislation] on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that all treated wood placed on the market is individually labelled ‘ For professional and industrial installation and use only, contains arsenic ’. In addition, all wood placed on the market in packs shall also bear a label stating ‘ Wear gloves when handling this wood. Wear a dust mask and eye protection when cutting or otherwise crafting this wood. Waste from this wood shall be treated as hazardous by an authorised undertaking ’.</p> <p>(d) Treated wood referred to under point (a) shall not be used:</p> <ul style="list-style-type: none"> <li>— in residential or domestic constructions, whatever the purpose,</li> <li>— in any application where there is a risk of repeated skin contact,</li> <li>— in marine waters,</li> <li>— for agricultural purposes other than for livestock fence posts and structural uses in accordance with point (b),</li> <li>— in any application where the treated wood may come into contact with intermediate or finished products intended for</li> </ul>
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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		human and/or animal consumption.
	5.	Wood treated with arsenic compounds that was in use in the Community before 30 September 2007 , or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.
	6.	Wood treated with CCA type C that was in use in the Community before 30 September 2007 , or that was placed on the market in accordance with paragraph 4:
	—	may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d),
	—	may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
	7.	[ <sup>F476</sup> The competent appropriate authority may, after having consulted the other appropriate authorities,] allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007:
	—	to be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (d),
	—	to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
20.	Organostannic compounds	1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint.

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|  | <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:</p> <p>(a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes;</p> <p>(b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming;</p> <p>(c) any totally or partly submerged appliance or equipment.</p> <p>3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.</p> <p><sup>F477</sup>4. Tri-substituted organostannic compounds:</p> <p>(a) Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used after 1 July 2010 in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.</p> <p>(b) Articles not complying with point (a) shall not be placed on the market after 1 July 2010, except for articles that were already in use in the Community before that date.</p> <p>5. Dibutyltin (DBT) compounds:</p> <p>(a) Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater</p> |
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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>than the equivalent of 0,1 % by weight of tin.</p> <p>(b) Articles and mixtures not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.</p> <p>(c) By way of derogation, points (a) and (b) shall not apply until 1 January 2015 to the following articles and mixtures for supply to the general public:</p> <ul style="list-style-type: none"> <li>— one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives,</li> <li>— paints and coatings containing DBT compounds as catalysts when applied on articles,</li> <li>— soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC,</li> <li>— fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications,</li> <li>— outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades,</li> </ul> <p>(d) By way of derogation, points (a) and (b) shall not apply to materials and articles regulated under Regulation (EC) No 1935/2004.</p> <p>6. Diocetyl tin (DOT) compound:</p> <p>(a) Diocetyl tin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article,</p>
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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>or part thereof, is greater than the equivalent of 0,1 % by weight of tin:</p> <ul style="list-style-type: none"> <li>— textile articles intended to come into contact with the skin,</li> <li>— gloves,</li> <li>— footwear or part of footwear intended to come into contact with the skin,</li> <li>— wall and floor coverings,</li> <li>— childcare articles,</li> <li>— female hygiene products,</li> <li>— nappies,</li> <li>— two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits).</li> </ul> <p>(b) Articles not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.]</p>
<p>21. Di-<math>\mu</math>-oxo-di-n-butylstanniohydroxyborane/ Dibutyltin hydrogen borate C<sub>8</sub> H<sub>19</sub> BO<sub>3</sub> Sn (DBB) CAS No 75113-37-0 EC No 401-040-5</p>	<p>Shall not be placed on the market, or used, as a substance, or in mixtures in a concentration equal to, or greater than 0,1 % by weight. However, the first paragraph shall not apply to this substance (DBB) or mixtures containing it if these are intended solely for conversion into articles, among which this substance will no longer feature in a concentration equal to or greater than 0,1 %.</p>
<p>22. Pentachlorophenol CAS No 87-86-5 EC No 201-778-6 and its salts and esters</p>	<p>Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as a substance,</li> <li>— as a constituent in other substances, or in mixtures, in a concentration equal to or greater than 0,1 % by weight.</li> </ul>
<p>23. Cadmium CAS No 7440-43-9 EC No 231-152-8 and its compounds</p>	<p>For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff</p>

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<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

as established by Council Regulation (EEC) No 2658/87 <sup>F478</sup>, as it has effect in EU law immediately before IP completion day. For the purposes of this entry that Regulation has effect as if the references to Euratom were omitted].

<sup>F479</sup><sup>F480</sup> Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material):

- polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]
- polyurethane (PUR) [3909 50]
- low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10]
- cellulose acetate (CA) [3912 11]
- cellulose acetate butyrate (CAB) [3912 11]
- epoxy resins [3907 30]
- melamine-formaldehyde (MF) resins [3909 20]
- urea-formaldehyde (UF) resins [3909 10]
- unsaturated polyesters (UP) [3907 91]
- polyethylene terephthalate (PET) [3907 60]
- polybutylene terephthalate (PBT)
- transparent/general-purpose polystyrene [3903 11]
- acrylonitrile methylmethacrylate (AMMA)
- cross-linked polyethylene (VPE)
- high-impact polystyrene
- polypropylene (PP) [3902 10]

Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.]

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[<sup>X6</sup>By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011.]

F481 ...

F482 ...

[<sup>F483</sup>2. Shall not be used or placed on the market in paints with codes [ 3208 ] [ 3209 ] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight.

For paints with codes [ 3208 ] [ 3209 ] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight.

Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.]

3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons.

4. By way of derogation, paragraph 1, second subparagraph shall not apply to:

— mixtures produced from PVC waste, hereinafter referred to as ‘ recovered PVC ’ ,

— mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications:

- (a) profiles and rigid sheets for building applications;
- (b) doors, windows, shutters, walls, blinds, fences, and roof gutters;
- (c) decks and terraces;
- (d) cable ducts;

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

- (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above.

Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: ‘*Contains recovered PVC*’ or with the following pictogram:



F484  
...]

5. For the purpose of this entry, ‘cadmium plating’ means any deposit or coating of metallic cadmium on a metallic surface.

Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:

- (a) equipment and machinery for:
- food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11]
  - agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436]
  - cooling and freezing [8418]
  - printing and book-binding [8440] [8442] [8443]

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

- (b) equipment and machinery for the production of:
- household goods [7321] [8421 12] [8450] [8509] [8516]
  - furniture [8465] [8466] [9401] [9402] [9403] [9404]
  - sanitary ware [7324]
  - central heating and air conditioning plant [7322] [8403] [8404] [8415]

In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited.

6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below:

- (a) equipment and machinery for the production of:
- paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452]
- (b) equipment and machinery for the production of:
- industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431]
  - road and agricultural vehicles [chapter 87]
  - rolling stock [chapter 86]
  - vessels [chapter 89]

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<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

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| 7.                 | However, the restrictions in paragraphs 5 and 6 shall not apply to: <ul style="list-style-type: none"> <li>— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels,</li> <li>— electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed.</li> </ul> |
| <sup>F485</sup> 8. | Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight.<br>Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight.<br>For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C.  |
| 9.                 | By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.  |
| 10.                | Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: <ul style="list-style-type: none"> <li>(i) metal beads and other metal components for jewellery making;</li> <li>(ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: <ul style="list-style-type: none"> <li>— bracelets, necklaces and rings,</li> <li>— piercing jewellery,</li> </ul> </li> </ul>   |

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<p>[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.</p>	
	<p>— wrist-watches and wrist-wear, — brooches and cufflinks.</p> <p>[<sup>X6</sup>11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011 .]]</p>
<p>24. Monomethyl — tetrachlorodiphenyl methane Trade name: Ugilec 141 CAS No 76253-60-6</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p> <p>2. By way of derogation, paragraph 1 shall not apply:</p> <p>(a) in the case of plant and machinery already in service on 18 June 1994 , until such plant and machinery is disposed of;</p> <p>(b) in the case of the maintenance of plant and machinery already in service within a Member State on 18 June 1994 .</p> <p>For the purposes of point (a) [<sup>F486</sup>the competent appropriate authority may, after having consulted the other appropriate authorities], on grounds of human health protection and environmental protection, prohibit within their territory the use of such plant or machinery before it is disposed of.</p>
<p>25. Monomethyl-dichloro-diphenyl methane Trade name: Ugilec 121 Ugilec 21</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p>
<p>26. Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers Trade name: DBBT CAS No 99688-47-8</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p>
<p>27. Nickel CAS No 7440-02-0</p>	<p>1. Shall not be used:</p>



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EC No 231-111-4 and its compounds	<p>(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than <math>0,2 \mu\text{g}/\text{cm}^2</math> /week (migration limit);</p> <p>(b) in articles intended to come into direct and prolonged contact with the skin such as:</p> <ul style="list-style-type: none"> <li>— earrings,</li> <li>— necklaces, bracelets and chains, anklets, finger rings,</li> <li>— wrist-watch cases, watch straps and tighteners,</li> <li>— rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,</li> </ul> <p>if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than <math>0,5 \mu\text{g}/\text{cm}^2</math> /week.</p> <p>(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed <math>0,5 \mu\text{g}/\text{cm}^2</math> /week for a period of at least two years of normal use of the article.</p> <p>2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for</p>
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<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	demonstrating the conformity of articles to paragraphs 1 and 2.
<sup>F487</sup> 28. Substances which are classified as carcinogen category 1A or 1B in <sup>F488</sup> the GB mandatory classification and labelling list] and are listed in Appendix 1 or Appendix 2, respectively.	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as substances,</li> <li>— as constituents of other substances, or,</li> <li>— in mixtures,</li> </ul> <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <ul style="list-style-type: none"> <li>— either the relevant specific concentration limit specified in <sup>F488</sup>the GB mandatory classification and labelling list], or,</li> <li>— <sup>F1</sup>the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.]</li> </ul> <p>Without prejudice to the implementation of other <sup>F489</sup>legislation] relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p style="padding-left: 40px;">Restricted to professional users</p>
29. Substances which are classified as germ cell mutagen category 1A or 1B in <sup>F488</sup> the GB mandatory classification and labelling list] and are listed in Appendix 3 or Appendix 4, respectively.	
30. Substances which are classified as reproductive toxicant category 1A or 1B in <sup>F488</sup> the GB mandatory classification and labelling list] and are listed in Appendix 5 or Appendix 6, respectively.]	
	<p>2. By way of derogation, paragraph 1 shall not apply to:</p> <p>(a) <sup>F490</sup>medicinal or veterinary medicinal products as defined by the Veterinary Medicines Regulations 2013 and</p>

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<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		<p>the Human Medicines Regulations 2012;]</p> <p>(b) cosmetic products as defined by <sup>F491</sup>Regulation 1223/2009];</p> <p>(c) the following fuels and oil products:</p> <ul style="list-style-type: none"> <li>— motor fuels which are covered by <sup>F492</sup>the Motor Fuel (Composition and Content) Regulations 1999],</li> <li>— mineral oil products intended for use as fuel in mobile or fixed combustion plants,</li> <li>— fuels sold in closed systems (e.g. liquid gas bottles);</li> </ul> <p>(d) <sup>F1</sup>artists' paints covered by Regulation (EC) No 1272/2008;]</p> <p>(e) <sup>F493</sup>the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.]</p>
31.		
(a)	Creosote; wash oil CAS No 8001-58-9 EC No 232-287-5	
(b)	Creosote oil; wash oil CAS No 61789-28-4	
	1.	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore,

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<p>(c) EC No 263-047-8 Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8</p> <p>(d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8 EC No 292-605-3</p> <p>(e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1</p> <p>(f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7</p> <p>(g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3</p> <p>(h) Creosote, wood CAS No 8021-39-4 EC No 232-419-1</p> <p>(i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5</p>	<p>wood so treated shall not be placed on the market.</p> <p>2. By way of derogation from paragraph 1:</p> <p>(a) The substances and mixtures may be used for wood treatment in industrial installations or by professionals covered by <sup>F494</sup>... legislation on the protection of workers for in situ retreatment only if they contain:</p> <p>(i) benzo[a]pyrene at a concentration of less than 50 mg/kg (0,005 % by weight), and</p> <p>(ii) water extractable phenols at a concentration of less than 3 % by weight.</p> <p>Such substances and mixtures for use in wood treatment in industrial installations or by professionals:</p> <p>— may be placed on the market only in packaging of a capacity equal to or greater than 20 litres,</p> <p>— shall not be sold to consumers.</p> <p>Without prejudice to the application of other [<sup>F495</sup>legislation] on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is visibly, legibly and indelibly marked as follows:</p> <p>For use in industrial installations or professional treatment only .</p> <p>(b) Wood treated in industrial installations or by professionals according to subparagraph (a) which is placed on the market for the first time or retreated in situ may be used for professional and industrial use only, for</p>
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	<p>example on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (for example stakes for tree support) and in harbours and waterways.</p> <p>(c) The prohibition in paragraph 1 on the placing on the market shall not apply to wood which has been treated with substances listed in entry 31 (a) to (i) before 31 December 2002 and is placed on the second-hand market for re-use.</p> <p>3. Treated wood referred to under paragraph 2(b) and (c) shall not be used:</p> <ul style="list-style-type: none"> <li>— inside buildings, whatever their purpose,</li> <li>— in toys,</li> <li>— in playgrounds,</li> <li>— in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact,</li> <li>— in the manufacture of garden furniture such as picnic tables,</li> <li>— for the manufacture and use and any re-treatment of: <ul style="list-style-type: none"> <li>— containers intended for growing purposes,</li> <li>— packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption,</li> <li>— other materials which may contaminate the articles mentioned above.</li> </ul> </li> </ul>
<p>32. Chloroform CAS No 67-66-3 EC No 200-663-8</p> <p>34. 1,1,2-Trichloroethane CAS No 79-00-5 EC No 201-166-9</p>	<p>Without prejudice to the other parts of this Annex, the following shall apply to entries 32 to 38.</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>— as substances,</li> </ul>

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<p>35. 1,1,2,2-Tetrachloroethane CAS No 79-34-5 EC No 201-197-8</p> <p>36. 1,1,1,2-Tetrachloroethane CAS No 630-20-6</p> <p>37. Pentachloroethane CAS No 76-01-7 EC No 200-925-1</p> <p>38. 1,1-Dichloroethene CAS No 75-35-4 EC No 200-864-0</p>	<p>— as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1 % by weight,</p> <p>where the substance or mixture is intended for supply to the general public and/or is intended for diffusive applications such as in surface cleaning and cleaning of fabrics.</p> <p>2. Without prejudice to the application of other [<sup>F496</sup>legislation] on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures containing them in concentrations equal to or greater than 0,1 % by weight is visibly, legibly and indelibly marked as follows:</p> <p>For use in industrial installations only . By way of derogation this provision shall not apply to:</p> <p>(a) [<sup>F497</sup>medicinal or veterinary medicinal products as defined by the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012;]</p> <p>(b) cosmetic products as defined by [<sup>F498</sup>Regulation 1223/2009].</p>
<p>[<sup>F140</sup>. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in [<sup>F499</sup>the GB mandatory classification and labelling list] or not.]</p>	<p>1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:</p> <p>— metallic glitter intended mainly for decoration,</p> <p>— artificial snow and frost,</p> <p>— ‘ whoopee ’ cushions,</p> <p>— silly string aerosols,</p> <p>— imitation excrement,</p> <p>— horns for parties,</p> <p>— decorative flakes and foams,</p> <p>— artificial cobwebs,</p>

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<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>— stink bombs.</p> <p>2. Without prejudice to the application of other <sup>F500</sup>legislation] on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:</p> <p>For professional users only .</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC <sup>b</sup>.</p> <p>4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.</p>
<p>41. Hexachloroethane CAS No 67-72-1 EC No 200-666-4</p>	<p>Shall not be placed on the market, or used, as substance or in mixtures, where the substance or mixture is intended for the manufacturing or processing of non-ferrous metals.</p>
<p><b>F501</b></p>	
<p>43. Azocolourants and Azodyes</p>	<p>1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:</p>

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	— clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags, footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,
	— textile or leather toys and toys which include textile or leather garments,
	— yarn and fabrics intended for use by the final consumer.
	2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.
	3. Azodyes, which are contained in Appendix 9, ‘ List of azodyes ’ shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.

F502

45. Diphenylether, octabromo derivative C <sub>12</sub> H <sub>2</sub> Br <sub>8</sub> O	1. Shall not be placed on the market, or used: — as a substance, — as a constituent of other substances, or in mixtures, in concentrations greater than 0,1 % by weight.
	2. Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than 0,1 % by weight.
	3. By way of derogation, paragraph 2 shall not apply:



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	<ul style="list-style-type: none"> <li>— to articles that were in use in the Community before 15 August 2004,</li> <li>— to electrical and electronic equipment within the scope of [<sup>F503</sup>the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012].</li> </ul>
<p>46.</p> <p>(a) Nonylphenol C<sub>6</sub>H<sub>4</sub>(OH)C<sub>9</sub>H<sub>19</sub> CAS 25154-52-3 EC 246-672-0</p> <p>(b) Nonylphenol ethoxylates (C<sub>2</sub>H<sub>4</sub>O)<sub>n</sub>C<sub>15</sub>H<sub>24</sub>O</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:</p> <p>(1) industrial and institutional cleaning except:</p> <ul style="list-style-type: none"> <li>— controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,</li> <li>— cleaning systems with special treatment where the washing liquid is recycled or incinerated.</li> </ul> <p>(2) domestic cleaning;</p> <p>(3) textiles and leather processing except:</p> <ul style="list-style-type: none"> <li>— processing with no release into waste water,</li> <li>— systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);</li> </ul> <p>(4) emulsifier in agricultural teat dips;</p> <p>(5) metal working except: uses in controlled closed systems where the washing liquid is recycled or incinerated;</p> <p>(6) manufacturing of pulp and paper;</p> <p>(7) cosmetic products;</p> <p>(8) other personal care products except: spermicides;</p>

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	<p>(9) co-formulants in pesticides and biocides. However national authorisations for pesticides or biocidal products containing nonylphenol ethoxylates as co-formulant, granted before 17 July 2003, shall not be affected by this restriction until their date of expiry.</p>
<p>[<sup>F504</sup>46a. Nonylphenol ethoxylates (NPE) (C<sub>2</sub> H<sub>4</sub> O)<sub>n</sub> C<sub>15</sub> H<sub>24</sub> O</p>	<p>1. Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.</p> <p>2. Paragraph 1 shall not apply to the placing on the market of second-hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.</p> <p>3. For the purposes of paragraphs 1 and 2, 'textile article' means any unfinished, semi-finished or finished product which is composed of at least 80 % textile fibres by weight, or any other product that contains a part which is composed of at least 80 % textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels.]</p>
<p>47. Chromium VI compounds</p>	<p>1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement.</p> <p>2. If reducing agents are used, then without prejudice to the</p>

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application of other [<sup>F505</sup>legislation] on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.

3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin.

[<sup>F506</sup>4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1.]

[<sup>F507</sup>5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.

6. Articles containing leather parts coming into contact with the skin shall not be placed on the

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	<p>market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.</p> <p>7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015 .]</p>
<p>48. Toluene CAS No 108-88-3 EC No 203-625-9</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.</p>
<p>49. Trichlorobenzene CAS No 120-82-1 EC No 204-428-0</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight for any use except:</p> <ul style="list-style-type: none"> <li>— as an intermediate of synthesis, or,</li> <li>— as a process solvent in closed chemical applications for chlorination reactions, or,</li> <li>— in the manufacture of 1,3,5-triamino — 2,4,6-trinitrobenzene (TATB).</li> </ul>
<p>50. Polycyclic-aromatic hydrocarbons (PAH)</p> <p>(a) Benzo[a]pyrene (BaP) CAS No 50-32-8</p> <p>(b) Benzo[e]pyrene (BeP) CAS No 192-97-2</p> <p>(c) Benzo[a]anthracene (BaA) CAS No 56-55-3</p> <p>(d) Chrysen (CHR) CAS No 218-01-9</p> <p>(e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2</p> <p>(f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3</p> <p>(g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9</p>	<p>1. From 1 January 2010 , extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain:</p> <ul style="list-style-type: none"> <li>— more than 1 mg/kg (0,0001 % by weight) BaP, or,</li> <li>— more than 10 mg/kg (0,001 % by weight) of the sum of all listed PAHs.</li> </ul> <p>[<sup>F508</sup>The standard [<sup>F509</sup>BS EN] 16143:2013 (Petroleum products — Determination of content of Benzo(a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils — Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for</p>

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(h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3	<p>demonstrating conformity with the limits referred to in the first subparagraph. Until 23 September 2016, the limits referred to in the first subparagraph may be regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3 % by weight as measured by the Institute of Petroleum standard IP 346:1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions — Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limits of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is measured by the manufacturer or importer every six months or after each major operational change, whichever is earlier.]</p> <p>2. Furthermore, tyres and treads for retreading manufactured after 1 January 2010 shall not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1.</p> <p>These limits shall be regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0,35 % Bay protons as measured and calculated by ISO 21461 (Rubber vulcanised — Determination of aromaticity of oil in vulcanised rubber compounds).</p> <p>3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils exceeding the limits referred to in paragraph 1.</p> <p>[<sup>F510</sup>4. For the purpose of this entry ‘tyres’ shall mean tyres for vehicles covered by: — Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and</p>
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separate technical units intended for such vehicles;

— Regulation (EU) No 167/2013 of the European Parliament and of the Council on the approval and market surveillance of agricultural and forestry vehicles;

— Regulation (EU) No 168/2013 of the European Parliament and of the Council on the approval and market surveillance of two- or three-wheel vehicles and quadricycles.]

[<sup>F511</sup>5. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs.

Such articles include amongst others:

- sport equipment such as bicycles, golf clubs, racquets
- household utensils, trolleys, walking frames
- tools for domestic use
- clothing, footwear, gloves and sportswear
- watch-straps, wrist-bands, masks, head-bands

6. Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005 % by weight of this

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	<p>component) of any of the listed PAHs.</p> <p>7. By way of derogation from paragraphs 5 and 6, these paragraphs shall not apply to articles placed on the market for the first time before 27 December 2015 .</p> <p>8. By 27 December 2017 , the Commission shall review the limit values in paragraphs 5 and 6 in the light of new scientific information, including migration of PAHs from the articles referred to therein, and information on alternative raw materials and, if appropriate, modify these paragraphs accordingly.]</p>
<p>[<sup>F512</sup>51. Bis(2-ethylhexyl) phthalate (DEHP) CAS No.: 117-81-7 EC No.: 204-211-0 Dibutyl phthalate (DBP) CAS No.: 84-74-2 EC No.: 201-557-4 Benzyl butyl phthalate (BBP) CAS No.: 85-68-7 EC No.: 201-622-7 Diisobutyl phthalate (DIBP) CAS No.: 84-69-5 EC No.: 201-553-2</p>	<p>1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.</p> <p>2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material.</p> <p>In addition, DIBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material.</p> <p>3. Shall not be placed on the market after 7 July 2020 in articles,</p>

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	<p>individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article.</p> <p>4. Paragraph 3 shall not apply to:</p> <p>(a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin;</p> <p>(b) aircraft, placed on the market before 7 January 2024 , or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft;</p> <p>(c) motor vehicles within the scope of <sup>F513</sup>Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles], placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles;</p> <p>(d) articles placed on the market before 7 July 2020;</p> <p>(e) measuring devices for laboratory use, or parts thereof;</p> <p>(f) materials and articles intended to come into contact with food within the scope of Regulation</p>
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	(g)	(EC) No 1935/2004 or Commission Regulation (EU) No 10/2011 <sup>u</sup> ; [ <sup>F514</sup> relevant] medical devices <sup>F515</sup> ..., or parts thereof;
	(h)	electrical and electronic equipment within the scope of [ <sup>F516</sup> the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012];
	(i)	the immediate packaging of medicinal products within the scope of [ <sup>F517</sup> the Veterinary Medicines Regulations 2013 or the Human Medicines Regulations 2012];
	(j)	toys and childcare articles covered by paragraphs 1 or 2.
5.		For the purposes of paragraphs 1, 2, 3 and 4(a),
	(a)	‘ plasticised material ’ means any of the following homogeneous materials: <ul style="list-style-type: none"> <li>— polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes,</li> <li>— any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings,</li> <li>— surface coatings, non-slip coatings, finishes, decals, printed designs,</li> <li>— adhesives, sealants, paints and inks.</li> </ul>
	(b)	‘ prolonged contact with human skin ’ means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.
	(c)	‘ childcare article ’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>children or sucking on the part of children.</p> <p>6. For the purposes of paragraph 4(b), 'aircraft' means one of the following:</p> <p>(a) a civil aircraft produced in accordance with a type certificate issued under [<sup>F518</sup>Regulation (EU) 2018/1139] or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944, in Chicago;</p> <p>(b) a military aircraft.]</p>
<p>52. The following phthalates (or other CAS- and EC numbers covering the substance):</p> <p>(a) Di- 'isononyl' phthalate (DINP) CAS No 28553-12-0 and 68515-48-0 EC No 249-079-5 and 271-090-9</p> <p>(b) Di- 'isodecyl' phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1 EC No 247-977-1 and 271-091-4</p> <p>(c) Di-n-octyl phthalate (DNOP) CAS No 117-84-0 EC No 204-214-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.</p> <p>2. Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p><sup>F519</sup>3. ....</p> <p>4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
<p><sup>F502</sup></p>	
<p>54. 2-(2-methoxyethoxy)ethanol (DEGME)</p>	<p>Shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers,</p>

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<p>[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.</p>	
<p>CAS No 111-77-3 EC No 203-906-6</p>	<p>cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by weight.</p>
<p>55. 2-(2-butoxyethoxy)ethanol (DEGBE) CAS No 112-34-5 EC No 203-961-6</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3 % by weight.</p> <p>2. Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>3. Without prejudice to other <sup>F520</sup>... legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that paints other than spray paints containing DEGBE in concentrations equal to or greater than 3 % by weight of that are placed on the market for supply to the general public are visibly, legibly and indelibly marked by 27 December 2010 as follows: Do not use in paint spraying equipment .</p>
<p>[<sup>F464</sup>56. Methylenediphenyl diisocyanate (MDI) CAS No 26447-40-5 EC No 247-714-0 including the following specific isomers: (a) 4,4'-Methylenediphenyl diisocyanate: CAS No 101-68-8 EC No 202-966-0; (b) 2,4'-Methylenediphenyl diisocyanate: CAS No 5873-54-1 EC No 227-534-9;</p>	<p>1. Shall not be placed on the market after 27 December 2010, as a constituent of mixtures in concentrations equal to or greater than 0,1 % by weight of MDI for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging: (a) contains protective gloves which comply with the requirements of [<sup>F521</sup>Regulation (EU) 2016/425];</p>

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<p>(c) 2,2'-Methylenediphenyl diisocyanate: CAS No 2536-05-2 EC No 219-799-4]</p>	<p>(b) is marked visibly, legibly and indelibly as follows, and without prejudice to other <sup>F522</sup>... legislation concerning the classification, packaging and labelling of substances and mixtures:</p> <ul style="list-style-type: none"> <li>— Persons already sensitised to diisocyanates may develop allergic reactions when using this product.</li> <li>— Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product.</li> <li>— This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard [<sup>F523</sup>BS EN] 14387) is used.</li> </ul> <p>2. By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives.</p>
<p>57. Cyclohexane CAS No 110-82-7 EC No 203-806-2</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0,1 % by weight in package sizes greater than 350 g.</p> <p>2. Neoprene-based contact adhesives containing cyclohexane and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>3. Without prejudice to other <sup>F524</sup>... legislation concerning the</p>

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	<p>classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that neoprene-based contact adhesives containing cyclohexane in concentrations equal to or greater than 0,1 % by weight that are placed on the market for supply to the general public after 27 December 2010 are visibly, legibly and indelibly marked as follows:</p> <ul style="list-style-type: none"> <li>— This product is not to be used under conditions of poor ventilation.</li> <li>— This product is not to be used for carpet laying.</li> </ul>
<p>58. Ammonium nitrate (AN) CAS No 6484-52-2 EC No 229-347-8</p>	<ol style="list-style-type: none"> <li>1. Shall not be placed on the market for the first time after 27 June 2010 as a substance, or in mixtures that contain more than 28 % by weight of nitrogen in relation to ammonium nitrate, for use as a solid fertiliser, straight or compound, unless the fertiliser complies with the technical provisions for ammonium nitrate fertilisers of high nitrogen content set out in Annex III to Regulation (EC) No 2003/2003 of the European Parliament and of the Council<sup>1</sup>.</li> <li>2. Shall not be placed on the market after 27 June 2010 as a substance, or in mixtures that contain 16 % or more by weight of nitrogen in relation to ammonium nitrate except for supply to: <ol style="list-style-type: none"> <li>(a) downstream users and distributors, including natural or legal persons licensed or authorised in accordance with [<sup>F525</sup>the retained EU law that transposed Directive 2014/28/EU];</li> <li>(b) farmers for use in agricultural activities, either full time or part</li> </ol> </li> </ol>

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	<p>time and not necessarily related to the size of the land area. For the purposes of this subparagraph:</p> <p>(i) ‘ farmer ’ shall mean a natural or legal person, or a group of natural or legal persons, whatever legal status is granted to the group and its members <sup>F526</sup> ..., whose holding is situated within [<sup>F527</sup>Great Britain], and who exercises an agricultural activity;</p> <p>(ii) ‘ agricultural activity ’ shall mean the production, rearing or growing of agricultural products including harvesting, milking, breeding animals and keeping animals for farming purposes, or maintaining the land in good agricultural and environmental condition <sup>F528</sup> ...;</p> <p>(c) natural or legal persons engaged in professional activities such as horticulture, plant growing in greenhouses, maintenance of parks, gardens or sport pitches, forestry or other similar activities.</p> <p><sup>F529</sup>3. ....</p>
<p>[<sup>F477</sup>59. Dichloromethane CAS No 75-09-2 EC No: 200-838-9</p>	<p>1. Paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall not be:</p> <p>(a) placed on the market for the first time for supply to the general public or to professionals after 6 December 2010;</p> <p>(b) placed on the market for supply to the general public or to</p>

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<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

- professionals after 6 December 2011;  
 (c) used by professionals after 6 June 2012.  
 For the purposes of this entry:  
 (i) ‘ professional ’ means any natural or legal person, including workers and self-employed workers undertaking paint stripping in the course of their professional activity outside an industrial installation;  
 (ii) ‘ industrial installation ’ means a facility used for paint stripping activities.
2. By way of derogation from paragraph 1, <sup>F530</sup>the competent appropriate authority may, after having consulted the other appropriate authorities,] allow <sup>F531</sup>... for certain activities the use, by specifically trained professionals, of paint strippers containing dichloromethane and may allow the placing on the market of such paint strippers for supply to those professionals.
- <sup>F532</sup>A] derogation shall define appropriate provisions for the protection of the health and safety of those professionals using paint strippers containing dichloromethane <sup>F533</sup>.... Those provisions shall include a requirement that a professional shall hold a certificate <sup>F534</sup>..., or provide other documentary evidence to that effect, <sup>F535</sup>..., so as to demonstrate proper training and competence to safely use paint strippers containing dichloromethane. <sup>F536</sup>...
3. <sup>F537</sup>... The training referred to in paragraph 2 shall cover as a minimum:  
 (a) awareness, evaluation and management of risks to health,

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|  | <p>including information on existing substitutes or processes, which under their conditions of use are less hazardous to the health and safety of workers;</p> <p>(b) use of adequate ventilation;</p> <p>(c) use of appropriate personal protective equipment that complies with [<sup>F538</sup>Regulation (EU) 2016/425].</p> <p>Employers and self-employed workers shall preferably replace dichloromethane with a chemical agent or process which, under its conditions of use, presents no risk, or a lower risk, to the health and safety of workers. Professional shall apply all relevant safety measures in practice, including the use of personal protective equipment.</p> <p>4. Without prejudice to other <sup>F539</sup>... legislation on workers protection, paint strippers containing dichloromethane in concentrations equal to or greater than 0,1 % by weight may be used in industrial installations only if the following minimum conditions are met:</p> <p>(a) effective ventilation in all processing areas, in particular for the wet processing and the drying of stripped articles: local exhaust ventilation at strip tanks supplemented by forced ventilation in those areas, so as to minimise exposure and to ensure compliance, where technically feasible, with relevant occupational exposure limits;</p> <p>(b) measures to minimise evaporation from strip tanks comprising: lids for covering strip tanks except during loading and unloading; suitable loading and unloading arrangements for strip tanks; and wash tanks with water or brine to remove excess solvent after unloading;</p> |
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	<p>(c) measures for the safe handling of dichloromethane in strip tanks comprising: pumps and pipework for transferring paint stripper to and from strip tanks; and suitable arrangements for safe cleaning of tanks and removal of sludge;</p> <p>(d) personal protective equipment that complies with [<sup>F540</sup>Regulation (EU) 2016/425] comprising: suitable protective gloves, safety goggles and protective clothing; and appropriate respiratory protective equipment where compliance with relevant occupational exposure limits cannot be otherwise achieved;</p> <p>(e) adequate information, instruction and training for operators in the use of such equipment.</p> <p>5. Without prejudice to other [<sup>F541</sup>legislation] concerning the classification, labelling and packaging of substances and mixtures, by 6 December 2011 paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall be visibly, legibly and indelibly marked as follows:  ‘ Restricted to industrial use and to [<sup>F542</sup>approved] professionals <sup>F543</sup>... — verify where use is allowed. ’</p>
[ <sup>F544</sup> 60. Acrylamide CAS No 79-06-1	Shall not be placed on the market or used as a substance or constituent of mixtures in a concentration, equal to or greater than 0,1 % by weight for grouting applications after 5 November 2012 .]
[ <sup>F545</sup> 61. Dimethylfumarate (DMF) CAS No 624-49-7 EC 210-849-0	Shall not be used in articles or any parts thereof in concentrations greater than 0,1 mg/kg. Articles or any parts thereof containing DMF in concentrations greater than 0,1 mg/kg shall not be placed on the market.]

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.]

<p>[<sup>F546</sup>62.</p> <p>(a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4</p> <p>(b) Phenylmercury propionate EC No: 203-094-3 CAS No: 103-27-5</p> <p>(c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6</p> <p>(d) Phenylmercury octanoate EC No: - CAS No: 13864-38-5</p> <p>(e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3</p>	<p>1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01 % by weight.</p> <p>2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.]</p>
<p>[<sup>F445</sup>63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds</p>	<p>1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight.</p> <p>2. For the purposes of paragraph 1: (i) ‘ jewellery articles ’ shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) ‘ any individual part ’ shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles.</p> <p>3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making.</p>

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4. By way of derogation, paragraph 1 shall not apply to:
- (a) crystal glass as defined in <sup>F547</sup>the Crystal Glass (Descriptions) Regulations 1973];
  - (b) internal components of watch timepieces inaccessible to consumers;
  - (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103 , as established by Regulation (EEC) No 2658/87 <sup>F548</sup>as it has effect in EU law immediately before IP completion day]), unless they have been treated with lead or its compounds or mixtures containing these substances;
  - (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.
5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961.

<sup>F549</sup>6. ....

<sup>F446</sup>7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.

That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such

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accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm<sup>2</sup> per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

8. By way of derogation, paragraph 7 shall not apply to:
- (a) jewellery articles covered by paragraph 1;
  - (b) crystal glass as defined in [<sup>F550</sup>the Crystal Glass (Descriptions) Regulations 1973];
  - (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87 [<sup>F551</sup>as it has effect in EU law immediately before IP completion day]) unless they have been treated with lead or its compounds or mixtures containing these substances;
  - (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 °C;
  - (e) keys and locks, including padlocks;
  - (f) musical instruments;
  - (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight;
  - (h) the tips of writing instruments;
  - (i) religious articles;

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	<p>(j) portable zinc-carbon batteries and button cell batteries;</p> <p>(k) articles within the scope of:</p> <p>(i) [<sup>F552</sup>the retained EU law that transposed] Directive 94/62/EC;</p> <p>(ii) Regulation (EC) No 1935/2004;</p> <p>(iii) [<sup>F553</sup>the Toys (Safety) Regulations 2011];</p> <p>(iv) [<sup>F554</sup>the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012.]</p> <p>9. By 1 July 2019 , the [<sup>F555</sup>Agency] shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, [<sup>F556</sup>make recommendations to the Secretary of State].</p> <p>10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016 .]]</p>
<p>[<sup>F557</sup>64. 1,4-dichlorobenzene CAS No 106-46-7 EC No 203-400-5</p>	<p>Shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.]</p>
<p>[<sup>F558</sup>65. Inorganic ammonium salts</p>	<p>1. Shall not be placed on the market, or used, in cellulose insulation mixtures or cellulose insulation articles after 14 July 2018 unless the emission of ammonia from</p>

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- those mixtures or articles results in a concentration of less than 3 ppm by volume (2,12 mg/m<sup>3</sup>) under the test conditions specified in paragraph 4.
- A supplier of a cellulose insulation mixture containing inorganic ammonium salts shall inform the recipient or consumer of the maximum permissible loading rate of the cellulose insulation mixture, expressed in thickness and density. A downstream user of a cellulose insulation mixture containing inorganic ammonium salts shall ensure that the maximum permissible loading rate communicated by the supplier is not exceeded.
- 2. By way of derogation, paragraph 1 shall not apply to placing on the market of cellulose insulation mixtures intended to be used solely for the production of cellulose insulation articles, or to the use of those mixtures in the production of cellulose insulation articles.
- 3. <sup>F559</sup> .....
- 4. Compliance with the emission limit specified in the first subparagraph of paragraph 1 shall be demonstrated in accordance with Technical Specification [<sup>F560</sup>BS EN 16516: 2017], adapted as follows:
  - (a) the duration of the test shall be at least 14 days instead of 28 days;
  - (b) the ammonia gas emission shall be measured at least once per day throughout the test;
  - (c) the emission limit shall not be reached or exceeded in any measurement taken during the test;

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	<ul style="list-style-type: none"> <li>(d) the relative humidity shall be 90 % instead of 50 %;</li> <li>(e) an appropriate method to measure the ammonia gas emission shall be used;</li> <li>(f) the loading rate, expressed in thickness and density, shall be recorded during the sampling of the cellulose insulation mixtures or articles to be tested.]</li> </ul>
[ <sup>F561</sup> 66. Bisphenol A CAS No 80-05-7 EC No 201-245-8	Shall not be placed on the market in thermal paper in a concentration equal to or greater than 0,02 % by weight after 2 January 2020 .]
[ <sup>F448</sup> , <sup>X5</sup> 67.Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	<ol style="list-style-type: none"> <li>1. Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019 .</li> <li>2. Shall not be used in the production of, or placed on the market in: <ul style="list-style-type: none"> <li>(a) another substance, as a constituent;</li> <li>(b) a mixture;</li> <li>(c) an article, or any part thereof,</li> </ul> in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019 .</li> <li>3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: <ul style="list-style-type: none"> <li>(a) in the production of an aircraft before 2 March 2027 .</li> <li>(b) in the production of spare parts for either of the following: <ul style="list-style-type: none"> <li>(i) an aircraft produced before 2 March 2027 ;</li> <li>(ii) motor vehicles within the scope of</li> </ul> </li> </ul> </li> </ol>

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

[<sup>F562</sup>Regulation (EU) 2018/858 of the European Parliament and of the Council], agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council ' or machinery within the scope of [<sup>F563</sup>the Supply of Machinery (Safety) Regulations 2008], produced before 2 March 2019.

4. Subparagraph 2(c) shall not apply to any of the following:
- (a) articles placed on the market before 2 March 2019;
  - (b) aircraft produced in accordance with subparagraph 3(a);
  - (c) spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b);
  - (d) electrical and electronic equipment within the scope of [<sup>F564</sup>the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012].
5. For the purposes of this entry ' aircraft ' means one of the following:



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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>(a) a civil aircraft produced in accordance with a type certificate issued under [<sup>F565</sup>Regulation (EU) 2018/1139 of the European Parliament and of the Council] or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation;</p> <p>(b) a military aircraft.]]</p>
F566 ...	F566 ...
[ <sup>F567</sup> [ <sup>X7</sup> 69]Methanol CAS No 67-56-1 EC No 200-659-6	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.]]
[ <sup>F568</sup> 70. Octamethylcyclotetrasiloxane (D4) CAS No 556-67-2 EC No 209-136-7 Decamethylcyclopentasiloxane (D5) CAS No 541-02-6 EC No 208-764-9	<p>1. Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020 .</p> <p>2. For the purposes of this entry, ‘ wash-off cosmetic products ’ means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.]</p>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

<p>[<sup>F569</sup>71. 1-methyl-2-pyrrolidone (NMP) CAS No 872-50-4 EC No 212-828-1</p>	<ol style="list-style-type: none"> <li>1. Shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after 9 May 2020 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 14,4 mg/m<sup>3</sup> for exposure by inhalation and 4,8 mg/kg/day for dermal exposure.</li> <li>2. Shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after 9 May 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.</li> <li>3. By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from 9 May 2024 in relation to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.]</li> </ol>
<p>[<sup>F570</sup>72. The substances listed in column 1 of the Table in Appendix 12</p>	<ol style="list-style-type: none"> <li>1. Shall not be placed on the market after 1 November 2020 in any of the following: <ol style="list-style-type: none"> <li>(a) clothing or related accessories;</li> <li>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;</li> <li>(c) footwear;</li> </ol> </li> </ol>

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12.

2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023 . The concentration specified in Appendix 12 shall apply thereafter.

3. Paragraph 1 shall not apply to:

(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;

(b) non-textile fasteners and non-textile decorative attachments;

(c) second-hand clothing, related accessories, textiles other than clothing or footwear

(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.

4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (\*) <sup>F571</sup>, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law] or <sup>F572</sup>The Medical Devices Regulations 2002].

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>5. Paragraph 1(b) shall not apply to disposable textiles. ‘ Disposable textiles ’ means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.</p> <p>6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable <sup>F573</sup> ... legislation.</p> <p>7. The [<sup>F574</sup>Secretary of State] shall review the exemption in paragraph 3(d) <sup>F575</sup> ....</p> <p>(* Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC ( <a href="#">OJ L 81, 31.3.2016, p. 51</a> ). ]</p>
<p>[<sup>F576</sup>73. (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol Any of its mono-, di- or tri-O-(alkyl) derivatives (TDFAs)</p>	<p>1. Shall not be placed on the market for supply to the general public after 2 January 2021 individually or in any combination, in a concentration equal to or greater than 2 ppb by weight of the mixtures containing organic solvents, in spray products.</p> <p>2. For the purpose of this entry, ‘ spray products ’ means aerosol dispensers, pump sprays, trigger sprays, marketed for proofing or impregnation spray applications.</p> <p>3. Without prejudice to the implementation of other Union provisions concerning the classification, packaging and labelling of substances and mixtures, the packaging of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol</p>

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	<p>and/or TDFAs combined with organic solvents as referred to in paragraph 1 and placed on the market for professional use shall be marked clearly and indelibly: ‘ for professional users only ’ and ‘ Fatal if inhaled ’ with the pictogram GHS06.</p> <p>4. Section 2.3 of Safety Data Sheets shall contain the following information: ‘ mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or any of its mono-, di- or tri-O-(alkyl) derivatives in a concentration equal to or greater than 2 ppb and organic solvents in spray products, are for professional users only and marked “ Fatal if inhaled ” ’ .</p> <p>5. Organic solvents referred to in paragraph 1, 3, and 4 include organic solvents used as aerosol propellants.]</p>
<p>[<sup>F577</sup>74. Diisocyanates, <math>O = C = N - R - N = C = O</math>, with R an aliphatic or aromatic hydrocarbon unit of unspecified length</p>	<p>1. Shall not be used as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 August 2023 , unless:</p> <p>(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or</p> <p>(b) the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s).</p> <p>2. Shall not be placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial</p>

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

and professional use(s) after 24 February 2022 , unless:

- (a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or
- (b) the supplier ensures that the recipient of the substance(s) or mixture(s) is provided with information on the requirements referred to in point (b) of paragraph 1 and the following statement is placed on the packaging, in a manner that is visibly distinct from the rest of the label information: ‘ As from 24 August 2023 adequate training is required before industrial or professional use ’ .

3. For the purpose of this entry ‘ industrial and professional user(s) ’ means any worker or self-employed worker handling diisocyanates on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) or supervising these tasks.

4. The training referred to in point (b) of paragraph 1 shall include the instructions for the control of dermal and inhalation exposure to diisocyanates at the workplace without prejudice to any national occupational exposure limit value or other appropriate risk management measures at national level. Such training shall be conducted by an expert on occupational safety and health with competence acquired by relevant vocational training. That training shall cover as a minimum:

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

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|  | <p>(a) the training elements in point (a) of paragraph 5 for all industrial and professional use(s).</p> <p>(b) the training elements in points (a) and (b) of paragraph 5 for the following uses:</p> <ul style="list-style-type: none"> <li>— handling open mixtures at ambient temperature (including foam tunnels);</li> <li>— spraying in a ventilated booth;</li> <li>— application by roller;</li> <li>— application by brush;</li> <li>— application by dipping and pouring;</li> <li>— mechanical post treatment (e.g. cutting) of not fully cured articles which are not warm anymore;</li> <li>— cleaning and waste;</li> <li>— any other uses with similar exposure through the dermal and/or inhalation route;</li> </ul> <p>(c) the training elements in points (a), (b) and (c) of paragraph 5 for the following uses:</p> <ul style="list-style-type: none"> <li>— handling incompletely cured articles (e.g. freshly</li> </ul> |
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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		<ul style="list-style-type: none"> <li>— cured, still warm);</li> <li>— foundry applications;</li> <li>— maintenance and repair that needs access to equipment;</li> <li>— open handling of warm or hot formulations (&gt; 45 °C);</li> <li>— spraying in open air, with limited or only natural ventilation (includes large industry working halls) and spraying with high energy (e.g. foams, elastomers);</li> <li>— and any other uses with similar exposure through the dermal and/or inhalation route.</li> </ul>
5.	Training elements:	
	(a) general training, including on-line training, on:	
	—	chemistry of diisocyanates;
	—	toxicity hazards (including acute toxicity);
	—	exposure to diisocyanates;
	—	occupational exposure limit values;
	—	how sensitisation can develop;



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- odour as indication of hazard;
- importance of volatility for risk;
- viscosity, temperature, and molecular weight of diisocyanates;
- personal hygiene;
- personal protective equipment needed, including practical instructions for its correct use and its limitations;
- risk of dermal contact and inhalation exposure;
- risk in relation to application process used;
- skin and inhalation protection scheme;
- ventilation;
- cleaning, leakages, maintenance;
- discarding empty packaging;
- protection of bystanders;
- identification of critical handling stages;

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

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|     | <ul style="list-style-type: none"> <li>— specific national code systems (if applicable);</li> <li>— behaviour-based safety;</li> <li>— certification or documented proof that training has been successfully completed</li> </ul>   |
| (b) | <p>intermediate level training, including on-line training, on:</p> <ul style="list-style-type: none"> <li>— additional behaviour-based aspects;</li> <li>— maintenance;</li> <li>— management of change;</li> <li>— evaluation of existing safety instructions;</li> <li>— risk in relation to application process used;</li> <li>— certification or documented proof that training has been successfully completed</li> </ul> |
| (c) | <p>advanced training, including on-line training, on:</p> <ul style="list-style-type: none"> <li>— any additional certification needed for the specific uses covered;</li> <li>— spraying outside a spraying booth;</li> <li>— open handling of hot or warm formulations (&gt; 45 °C);</li> </ul>   |

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

		—	certification or documented proof that training has been successfully completed
6.	[ <sup>F578</sup> The training:	a	must comply with any other requirements contained in any other legislation that relate to the delivery of the training elements referred to in paragraph 5, and
		b	is in addition to any other training required by any other legislation.]
7.	The supplier referred to in point (b) of paragraph 2 shall ensure that the recipient is provided with training material and courses pursuant to paragraphs 4 and 5		<sup>F579</sup> .... The training shall take into consideration the specificity of the products supplied, including composition, packaging, and design.
8.	The employer or self-employed shall document the successful completion of the training referred to in paragraphs 4 and 5. The training shall be renewed at least every five years.		
9.	[ <sup>F580</sup> The Agency] shall include in [ <sup>F581</sup> its report] pursuant to Article [ <sup>F582</sup> 117(2)] the following information:	(a)	<sup>F583</sup> .....
		(b)	the number of cases of reported and recognised occupational asthma and occupational respiratory and dermal diseases in relation to diisocyanates;
		(c)	<sup>F583</sup> .....

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[<sup>F443</sup>For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

	(d) information about enforcement activities related to this restriction.
10.	This restriction shall apply without prejudice to other <sup>F584</sup> ... legislation on the protection of safety and health of workers at the workplace.]
a	<a href="#">OJ L 256, 7.9.1987, p. 42 .</a>
b	<a href="#">OJ L 147, 9.6.1975, p. 40 .</a>
c	<a href="#">OJ L 37, 13.2.2003, p. 19 .</a>
d	<a href="#">OJ L 263, 9.10.2007, p. 1 .</a>
e	<a href="#">OJ L 171, 9.7.2003, p. 1 .</a>
f	<a href="#">OJ L 124, 9.5.2002, p. 1 .</a>
g	<a href="#">OJ L 24, 29.1.2008, p. 8 .</a>
h	<a href="#">OJ L 104, 8.4.2004, p. 1 .</a>
i	<a href="#">OJ L 399, 30.12.1989, p. 18 .</a>
j	<a href="#">OJ L 304, 21.11.2003, p. 1 .</a>
k	<a href="#">OJ L 121, 15.5.1993, p. 20 .</a>
l	<a href="#">OJ L 270, 21.10.2003, p. 1 .</a>
m	<a href="#">OJ L 365, 31.12.1994, p. 10 .</a>
n	[ <sup>F445</sup> <a href="#">OJ L 326, 29.12.1969, p. 36 .</a> ]
o	[ <sup>F446</sup> <a href="#">Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ( OJ L 170, 30.6.2009, p. 1 ).</a>
p	<a href="#">Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ( OJ L 174, 1.7.2011, p. 88 ).</a> ]
q	[ <sup>F447</sup> <a href="#">Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) ( OJ L 334, 17.12.2010, p. 17 ).</a> ]
r	[ <sup>F448</sup> <a href="#">Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles ( OL L 60, 2.3.2013, p. 1 ).</a>
s	<a href="#">Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC ( OJ L 157, 9.6.2006, p. 24 ).</a>
t	[ <sup>X5</sup> <a href="#">Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ( OJ L 79, 19.3.2008, p. 1 ).</a> ]]
u	[ <sup>F449</sup> <a href="#">Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food ( OJ L 12, 15.1.2011, p. 1 ).</a> ]]

### Editorial Information

**X5** Substituted by [Corrigendum to Commission Regulation \(EU\) 2017/227 of 9 February 2017 amending Annex XVII to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council](#)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(pentabromophenyl)ether (Official Journal of the European Union L 35 of 10 February 2017).
- X6** Substituted by Corrigendum to Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (Official Journal of the European Union L 134 of 21 May 2011).
- X7** Substituted by Corrigendum to Commission Regulation (EU) 2018/589 of 18 April 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards methanol (Official Journal of the European Union L 99 of 19 April 2018).

### Textual Amendments

- F445** Inserted by Commission Regulation (EU) No 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead (Text with EEA relevance).
- F446** Inserted by Commission Regulation (EU) 2015/628 of 22 April 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') as regards lead and its compounds (Text with EEA relevance).
- F447** Inserted by Commission Regulation (EU) 2016/1005 of 22 June 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards asbestos fibres (chrysotile) (Text with EEA relevance).
- F448** Inserted by Commission Regulation (EU) 2017/227 of 9 February 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(pentabromophenyl)ether (Text with EEA relevance).
- F449** Inserted by Commission Regulation (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) (Text with EEA relevance).
- F450** Substituted by Commission Regulation (EU) No 276/2010 of 31 March 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds) (Text with EEA relevance).
- F451** Words in Annex 17 Table Entry 3 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 14(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F452** Word in Annex 17 Table Entry 3 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 14(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F453** Words in Annex 17 Table Entry 3 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 14(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F454** Word in Annex 17 Table Entry 3 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 14(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F455** Words in Annex 17 Table Entry 5 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 15**; 2020 c. 1, Sch. 5 para. 1(1)
- F456** Substituted by Commission Regulation (EU) 2015/1494 of 4 September 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards benzene (Text with EEA relevance).
- F457** Inserted by Commission Regulation (EU) 2015/1494 of 4 September 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the

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- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards benzene (Text with EEA relevance).
- F458** Substituted by Commission Regulation (EU) 2016/1005 of 22 June 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards asbestos fibres (chrysotile) (Text with EEA relevance).
- F459** Words in Annex 17 Table Entry 6 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 16(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F460** Words in Annex 17 Table Entry 6 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 16(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F461** Words in Annex 17 Table Entry 6 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 16(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F462** Words in Annex 17 Table Entry 6 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 16(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F463** Word in Annex 17 Table Entry 6 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 16(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F464** Substituted by Commission Regulation (EU) No 126/2013 of 13 February 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F465** Words in Annex 17 Table Entry 16 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 17(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F466** Words in Annex 17 Table Entry 16 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 17(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F467** Words in Annex 17 Table Entry 16 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 17(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F468** Words in Annex 17 Table Entry 17 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 17(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F469** Words in Annex 17 Table Entry 17 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 17(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F470** Words in Annex 17 Table Entry 17 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 17(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F471** Words in Annex 17 Table Entry 18a substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 18**; 2020 c. 1, Sch. 5 para. 1(1)
- F472** Deleted by Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury (Text with EEA relevance).
- F473** Inserted by Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury (Text with EEA relevance).
- F474** Words in Annex 17 Table Entry 19 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 19(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F475** Word in Annex 17 Table Entry 19 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 19(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F476** Words in Annex 17 Table Entry 19 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 19(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F477** Inserted by Commission Regulation (EU) No 276/2010 of 31 March 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds) (Text with EEA relevance).

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F478** Words in Annex 17 Table Entry 23 inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 20(a)** (as amended by S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F479** Substituted by Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (Text with EEA relevance).
- F480** Substituted by Commission Regulation (EU) No 835/2012 of 18 September 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (Text with EEA relevance).
- F481** Words in Annex 17 Table Entry 23 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 20(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F482** Words in Annex 17 Table Entry 23 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 20(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F483** Substituted by Commission Regulation (EU) 2016/217 of 16 February 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards cadmium (Text with EEA relevance).
- F484** Words in Annex 17 Table Entry 23 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 20(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F485** Inserted by Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (Text with EEA relevance).
- F486** Words in Annex 17 Table Entry 24 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 21**; 2020 c. 1, Sch. 5 para. 1(1)
- F487** Substituted by Commission Regulation (EU) 2018/675 of 2 May 2018 amending the Appendices to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards CMR substances (Text with EEA relevance).
- F488** Words in Annex 17 Table Entries 28-30 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 7(a)(i)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2**, para. 2(f)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F489** Word in Annex 17 Table Entries 28-30 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 22(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F490** Words in Annex 17 Table Entries 28-30 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 22(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F491** Words in Annex 17 Table Entries 28-30 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 22(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F492** Words in Annex 17 Table Entries 28-30 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 22(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F493** Inserted by Commission Regulation (EU) No 109/2012 of 9 February 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances) (Text with EEA relevance).
- F494** Word in Annex 17 Table Entry 31 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 23(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F495** Word in Annex 17 Table Entry 31 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 23(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F496** Word in Annex 17 Table Entries 32-38 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 24(a)**; 2020 c. 1, Sch. 5 para. 1(1)



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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- F497** Words in Annex 17 Table Entries 32-38 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 24(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F498** Words in Annex 17 Table Entries 32-38 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 24(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F499** Words in Annex 17 Table Entry 40 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 7(b)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F500** Word in Annex 17 Table Entry 40 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 25**; 2020 c. 1, Sch. 5 para. 1(1)
- F501** Deleted by Commission Regulation (EU) No 126/2013 of 13 February 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F502** Deleted by Commission Regulation (EU) No 207/2011 of 2 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Diphenylether, pentabromo derivative and PFOS).
- F503** Words in Annex 17 Table Entry 45 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 26**; 2020 c. 1, Sch. 5 para. 1(1)
- F504** Inserted by Commission Regulation (EU) 2016/26 of 13 January 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards nonylphenol ethoxylates (Text with EEA relevance).
- F505** Word in Annex 17 Table Entry 47 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 27**; 2020 c. 1, Sch. 5 para. 1(1)
- F506** Inserted by Commission Regulation (EU) No 126/2013 of 13 February 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F507** Inserted by Commission Regulation (EU) No 301/2014 of 25 March 2014 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards chromium VI compounds (Text with EEA relevance).
- F508** Substituted by Commission Regulation (EU) 2015/326 of 2 March 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons and phthalates (Text with EEA relevance).
- F509** Words in Annex 17 Table Entry 50 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 28(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F510** Words in Annex 17 Table Entry 50 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 28(3)** (as amended by S.I. 2020/818, reg. 1(b), Sch. 6 para. 41(2)(a) (with Sch. 4 paras. 16, 17)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F511** Inserted by Commission Regulation (EU) No 1272/2013 of 6 December 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons (Text with EEA relevance).
- F512** Substituted by Commission Regulation (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) (Text with EEA relevance).
- F513** Words in Annex 17 Table Entry 51 substituted (31.12.2020) by S.I. 2019/758, **Sch. 3 para. 28A(2)** (as inserted by The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144),



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- regs. 1, **5(2)** (as amended by S.I. 2020/818, reg. 1(b), Sch. 6 para. 42(2) (with Sch. 4 paras. 16, 17) and S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F514** Word in Annex 17 Entry 51 inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **8(2)(a)**
- F515** Words in Annex 17 Entry 51 omitted (30.9.2021) by virtue of The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **8(2)(b)**
- F516** Words in Annex 17 Table Entry 51 substituted (31.12.2020) by S.I. 2019/758, **Sch. 3 para. 28A(4)** (as inserted by The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144), regs. 1, **5(2)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F517** Words in Annex 17 Table Entry 51 substituted (31.12.2020) by S.I. 2019/758, **Sch. 3 para. 28A(5)** (as inserted by The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144), regs. 1, **5(2)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F518** Words in Annex 17 Table Entry 51 substituted (31.12.2020) by S.I. 2019/758, **Sch. 3 para. 28A(6)** (as inserted by The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144), regs. 1, **5(2)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F519** Deleted by Commission Regulation (EU) 2015/326 of 2 March 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons and phthalates (Text with EEA relevance).
- F520** Word in Annex 17 Table Entry 55 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 29**; 2020 c. 1, Sch. 5 para. 1(1)
- F521** Words in Annex 17 Table Entry 56 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 30(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F522** Word in Annex 17 Table Entry 56 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 30(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F523** Words in Annex 17 Table Entry 56 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 30(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F524** Word in Annex 17 Table Entry 57 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 31**; 2020 c. 1, Sch. 5 para. 1(1)
- F525** Words in Annex 17 Table Entry 58 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 32(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F526** Words in Annex 17 Table Entry 58 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 32(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F527** Words in Annex 17 Table Entry 58 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 32(3)(a)(ii)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **7(7)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F528** Words in Annex 17 Table Entry 58 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 32(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F529** Words in Annex 17 Table Entry 58 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 32(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F530** Words in Annex 17 Table Entry 59 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F531** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F532** Word in Annex 17 Table Entry 59 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F533** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- F534** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F535** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F536** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(2)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F537** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F538** Words in Annex 17 Table Entry 59 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F539** Word in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F540** Words in Annex 17 Table Entry 59 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F541** Word in Annex 17 Table Entry 59 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F542** Word in Annex 17 Table Entry 59 inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(5)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F543** Words in Annex 17 Table Entry 59 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 33(5)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F544** Inserted by Commission Regulation (EU) No 366/2011 of 14 April 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Acrylamide) (Text with EEA relevance).
- F545** Inserted by Commission Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
- F546** Inserted by Commission Regulation (EU) No 848/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards phenylmercury compounds (Text with EEA relevance).
- F547** Words in Annex 17 Table Entry 63 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F548** Words in Annex 17 Table Entry 63 inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(3)** (as amended by S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F549** Words in Annex 17 Table Entry 63 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F550** Words in Annex 17 Table Entry 63 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F551** Words in Annex 17 Table Entry 63 inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(6)** (as amended by S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F552** Words in Annex 17 Table Entry 63 inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(7)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F553** Words in Annex 17 Table Entry 63 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F554** Words in Annex 17 Table Entry 63 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(7)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F555** Word in Annex 17 Table Entry 63 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

- F556** Words in Annex 17 Table Entry 63 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 34(8)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F557** Inserted by Commission Regulation (EU) No 474/2014 of 8 May 2014 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') as regards 1,4-dichlorobenzene (Text with EEA relevance).
- F558** Inserted by Commission Regulation (EU) 2016/1017 of 23 June 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards inorganic ammonium salts (Text with EEA relevance).
- F559** Words in Annex 17 Table Entry 65 omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 35(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F560** Words in Annex 17 Table Entry 65 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 35(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F561** Inserted by Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A (Text with EEA relevance).
- F562** Words in Annex 17 Table Entry 67 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 36(2)(a)** (as amended by S.I. 2020/818, reg. 1(b), Sch. 6 para. 41(2)(b) (with Sch. 4 paras. 16, 17)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F563** Words in Annex 17 Table Entry 67 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 36(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F564** Words in Annex 17 Table Entry 67 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 36(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F565** Words in Annex 17 Table Entry 67 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 36(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F566** Deleted by Commission Regulation (EU) 2020/2096 of 15 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants (Text with EEA relevance)
- F567** Inserted by Commission Regulation (EU) 2018/589 of 18 April 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards methanol (Text with EEA relevance).
- F568** Inserted by Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5') (Text with EEA relevance).
- F569** Inserted by Commission Regulation (EU) 2018/588 of 18 April 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards 1-methyl-2-pyrrolidone (Text with EEA relevance).
- F570** Inserted by Commission Regulation (EU) 2018/1513 of 10 October 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B (Text with EEA relevance).
- F571** Words in Annex 17 Entry 72 inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **8(4)**

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- F572** Words in Annex 17 Table Entry 72 substituted (31.12.2020) by S.I. 2019/758, **Sch. 3 para. 37A(2)** (as inserted by **The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019** (S.I. 2019/1144), regs. 1, **5(4)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F573** Word in Annex 17 Table Entry 72 omitted (31.12.2020) by virtue of S.I. 2019/758, **Sch. 3 para. 37A(3)** (as inserted by **The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019** (S.I. 2019/1144), regs. 1, **5(4)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F574** Words in Annex 17 Table Entry 72 substituted (31.12.2020) by S.I. 2019/758, **Sch. 3 para. 37A(4)(a)** (as inserted by **The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019** (S.I. 2019/1144), regs. 1, **5(4)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F575** Words in Annex 17 Table Entry 72 omitted (31.12.2020) by virtue of S.I. 2019/758, **Sch. 3 para. 37A(4)(b)** (as inserted by **The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019** (S.I. 2019/1144), regs. 1, **5(4)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F576** Inserted by Commission Regulation (EU) 2019/957 of 11 June 2019 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and TDFAs (Text with EEA relevance).
- F577** Inserted by Commission Regulation (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates (Text with EEA relevance).
- F578** Words in Annex 17 Entry 74 substituted (30.9.2021) by **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(a)**)
- F579** Words in Annex 17 Entry 74 omitted (30.9.2021) by virtue of **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(b)**)
- F580** Words in Annex 17 Entry 74 substituted (30.9.2021) by **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(c)(i)**)
- F581** Words in Annex 17 Entry 74 substituted (30.9.2021) by **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(c)(ii)**)
- F582** Word in Annex 17 Entry 74 substituted (30.9.2021) by **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(c)(iii)**)
- F583** Words in Annex 17 Entry 74 omitted (30.9.2021) by virtue of **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(d)**)
- F584** Word in Annex 17 Entry 74 omitted (30.9.2021) by virtue of **The REACH etc. (Amendment) Regulations 2021** (S.I. 2021/904), regs. 1(2), **8(5)(e)**)



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Appendices 1 to 6

### [<sup>F443</sup>FORWARD] **Explanations of column headings**

#### *Substances:*

The name corresponds to the International Chemical Identification used for the substance in [<sup>F585</sup>the GB mandatory classification and labelling list].

#### **Textual Amendments**

**F585** Words in Annex 17 Appendices substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), **Sch. 2 para. 8(2)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Whenever possible, substances are designated by their IUPAC names. Substances listed in EINECS (European Inventory of Existing Commercial Chemical Substances), ELINCS (European List of Notified Substances) or the list of ‘ No-longer-polymers ’ are designated using the names in these lists. Other names, such as usual or common names, are included in some cases. Whenever possible, plant protection products and biocides are designated by their ISO names.

#### *Entries for groups of substances:*

A number of group entries are included in [<sup>F586</sup>the GB mandatory classification and labelling list]. In these cases, the classification requirements will apply to all substances covered by the description.

#### **Textual Amendments**

**F586** Words in Annex 17 Appendices substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), **Sch. 2 para. 8(3)(a)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

In some cases, there are classification requirements for specific substances that would be covered by the group entry. In such cases a specific entry is included in [<sup>F586</sup>the GB mandatory classification and labelling list] for the substance and the group entry will be annotated with the phrase ‘except those specified [<sup>F587</sup>elsewhere in the GB mandatory classification and labelling list]’.

#### **Textual Amendments**

**F587** Words in Annex 17 Appendices substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/720\)](#), reg. 1(2), **Sch. 2 para. 8(3)(b)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

In some cases, individual substances may be covered by more than one group entry. In these cases, the classification of the substance reflects the classification for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification will be applied.

#### *Index number:*

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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The Index number is the identification code given to the substance in [<sup>F588</sup>the GB mandatory classification and labelling list]. Substances are listed in the Appendix according to this index number.

#### Textual Amendments

**F588** Words in Annex 17 Appendices substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 8(4)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

#### EC numbers:

The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union. The EINECS number can be obtained from the European Inventory of Existing Commercial Chemical Substances (EINECS). The ELINCS number can be obtained from the European List of Notified Substances. The NLP number can be obtained from the list of ‘No-longer-polymers’. These lists are published by the Office for Official Publications of the European Communities.

The EC number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8 (EINECS), at 400-010-9 (ELINCS) and at 500-001-0 (NLP). This number is indicated in the column entitled ‘EC No’.

#### CAS number:

Chemical Abstracts Service (CAS) numbers have been defined for substances to help in their identification.

#### Notes:

The full text of the notes can be found in Part 1 of Annex VI to Regulation (EC) No 1272/2008.

The notes to be taken into account for the purposes of this Regulation are the following:

#### Note A:

Without prejudice to Article 17(2) of Regulation (EC) No 1272/2008, the name of the substance must appear on the label in the form of one of the designations given in [<sup>F589</sup>the GB mandatory classification and labelling list].

In that Part, use is sometimes made of a general description such as ‘... compounds’ or ‘... salts’. In this case, the supplier who places such a substance on the market is required to state on the label the correct name, due account being taken of Section 1.1.1.4 of Annex VI to Regulation (EC) No 1272/2008.

#### <sup>F493</sup>Note B:

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.]

#### Note C:

Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers.

#### Note D:

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Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in [<sup>F590</sup>the GB mandatory classification and labelling list].

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, supplier who places such a substance on the market must state on the label the name of the substance followed by the words ‘ non-stabilised ’.

*Note J:*

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EC No 200-753-7).

*Note K:*

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (EC No 203-450-8).

*Note L:*

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346.

*Note M:*

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (EC No 200-028-5).

*Note N:*

The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.

*Note P:*

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EC No 200-753-7).

*Note R:*

The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter, less two standard errors, greater than 6µm.]

#### Textual Amendments

**F589** Words in Annex 17 Appendices substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 8(5)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F590** Words in Annex 17 Appendices substituted (31.12.2020) by [The Chemicals \(Health and Safety\) and Genetically Modified Organisms \(Contained Use\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 8(6)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## Appendix 1

[<sup>F443</sup>Entry 28 — Carcinogens: category 1A <sup>F591</sup>.../category 1 <sup>F591</sup>...]

ANNEX XVII Table 2: rows 1 - 50

ANNEX XVII Table 2: rows 51 - 100

ANNEX XVII Table 2: rows 101 - 150

ANNEX XVII Table 2: rows 151 - 200

ANNEX XVII Table 2: rows 201 - 250

ANNEX XVII Table 2: rows 251 - 300

ANNEX XVII Table 2: rows 301 - 332



## Appendix 2

[<sup>F443</sup>Entry 28 — Carcinogens: category 1B <sup>F592</sup>.../category 2 <sup>F592</sup> ...]

ANNEX XVII Table 3: rows 1 - 50

ANNEX XVII Table 3: rows 51 - 100

ANNEX XVII Table 3: rows 101 - 150

ANNEX XVII Table 3: rows 151 - 200

ANNEX XVII Table 3: rows 201 - 250

ANNEX XVII Table 3: rows 251 - 300

ANNEX XVII Table 3: rows 301 - 350

ANNEX XVII Table 3: rows 351 - 400

ANNEX XVII Table 3: rows 401 - 450

ANNEX XVII Table 3: rows 451 - 500

ANNEX XVII Table 3: rows 501 - 550

ANNEX XVII Table 3: rows 551 - 600

ANNEX XVII Table 3: rows 601 - 650

ANNEX XVII Table 3: rows 651 - 700

ANNEX XVII Table 3: rows 701 - 750

ANNEX XVII Table 3: rows 751 - 800

ANNEX XVII Table 3: rows 801 - 829

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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### Appendix 3

[<sup>F443</sup>Entry 29 — Mutagens: category 1A <sup>F593</sup>.../category 1 <sup>F593</sup>...]

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## Appendix 4

[<sup>F443</sup>Entry 29 — Mutagens: category 1B <sup>F594</sup>.../category 2 <sup>F594</sup>...]

ANNEX XVII Table 4: rows 1 - 50

ANNEX XVII Table 4: rows 51 - 100

ANNEX XVII Table 4: rows 101 - 150

ANNEX XVII Table 4: rows 151 - 200

ANNEX XVII Table 4: rows 201 - 250

ANNEX XVII Table 4: rows 251 - 300

ANNEX XVII Table 4: rows 301 - 350

ANNEX XVII Table 4: rows 351 - 400

ANNEX XVII Table 4: rows 401 - 429

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Appendix 5

[<sup>F443</sup>Entry 30 — Toxic to reproduction: category 1A <sup>F595</sup>.../category 1 <sup>F595</sup>...]

Substances	Index No	EC No	CAS No	Notes
Carbon monoxide	006-001-00-2	211-128-3	630-08-0	
Lead hexafluorosilicate	009-014-00-1	247-278-1	25808-74-6	
[ <sup>F493</sup> Slimes and sludges, copper electrolyte refining, decopperised	028-015-00-8	305-433-1	94551-87-8	
Silicic acid, lead nickel salt	028-050-00-9	—	68130-19-8 ]	
Lead compounds with the exception of those specified elsewhere in this Annex	082-001-00-6			A [ <sup>F596</sup> , E]
Lead alkyls	082-002-00-1			A [ <sup>F596</sup> , E]
Lead azide	082-003-00-7	236-542-1	13424-46-9	
Lead chromate	082-004-00-2	231-846-0	7758-97-6	
Lead di(acetate)	082-005-00-8	206-104-4	301-04-2	
Trilead bis(orthophosphate)	082-006-00-3	231-205-5	7446-27-7	
Lead acetate	082-007-00-9	215-630-3	1335-32-6	
Lead(II) methanesulphonate	082-008-00-4	401-750-5	17570-76-2	
C.I. Pigment Yellow 34; (This substance is identified in the Colour Index by Colour Index Constitution No C.I. 77603.)	082-009-00-X	215-693-7	1344-37-2	
C.I. Pigment Red 104; (This substance is identified in the Colour Index	082-010-00-5	235-759-9	12656-85-8	

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by Colour Index Constitution No C.I. 77605.)				
Lead hydrogen arsenate	082-011-00-0	232-064-2	7784-40-9	
[ <sup>F597</sup> Lead powder; [particle diameter < 1 mm]	082-013-00-1	231-100-4	7439-92-1	
Lead massive: [particle diameter ≥ 1 mm]	082-014-00-7	231-100-4	7439-92-1 ]	
1,2-Dibromo-3-chloropropane	602-021-00-6	202-479-3	96-12-8	
2-bromopropane	602-085-00-5	200-855-1	75-26-3	[ <sup>F596</sup> E]
[ <sup>F598</sup> Warfarin (ISO); 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one; [1] (S)-4-hydroxy-3-(3-oxo-1-phenylbutyl)-2-benzopyrone; [2] (R)-4-hydroxy-3-(3-oxo-1-phenylbutyl)-2-benzopyrone [3]	607-056-00-0	201-377-6 [1] 226-907-3 [2] 226-908-9 [3]	81-81-2 [1] 5543-57-7 [2] 5543-58-8 [3] ]	
[ <sup>F597</sup> Brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	607-172-00-1	259-980-5	56073-10-0 ]	
Lead 2,4,6-trinitroresorcinoxide, lead styphnate	609-019-00-4	239-290-0	15245-44-0	

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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## Appendix 6

[<sup>F443</sup>Entry 30 — Toxic to reproduction: category 1B <sup>F599</sup>.../category 2 <sup>F599</sup>...]

ANNEX XVII Table 6: rows 1 - 50

ANNEX XVII Table 6: rows 51 - 100

ANNEX XVII Table 6: rows 101 - 150

ANNEX XVII Table 6: rows 151 - 200

ANNEX XVII Table 6: rows 201 - 241

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Appendix 7

### Special provisions on the labelling of articles containing asbestos

1. All articles containing asbestos or the packaging thereof must bear the label defined as follows:
    - (a) the label conforming to the specimen below shall be at least 5 cm high (H) and 2,5 cm wide;
    - (b) it shall consist of two parts:
      - the top part ( $h_1 = 40\% H$ ) shall include the letter 'a' in white, on a black background,
      - the bottom part ( $h_2 = 60\% H$ ) shall include the standard wording in white and/or black, on a red background, and shall be clearly legible;
    - (c) if the article contains crocidolite, the words 'contains asbestos' used in the standard wording shall be replaced by 'contains crocidolite/blue asbestos';
- F600** ...
- (d) if labelling takes the form of direct printing on the articles, a single colour contrasting with the background colour is sufficient.

#### Textual Amendments

**F600** Words in [Annex 17 Appendix 7](#) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 3 para. 38\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

2. The label mentioned in this Appendix shall be affixed in accordance with the following rules:
  - (a) on each of the smallest units supplied;
  - (b) if an article has asbestos-based components, it is sufficient for these components only to bear the label. The labelling may be dispensed with if smallness of size or unsuitability of packaging make it impossible for a label to be affixed to the component.
3. Labelling of packaged articles containing asbestos
  - 3.1. The following particulars shall appear on clearly legible and indelible labelling on the packaging of packaged articles containing asbestos:
    - (a) the symbol and relevant indications of danger in accordance with this Annex;
    - (b) safety instructions which must be selected in accordance with the particulars in this Annex, inasmuch as they are relevant for the particular article.

Where additional safety information is provided on the packaging, this shall not weaken or contradict the particulars given in accordance with points (a) and (b).
  - 3.2. Labelling in accordance with 3.1 shall be effected by means of:
    - a label firmly affixed to the packaging, or

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)*

- a (tie-on) label securely attached to the package, or
  - direct printing of the packaging.
- 3.3. Articles containing asbestos and which are packaged only in loose plastic wrapping or the like shall be regarded as packaged articles and shall be labelled in accordance with 3.2. If articles are separated from such packages and placed on the market unpackaged, each of the smallest units supplied shall be accompanied by labelling particulars in accordance with 3.1.

#### 4. Labelling of unpackaged articles containing asbestos

For unpackaged articles containing asbestos, labelling in accordance with 3.1 shall be effected by means of:

- a label firmly affixed to the article containing asbestos,
- a (tie-on) label securely attached to such an article,
- direct printing on the articles,

or, if the abovementioned is not reasonably practicable as in the case of, for example, smallness of size of the article, the unsuitable nature of the article's properties or certain technical difficulties by means of a hand-out with labelling in accordance with 3.1.

5. Without prejudice to [<sup>F601</sup>legislation] on safety and hygiene at work, the label affixed to the article which may, in the context of its use, be processed or finished, shall be accompanied by any safety instructions which may be appropriate for the article concerned, and in particular by the following:

#### Textual Amendments

**F601** Word in [Annex 17 Appendix 7](#) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 38(b)**; 2020 c. 1, Sch. 5 para. 1(1)

- operate if possible out of doors or in a well-ventilated place,
  - preferably use hand tools or low-speed tools equipped, if necessary, with an appropriate dust-extraction facility. If high-speed tools are used, they should always be equipped with such a facility,
  - if possible, dampen before cutting or drilling,
  - dampen dust and place it in a properly closed receptacle and dispose of it safely.
6. The labelling of any article intended for domestic use which is not covered by Section 5 and which is likely, during use, to release asbestos fibres shall, if necessary, contain the following safety instruction: ‘ replace when worn ’ .
7. The labelling of articles containing asbestos shall be in [<sup>F602</sup>English, and may also be done in other languages].

#### Textual Amendments

**F602** Words in [Annex 17 Appendix 7](#) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), **Sch. 3 para. 38(c)**; 2020 c. 1, Sch. 5 para. 1(1)



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Appendix 8

[<sup>F443</sup>Entry 43 — Azocolourants — List of aromatic amines]

## List of aromatic amines

	<b>CAS No</b>	<b>Index No</b>	<b>EC No</b>	<b>Substances</b>
1.	92-67-1	612-072-00-6	202-177-1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine
2.	92-87-5	612-042-00-2	202-199-1	benzidine
3.	95-69-2		202-441-6	4-chloro-o-toluidine
4.	91-59-8	612-022-00-3	202-080-4	2-naphthylamine
5.	97-56-3	611-006-00-3	202-591-2	o-aminoazotoluene 4-amino-2',3'-dimethylazobenzene 4-o-tolylazo-o-toluidine
6.	99-55-8		202-765-8	5-nitro-o-toluidine
7.	106-47-8	612-137-00-9	203-401-0	4-chloroaniline
8.	615-05-4		210-406-1	4-methoxy-m-phenylenediamine
9.	101-77-9	612-051-00-1	202-974-4	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane
10.	91-94-1	612-068-00-4	202-109-0	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine
11.	119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine o-dianisidine
12.	119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine
13.	838-88-0	612-085-00-7	212-658-8	4,4'-methylenedi-o-toluidine

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

14.	120-71-8		204-419-1	6-methoxy-m-toluidine p-cresidine
15.	101-14-4	612-078-00-9	202-918-9	4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline
16.	101-80-4		202-977-0	4,4'-oxydianiline
17.	139-65-1		205-370-9	4,4'-thiodianiline
18.	95-53-4	612-091-00-X	202-429-0	o-toluidine 2-aminotoluene
19.	95-80-7	612-099-00-3	202-453-1	4-methyl-m-phenylenediamine
20.	137-17-7		205-282-0	2,4,5-trimethylaniline
21.	90-04-0	612-035-00-4	201-963-1	o-anisidine 2-methoxyaniline
22.	60-09-3	611-008-00-4	200-453-6	4-amino azobenzene

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

## Appendix 9

[<sup>F443</sup>Entry 43 — Azocolourants — List of azodyes]

## List of azodyes

	<b>CAS No</b>	<b>Index No</b>	<b>EC No</b>	<b>Substances</b>
1.	Not allocated Component 1: CAS-No: 118685-33-9 C <sub>39</sub> H <sub>23</sub> ClCrN <sub>7</sub> O <sub>12</sub> S.2Na Component 2: C <sub>46</sub> H <sub>30</sub> CrN <sub>10</sub> O <sub>20</sub> S <sub>2</sub> .3Na	611-070-00-2	405-665-4	A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato) (1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

[<sup>F464</sup>Appendix 10

**Entry** List of testing methods

**43** —

**Azocolourants** —

**List of  
testing  
methods**

F603 ... Standardisation organisation	Reference and title of the harmonised standard	Reference of the superseded standard
[ <sup>F604</sup> BSI]	[ <sup>F605</sup> BS EN] ISO <b>17234-1:2010</b> Leather — Chemical tests for the determination of certain azo colorants in dyed leathers — Part 1: Determination of certain aromatic amines derived from azo colorants	CEN ISO/TS 17234:2003
[ <sup>F604</sup> BSI]	[ <sup>F605</sup> BS EN] ISO <b>17234-2:2011</b> Leather — Chemical tests for the determination of certain azo colorants in dyed leathers — Part 2: Determination of 4- aminoazobenzene	CEN ISO/TS 17234:2003
[ <sup>F604</sup> BSI]	[ <sup>F605</sup> BS EN] <b>14362-1:2012</b> Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres	EN 14362-1:2003 EN 14362-2:2003
[ <sup>F604</sup> BSI]	[ <sup>F605</sup> BS EN] <b>14362-3:2012</b> Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 3: Detection of the use of certain azo colorants, which may release 4- aminoazobenzene ]	

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

[<sup>F493</sup>Appendix 11

ENTRIES 28 TO 30 — DEROGATIONS FOR SPECIFIC SUBSTANCES

Substances	Derogations
<p>1.</p> <p>(a) Sodium perborate; perboric acid, sodium salt; perboric acid, sodium salt, monohydrate; sodium peroxometaborate; perboric acid (HBO(O<sub>2</sub>)), sodium salt, monohydrate; sodium peroxoborate CAS No 15120-21-5; 11138-47-9; 12040-72-1; 7632-04-4; 10332-33-9 EC No 239-172-9; 234-390-0; 231-556-4</p> <p>(b) Perboric acid (H<sub>3</sub>BO<sub>2</sub>(O<sub>2</sub>)), monosodium salt trihydrate; perboric acid, sodium salt, tetrahydrate; perboric acid (HBO(O<sub>2</sub>)), sodium salt, tetrahydrate; sodium peroxoborate hexahydrate CAS No 13517-20-9; 37244-98-7; 10486-00-7 EC No 239-172-9; 234-390-0; 231-556-4</p>	<p>Detergents as defined by Regulation (EC) No 648/2004 of the European Parliament and of the Council <sup>a</sup>. The derogation shall apply until 1 June 2013.</p>

<sup>a</sup> OJ L 104, 8.4.2004, p. 1 . ]

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

1<sup>F570</sup> Appendix 12

Entry 72 — restricted substances and maximum concentration limits by weight in homogeneous materials:

Substances	Index- No	CAS No	EC No	Concentration limit by weight
Cadmium and its compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as Cd metal that can be extracted from the material)
Chromium VI compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as Cr VI that can be extracted from the material)
Arsenic compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as As metal that can be extracted from the material)
Lead and its compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as Pb metal that can be extracted from the material)
Benzene	601-020-00-8	71-43-2	200-753-7	5 mg/kg
Benz[ <i>a</i> ]anthracene	601-033-00-9	56-55-3	200-280-6	1 mg/kg
Benz[ <i>e</i> ]acephenanthrylene	601-034-00-4	205-99-2	205-911-9	1 mg/kg
benzo[ <i>a</i> ]pyrene; benzo[ <i>def</i> ]chrysene	601-032-00-3	50-32-8	200-028-5	1 mg/kg
Benzo[ <i>e</i> ]pyrene	601-049-00-6	192-97-2	205-892-7	1 mg/kg
Benzo[ <i>j</i> ]fluoranthene	601-035-00-X	205-82-3	205-910-3	1 mg/kg

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

Benzo[ <i>k</i> ]fluoranthene	601-036-00-5	207-08-9	205-916-6	1 mg/kg
Chrysene	601-048-00-0	218-01-9	205-923-4	1 mg/kg
Dibenz[ <i>a,h</i> ]anthracene	601-041-00-2	53-70-3	200-181-8	1 mg/kg
$\alpha, \alpha, \alpha$ ,4-tetrachlorotoluene; p-chlorobenzotrichloride	602-093-00-9	5216-25-1	226-009-1	1 mg/kg
$\alpha, \alpha, \alpha$ - trichlorotoluene; benzotrichloride	602-038-00-9	98-07-7	202-634-5	1 mg/kg
$\alpha$ - chlorotoluene; benzyl chloride	602-037-00-3	100-44-7	202-853-6	1 mg/kg
Formaldehyde	605-001-00-5	50-00-0	200-001-8	75 mg/kg
1,2-benzenedicarboxylic acid; di-C 6-8-branched alkylesters, C 7-rich	607-483-00-2	71888-89-6	276-158-1	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in [ <sup>F606</sup> the GB mandatory classification and labelling list] in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Bis(2-methoxyethyl) phthalate	607-228-00-5	117-82-8	204-212-6	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in [ <sup>F606</sup> the GB mandatory

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

				classification and labelling list] in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Diisopentylphthalate	607-426-00-1	605-50-5	210-088-4	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in [F606 the GB mandatory classification and labelling list] in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Di- n -pentyl phthalate (DPP)	607-426-00-1	131-18-0	205-017-9	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in [F606 the GB mandatory classification and labelling list] in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive



**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

				toxicity, category 1A or 1B
Di- <i>n</i> -hexyl phthalate (DnHP)	607-702-00-1	84-75-3	201-559-5	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in [F606the GB mandatory classification and labelling list] in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
<i>N</i> -methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone (NMP)	606-021-00-7	872-50-4	212-828-1	3 000 mg/kg
<i>N,N</i> -dimethylacetamide (DMAC)	616-011-00-4	127-19-5	204-826-4	3 000 mg/kg
<i>N,N</i> -dimethylformamide; dimethyl formamide (DMF)	616-001-00-X	68-12-2	200-679-5	3 000 mg/kg
1,4,5,8-tetraaminoanthraquinone; C.I. Disperse Blue 1	611-032-00-5	2475-45-8	219-603-7	50 mg/kg
Benzenamine, 4,4'-(4-iminocyclohexa-2,5-dienylidene)methy]ene)dianiline hydrochloride; C.I. Basic Red 9	611-031-00-X	569-61-9	209-321-2	50 mg/kg
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-	612-205-00-8	548-62-9	208-953-6	50 mg/kg

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

ylidene]dimethylammonium chloride; C.I. Basic Violet 3 with $\geq 0,1$ % of Michler's ketone (EC no. 202-027-5)				
4-chloro- <i>o</i> -toluidinium chloride	612-196-00-0	3165-93-3	221-627-8	30 mg/kg
2-Naphthylammoniumacetate	612-071-00-0	553-00-4	209-030-0	30 mg/kg
4-methoxy- <i>m</i> -phenylene diammonium sulphate; 2,4-diaminoanisole sulphate	612-200-00-0	39156-41-7	254-323-9	30 mg/kg
2,4,5-trimethylaniline hydrochloride	612-197-00-6	21436-97-5	—	30 mg/kg
Quinoline	613-281-00-5	91-22-5	202-051-6	50 mg/kg]]

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (1) [<sup>XI</sup>OJ C 112, 30.4.2004, p. 92 and OJ C 294, 25.11.2005, p. 38.]
- (2) [<sup>XI</sup>OJ C 164, 5.7.2005, p. 78.]
- (3) [<sup>XI</sup>Opinion of the European Parliament of 17 November 2005 (OJ C 280 E, 18.11.2006, p. 303), Council Common Position of 27 June 2006 (OJ C 276 E, 14.11.2006, p. 1) and Position of the European Parliament of 13 December 2006 (not yet published in the Official Journal). Council Decision of 18 December 2006.]
- (4) [<sup>XI</sup>OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1). Corrected in OJ L 216, 16.6.2004, p. 3.]
- (5) [<sup>XI</sup>OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2006/139/EC (OJ L 384, 29.12.2006, p. 94).]
- (6) [<sup>XI</sup>OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).]
- (7) [<sup>XI</sup>OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).]
- (8) [<sup>XI</sup>OJ L 158, 30.4.2004, p. 50, corrected in OJ L 229, 29.6.2004, p. 23.]
- (9) [<sup>XI</sup>OJ L 131, 5.5.1998, p. 11.]
- (10) [<sup>XI</sup>OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/1/EC (OJ L 25, 1.2.2007, p. 9).]
- (11) [<sup>XI</sup>OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).]
- (12) [<sup>XI</sup>OJ L 50, 20.2.2004, p. 44.]
- (13) [<sup>XI</sup>OJ L 357, 31.12.2002, p. 72.]
- (14) [<sup>XI</sup>OJ L 136, 30.4.2004, p. 1. Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).]
- (15) [<sup>XI</sup>OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).]
- (16) [<sup>XI</sup>OJ C 218, 13.9.2003, p. 1.]
- (17) [<sup>XI</sup>OJ L 41, 14.2.2003, p. 26.]
- (18) [<sup>XI</sup>OJ L 145, 31.5.2001, p. 43.]
- (19) [<sup>XI</sup>OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).]
- (20) [<sup>XI</sup>Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (OJ L 76, 22.3.1991, p. 35). Directive as last amended by Directive 2001/58/EC (OJ L 212, 7.8.2001, p. 24).]
- (21) [<sup>XI</sup>Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC (OJ L 227, 8.9.1993, p. 9).]
- (22) [<sup>XI</sup>Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC (OJ L 294, 30.11.1993, p. 21).]
- (23) [<sup>XI</sup>Commission Directive 2000/21/EC of 25 April 2000 concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC (OJ L 103, 28.4.2000, p. 70).]

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*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (24) [<sup>X1</sup>Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (OJ L 161, 29.6.1994, p. 3).]
- (25) [<sup>X1</sup>OJ C 364, 18.12.2000, p. 1.]
- (26) [<sup>X1</sup>OJ L 114, 27.4.2006, p. 9.]
- (27) [<sup>X1</sup>OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).]
- (28) [<sup>X1</sup>OJ L 124, 20.5.2003, p. 36.]
- (29) [<sup>X1</sup>OJ L 338, 13.11.2004, p. 4.]
- (30) [<sup>X1</sup>OJ L 158, 30.4.2004, p. 7, corrected in OJ L 229, 29.6.2004, p. 5. Regulation as amended by Council Regulation (EC) No 1195/2006 (OJ L 217, 8.8.2006, p. 1).]
- (31) [<sup>X1</sup>In general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor. An assessment factor of 1 000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10 to the lowest of three long-term NOEC values derived from species representing different trophic levels.]
- (32) [<sup>X1</sup><sup>F369</sup>Marpol — Consolidated edition 2006, London, IMO 2007, ISBN 978-92-801-4216-7.]]
- (33) [<sup>X1</sup><sup>F369</sup>IBC Code, 2007 edition, London, IMO 2007, ISBN 978-92-801-4226-6.]]
- (34) [<sup>X1</sup><sup>F369</sup>Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40).]]
- (35) [<sup>X1</sup><sup>F369</sup>Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).]]
- (36) [<sup>X1</sup><sup>F369</sup>United Nations, Economic Commission for Europe, version applicable as from 1 January 2015, ISBN-978-92-1-139149-7.]]
- (37) [<sup>X1</sup><sup>F369</sup>Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) of the Convention concerning International Carriage by Rail, version with effect from 1 January 2009.]]
- (38) [<sup>X1</sup><sup>F369</sup>Version as revised as of 1 January 2007.]]
- (39) [<sup>X1</sup><sup>F369</sup>International Maritime Organisation, 2006 edition, ISBN 978-92-8001-4214-3.]]
- (40) [<sup>X1</sup><sup>F369</sup>IATA, 2007-2008 edition.]]
- (41) [<sup>X1</sup><sup>F369</sup>MEPC.2/Circular, Provisional categorisation of liquid substances, version 19, effective 17 December 2013.]]
- (42) [<sup>X1</sup><sup>F369</sup>Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1).]]
- (43) [<sup>X1</sup><sup>F369</sup>Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).]]
- (44) [<sup>X1</sup><sup>F369</sup>Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).]]
- (45) [<sup>X1</sup><sup>F359</sup>OJ L 275, 20.10.2011, p. 38.]]
- (46) [<sup>X1</sup>This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.]
- (47) [<sup>X1</sup>Note: conditions for not requiring a specific test that are set out in [regulations under] Article 13(3) that are not repeated in column 2, also apply.]

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (See end of Document for details)

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- (48) [<sup>X1</sup>This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.]
- (49) [<sup>X1</sup>Note: conditions for not requiring a specific test that are set out in [regulations under] Article 13(3) that are not repeated in column 2, also apply.]
- (50) [<sup>X1</sup>This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.]
- (51) [<sup>X1</sup>Note: conditions for not requiring a specific test that are set out in [regulations under] Article 13(3) that are not repeated in column 2, also apply.]
- (52) [<sup>X1</sup>This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.]
- (53) [<sup>X1</sup>Note: conditions for not requiring a specific test that are set out in [regulations under] Article 13(3) that are not repeated in column 2, also apply.]
- (54) [<sup>X1</sup>[<sup>F412</sup>For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of Section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study. For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study.]]

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#### Editorial Information

- X1** Substituted by [Corrigendum to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation \(EEC\) No 793/93 and Commission Regulation \(EC\) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC \(Official Journal of the European Union L 396 of 30 December 2006\).](#)

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#### Textual Amendments

- F359** Substituted by [Commission Regulation \(EU\) 2018/1881 of 3 December 2018 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances \(Text with EEA relevance\).](#)
- F369** Substituted by [Commission Regulation \(EU\) 2015/830 of 28 May 2015 amending Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) \(Text with EEA relevance\).](#)
- F412** Inserted by [Commission Regulation \(EU\) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals \('REACH'\) \(Text with EEA relevance\).](#)

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council.