STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part III

Biocidal Products

Prohibitions

8.—(1) Subject to paragraphs (3) and (4), a person shall not place on the market a biocidal product unless that biocidal product—

(a) has been authorised or registered in accordance with these Regulations or the Great Britain Regulations; and

(b) is placed on the market in accordance with any condition or restriction which is specified in that authorisation or registration.

(2) Subject to paragraphs (3) and (4), a person shall not use a biocidal product which has been placed on the market unless that biocidal product—

(a) has been authorised or registered in accordance with these Regulations or the Great Britain Regulations; and

(b) is properly used.

(3) Paragraphs (1) and (2)(*a*) shall not apply to a biocidal product which is placed on the market for use in an experiment or test for the purposes of—

(a) scientific research and development; or

(b) process orientated research and development,

pursuant to regulation 16.

(4) Paragraphs (1) and (2) shall not apply to a biocidal product which does not contain any active substance other than an active substance included only in Annex IB.

(5) A person shall not use a biocidal product containing an active substance which is included in Annex IB unless that biocidal product is used in a manner which involves the rational application of a combination of physical, biological, chemical or other measures as appropriate to limit the use of biocidal products to the minimum necessary for the effective control of target organisms.

(6) In this regulation, "properly used" means used both—

(a) in accordance with the conditions of use specified in the label of the biocidal product in question; and

(b) in a manner which involves the rational application of a combination of physical, biological, chemical or other measures as appropriate to limit the use of biocidal products to the minimum necessary for the effective control of target organisms.

Authorisation of a biocidal product

9.—(1) Subject to the following paragraphs, the Executive may authorise a biocidal product for placing on the market and use for a period of time which ends on a date not later than the earliest date on which the entry in Annex I of any active substance in that biocidal product expires.

(2) The Executive shall not authorise a biocidal product under paragraph (1) unless—

(a) the following conditions are satisfied, namely—

(i) at least one active substance in the biocidal product is included in Annex I at the time the authorisation is granted;

(ii) any other active substances in the biocidal product are included in Annex I or Annex IA at the time the authorisation is granted, and

(iii) any requirements set out in Annex I or Annex IA relating to the active substances in the biocidal product have been fulfilled; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not authorise a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(4) An applicant for the authorisation of a biocidal product under paragraph (1) shall submit his application to the Executive and with that application shall include—

(a) a dossier for that biocidal product satisfying, in the light of current scientific and technical knowledge—

(i) the requirements set out in Annex IVB where that biocidal product is a micro-organism, or

(ii) the requirements set out in Annexes IIB and IIIB where that biocidal product is not a micro-organism; and

(b) a dossier for each active substance in that biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements of—

(i) Annex IVA, where the active substance in question is a micro-organism, and

(ii) Annexes IIA and IIIA, where the active substance in question is not a micro-organism.

(5) A dossier submitted in accordance with paragraph (4) shall include—

(a) a detailed and full description of any studies referred to in that dossier; and

(b) either—

(i) a detailed and full description of the methods used in carrying out such studies, or

(ii) a bibliographical reference to such methods.

(6) The information in dossiers submitted to the Executive in accordance with paragraph (4) shall be sufficient to enable the Executive to make the determination referred to in Schedule 3.

(7) The Executive—

(a) shall evaluate dossiers submitted in accordance with paragraph (4) in accordance with the common principles set out in Annex VI; and

(b) subject to regulations 18(3) and 39(2), shall decide without undue delay whether or not to authorise the biocidal product in question.

(8) If the evaluation of a dossier shows that additional information, which may include data and results from further testing, is necessary for the purpose of evaluating the risks of the biocidal product in question, the Executive shall request in writing the applicant to provide such additional information as it may specify.

(9) Where the Executive requests additional information under paragraph (8), the period of time within which the Executive shall decide whether or not to authorise the biocidal product in question shall not commence until the dossier is complete.

(10) In an authorisation granted under paragraph (1), the Executive shall specify—

(a) the conditions and requirements relating to the placing on the market and use of the biocidal product referred to in the authorisation necessary to ensure—

(i) compliance with any requirements set out in Annex I or Annex IA relating to the active substance in that biocidal product; and

(ii) that the requirements referred to in paragraphs 1(a)–(d) and 4(b) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the authorisation is granted.

(11) The Executive may renew an authorisation granted under this regulation for a period of time which ends on a date not later than the earliest date on which the entry in Annex I of any active substance in the biocidal product the subject of the authorisation expires.

(12) Paragraphs (2) to (10) shall apply in the case of an application for the renewal of an authorisation under paragraph (11) as they apply in the case of an application for an authorisation under paragraph (1).

(13) Where an application for the renewal of an authorisation of a biocidal product granted under this regulation has been made, the Executive may, where necessary, renew that authorisation for such further period as is required to enable the Executive—

(a) to verify that the conditions specified in paragraph 2(*a*) continue to be satisfied; and

(b) to confirm, or otherwise, the determinations referred to in paragraph 2(*b*).

Registration of a low-risk biocidal product

10.—(1) Subject to the following paragraphs, the Executive may register a low-risk biocidal product for placing on the market and use for a period of time which ends on a date not later than the earliest date on which the entry in Annex IA of any active substance in that low-risk biocidal product expires.

(2) The Executive shall not register a low-risk biocidal product under paragraph (1) unless—

(a) any requirements set out in Annex IA relating to the active substance in that low-risk biocidal product have been fulfilled; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not register a low-risk biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that low-risk biocidal product is classified as toxic or very toxic.

(4) Subject to paragraph (7), an applicant for the registration of a low-risk biocidal product under paragraph (1) shall submit his application to the Executive and with that application shall include—

(a) a dossier containing the information set out in Schedule 4; and

(b) a dossier for each active substance in that low-risk biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements of—

(i) Annex IVA, where the active substance in question is a micro-organism, and

(ii) Annexes IIA and IIIA, where the active substance in question is not a micro-organism.

(5) A dossier submitted in accordance with paragraph (4) shall include—

(a) a detailed and full description of any studies referred to in that dossier; and

(b) either—

(i) a detailed and full description of the methods used in carrying out such studies, or

(ii) a bibliographical reference to such methods.

(6) The information in dossiers submitted to the Executive in accordance with paragraph (4) shall be sufficient to enable the Executive to make the determinations referred to in Schedule 3.

(7) Where the applicant justifies the omission to the satisfaction of the Executive, the applicant may omit from a dossier submitted in accordance with paragraph (4)(*a*) information which—

(a) is not necessary owing to the nature of—

(i) the low-risk biocidal product, or

(ii) its proposed uses;

(b) it is not scientifically necessary or technically possible to supply.

(8) The Executive—

(a) shall evaluate dossiers submitted in accordance with paragraph (4) in accordance with the common principles set out in Annex VI; and

(b) subject to regulation 39(2), shall decide within 60 days of its receiving an application whether or not to register the low-risk biocidal product in question.

(9) If the evaluation of a dossier shows that additional information, which may include data and results from further testing, is necessary for the purpose of evaluating the risks of the low-risk biocidal product in question, the Executive shall request in writing the applicant to provide such additional information as it may specify.

(10) Where the Executive requests additional information under paragraph (9), the period of time referred to in paragraph (8)(*b*) shall not commence until the dossier is complete.

(11) In a registration granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the low-risk biocidal product referred to in the registration necessary to ensure—

(i) compliance with any requirements set out in Annex IA relating to the active substance in that low-risk biocidal product, and

(ii) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the registration is granted.

(12) The Executive may renew a registration granted under this regulation for a period of time which ends on a date not later than the earliest date on which the entry in Annex IA of any active substance in the low-risk biocidal product the subject of the registration expires.

(13) Paragraphs (2) to (11) shall apply in the case of an application for the renewal of a registration under paragraph (12) as they apply in the case of an application for a registration under paragraph (1).

(14) Where an application for the renewal of a registration of a low-risk biocidal product granted under this regulation has been made, the Executive may, where necessary, renew that registration for such further period as is required to enable the Executive—

(a) to verify that the requirements referred to in paragraph (2)(*a*) continue to be fulfilled; and

(b) to confirm, or otherwise, the determinations referred to in paragraph (2)(*b*).

Mutual recognition of authorisations

11.—(1) Where a biocidal product has been authorised for placing on the market and use under the Directive in a member State, a person may apply to the Executive for authorisation of that biocidal product for placing on the market and use under this regulation.

(2) Subject to the following paragraphs and to regulations 18(3) and 39(2), within 120 days of the Executive receiving an application in accordance with this regulation, it shall authorise the biocidal product in question subject to the conditions and restrictions imposed on authorisation of that biocidal product in the member State where authorisation was first granted.

(3) Subject to paragraphs (8) and (9), the Executive shall not authorise a biocidal product under this regulation unless the following conditions are satisfied, namely—

(a) at least one of the active substances in the biocidal product is included in Annex I;

(b) any other active substances in the biocidal product are included in Annex I or Annex IA; and

(c) any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product have been fulfilled.

(4) Subject to paragraphs (8) and (9), the Executive shall not authorise a biocidal product under this regulation if it considers that—

(a) the biocidal product does not satisfy the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3; or

(b) the nature and quantity of—

(i) the active substance in,

(ii) where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants in, or

(iii) the residues of toxicological or environmental significance which result from authorised uses of,

the biocidal product cannot be determined according to the relevant requirements in Annexes IIA, IIB, IIIA, IIIB, IVA and IVB.

(5) An applicant for authorisation of a biocidal product under this regulation shall submit with his application—

(a) a summary of the dossier submitted in support of the application for authorisation of that biocidal product in the member State in which the authorisation was first granted; and

(b) a certified copy of that authorisation.

(6) Where the Executive is satisfied that—

(a) the target species is not present in harmful quantities;

(b) there is unacceptable tolerance or resistance of the target organism to the biocidal product; or

(c) the relevant circumstances of use differ significantly from those in the member State where the biocidal product was first authorised, such that an authorisation without additional conditions may present unacceptable risks to humans, animals or the environment,

it may propose conditions and restrictions relating to the matters referred to in Schedule 5 concerning the placing on the market and the use of the biocidal product in addition to those conditions and restrictions imposed in the member State in which the biocidal product was first authorised.

(7) The additional conditions and restrictions proposed pursuant to paragraph (6) shall be such as to ensure—

(a) compliance with any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product in question; and

(b) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied.

(8) Where, under this regulation, the Executive proposes to refuse to authorise a biocidal product or to impose conditions or restrictions in addition to those imposed in the member State in which the biocidal product was first authorised, it shall—

(a) notify the Commission, member States and the applicant; and

(b) provide the Commission, member States and the applicant with an explanatory document setting out—

(i) the name and specification of the biocidal product, and

(ii) the grounds on which it proposes to refuse authorisation, or to impose additional conditions or restrictions on authorisation.

(9) Where a Commission decision—

(a) confirms a proposed refusal, the Executive shall refuse to authorise the biocidal product in question;

(b) confirms any of the proposed additional conditions and restrictions, the Executive shall authorise the biocidal product in question subject to—

(i) the conditions and restrictions confirmed by the Commission decision, and

(ii) any conditions and restrictions imposed in the member State in which the biocidal product was first authorised;

(c) confirms that an authorisation, which the Executive proposes should be refused, should be granted, the Executive shall authorise the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first authorised;

(d) confirms that none of the additional conditions and restrictions proposed by the Executive should be imposed, the Executive shall authorise the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first authorised but without imposing the additional conditions and restrictions which it proposed.

Mutual recognition of registrations

12.—(1) Where a biocidal product has been registered for placing on the market and use under the Directive in a member State, a person may apply to the Executive for registration of that biocidal product for placing on the market and use under this regulation.

(2) Subject to the following paragraphs and to regulation 39(2), within 60 days of the Executive receiving an application in accordance with this regulation, it shall register the biocidal product in question subject to the conditions and restrictions imposed on registration of that biocidal product in the member State where registration was first granted.

(3) Subject to paragraphs (10) to (13), the Executive shall not register a biocidal product under this regulation unless—

(a) the biocidal product is a low-risk biocidal product; and

(b) any requirements set out in Annex IA relating to the active substance in the biocidal product have been fulfilled.

(4) Subject to paragraphs (12) and (13), the Executive shall not register a biocidal product under this regulation if it considers that—

(a) the biocidal product does not satisfy the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3; or

(b) the nature and quantity of—

(i) the active substance in,

(ii) where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants in, or

(iii) the residues of toxicological or environmental significance which result from authorised uses of,

the biocidal product cannot be determined according to the relevant requirements in Annexes IIA, IIB, IIIB, IVA and IVB.

(5) Subject to paragraphs (6) and (7), an applicant for registration of a biocidal product under this regulation shall submit with his application—

(a) a dossier containing the information set out in Schedule 4; and

(b) a certified copy of the registration of that biocidal product in the member State in which registration was first granted.

(6) Where the applicant justifies the omission to the satisfaction of the Executive, the applicant may omit from a dossier submitted in accordance with paragraph (5)(*a*) information which—

(a) is not necessary owing to the nature of—

(i) the low-risk biocidal product, or

(ii) its proposed uses;

(b) it is not scientifically necessary or technically possible to supply.

(7) The data referred to in paragraph 10 of Schedule 4 may be provided in summary form.

(8) Where the Executive is satisfied that—

(a) the target species is not present in harmful quantities;

(b) there is unacceptable tolerance or resistance of the target organism to the biocidal product; or

(c) the relevant circumstances of use differ significantly from those in the member State where the biocidal product was first registered, such that registration without additional requirements or conditions may present unacceptable risks to humans, animals or the environment,

it may propose conditions and restrictions relating to the matters referred to in Schedule 5 concerning the placing on the market and the use of the biocidal product in addition to those conditions and restrictions imposed in the member State in which the first registration was granted.

(9) The additional conditions and restrictions proposed pursuant to paragraph (8) shall be such as to ensure—

(a) compliance with any requirements set out in Annex IA relating to the active substance in the biocidal product in question; and

(b) that the requirements referred to in paragraph 1(a)–(d) and 4(b) of Schedule 3 remain satisfied.

(10) If the Executive is satisfied that the biocidal product, in respect of which an application has been made under paragraph (1), is not a low-risk biocidal product, it—

(a) may provisionally refuse to register the biocidal product; and

(b) shall immediately communicate its concerns to the competent authority which verified the dossier submitted in support of the application for first registration.

(11) If, within 90 days of the Executive communicating its concerns in accordance with paragraph 10(b), the Executive and the competent authority which verified the dossier submitted in support of the application for first registration cannot reach an agreement as to whether a biocidal product is a low-risk biocidal product, the Executive shall notify the Commission of the lack of agreement.

(12) Notwithstanding paragraphs (10) and (11), where, under this regulation the Executive proposes to refuse to register a biocidal product, or to impose conditions or restrictions in addition to those imposed in the member State in which the low-risk biocidal product was first registered, it shall—

(a) notify the Commission, member States and the applicant; and

(b) provide the Commission, member States and the applicant with an explanatory document setting out—

(i) the name and specification of the biocidal product, and

(ii) the grounds on which it proposes to refuse registration, or to impose additional conditions or restrictions on, registration.

(13) Where a Commission decision—

(a) confirms a proposed or provisional refusal, the Executive shall refuse to register the biocidal product in question;

(b) confirms any of the proposed additional conditions or restrictions, the Executive shall register the biocidal product in question subject to—

(i) the conditions and restrictions confirmed by the Commission decision, and

(ii) any conditions and restrictions imposed in the member State in which the biocidal product was first registered;

(c) confirms that a registration, which the Executive proposes should be refused or has provisionally refused, should be granted, the Executive shall register the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first registered;

(d) confirms that none of the additional conditions and restrictions proposed by the Executive should be imposed, the Executive shall register the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first registered but without imposing the additional conditions and restrictions which it proposed.

Provisional authorisation

13.—(1) Subject to the following paragraphs, the Executive may authorise, for a period not exceeding three years, a biocidal product for placing on the market and use which contains a new active substance which is not included in Annex I or Annex IA but in respect of which an application has been made to the Executive under regulation 5.

(2) The Executive shall not authorise a biocidal product under paragraph (1) unless—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex I or Annex IA and has recommended that that new active substance should be included in Annex I; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not authorise a biocidal product under paragraph (1) where—

(a) a member State has made an objection in accordance with Article 18(2) to the completeness of the dossiers submitted in support of the application under regulation 5; and

(b) objection has been upheld by a Commission decision.

(4) The Executive shall not authorise a biocidal product under paragraph (1) where the evaluation required by paragraph (2)(*a*) shows that—

(a) under normal conditions under which the new active substance may be used in the biocidal product, there are risks to the health of humans or animals or to the environment which give rise to concern; and

(b) there is another active substance included in Annex I for the same product-type which, having regard to current scientific and technical knowledge, presents significantly less risk than the new active substances to the health of humans or animals or to the environment when used under normal conditions in biocidal products authorised in accordance with these Regulations, provided that—

(i) the chemical diversity of all the active substances included in Annex I is adequate to minimise the occurrence of resistance in organisms targeted by that biocidal product,

(ii) the Executive does not consider that it is necessary to acquire experience of using the new active substance in practice, and

(iii) the active substance included in Annex I can be used on the target organism with similar efficacy as the new active substance without significant economic and practical disadvantages for the user and without an increased risk to the health of humans or animals or to the environment.

(5) The Executive shall not authorise a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(6) Paragraphs (4) to (9) of regulation 9 shall apply in the case of an application for an authorisation under paragraph (1) as they apply in the case of an application for an authorisation under paragraph (1) of that regulation.

(7) In an authorisation granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the biocidal product referred to in the authorisation necessary to ensure—

(i) compliance with any requirements which it has recommended should attach to the inclusion in Annex I of the new active substance in that biocidal product, and

(ii) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the authorisation is granted.

(8) If, on the expiry of the period for which an authorisation has been granted under paragraph (1), a decision has not been taken concerning the inclusion in Annex I of the new active substance in the biocidal product referred to in that authorisation, the Executive may authorise that biocidal product for placing on the market and use for a further period of one year.

(9) Paragraphs (2) to (7) shall apply in the case of an application for an authorisation under paragraph (8) as they apply in the case of an application for an authorisation under paragraph (1).

(10) The Executive shall inform the Commission and the member States of every authorisation granted in accordance with paragraph (8).

Provisional registration

14.—(1) Subject to the following paragraphs of this regulation, the Executive may register, for a period not exceeding three years, a biocidal product for placing on the market and use which—

(a) contains a new active substance which is not included in Annex IA but in respect of which an application has been made to the Executive under regulation 5;

(b) does not contain a substance of concern;

(c) does not contain an active substance included in Annex I; and

(d) under the conditions under which that biocidal product may be used poses a low risk to humans, animals and the environment.

(2) The Executive shall not register a biocidal product under paragraph (1) unless—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex IA and has recommended that the new active substance should be included in Annex IA; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not register a biocidal product under paragraph (1) where—

(a) a member State has made an objection in accordance with Article 18(2) to the completeness of the dossiers submitted in support of the application under regulation 5; and

(b) that objection has been upheld by a Commission decision.

(4) The Executive shall not register a biocidal product under paragraph (1) where the new active substance contained in that biocidal product which is not included in Annex IA—

(a) is classified as carcinogenic, mutagenic, sensitising or toxic for reproduction; or

(b) is bioaccumulative and does not readily degrade.

(5) The Executive shall not register a biocidal product under paragraph (1) where the evaluation required by paragraph (2)(*a*) shows that—

(a) under normal conditions under which the new active substance may be used in the biocidal product, there are risks to the health of humans or animals or to the environment which give rise to concern; and

(b) there is another active substance included in Annex I for the same product-type which, having regard to current scientific and technical knowledge, presents significantly less risk than the new active substance to the health of humans or animals or to the environment when used under normal conditions in biocidal products authorised in accordance with these Regulations, provided that—

(i) the chemical diversity of all the active substances included in Annex I is adequate to minimise the occurrence of resistance in organisms targeted by that biocidal product,

(ii) the Executive does not consider that it is necessary to acquire experience of using the new active substance in practice, and

(iii) the active substance included in Annex I can be used on the target organism with similar efficacy as the new active substance without significant economic and practical disadvantages for the user and without an increased risk to the health of humans or animals or to the environment.

(6) The Executive shall not register a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as toxic or very toxic.

(7) Paragraphs (4)–(10) of regulation 10 shall apply in the case of an application for a registration granted under paragraph (1) as it applies in the case of an application for a registration granted under paragraph (1) of that regulation, and, in the application of this paragraph, a reference to a low-risk biocidal product in paragraphs (4)–(10) of regulation 10 shall be deemed to be a reference to a biocidal product.

(8) In a registration granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the biocidal product referred to in the registration necessary to ensure—

(i) compliance with any requirements which it has recommended should attach to the inclusion in Annex IA of the new active substance in the biocidal product, and

(ii) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the registration is granted.

(9) If, on the expiry of the period for which a registration has been granted under paragraph (1), a decision has not been taken concerning the inclusion in Annex IA of the new active substance in the biocidal product referred to in that registration, the Executive may register that biocidal product for placing on the market and use for a further period of one year.

(10) Paragraphs (2) to (8) shall apply to an application for a registration under paragraph (9) as they apply to an application for registration under paragraph (1).

(11) The Executive shall inform the Commission and the member States of every registration granted under paragraph (9).

Emergency authorisation

15.—(1) Where a person submits an application to the Executive for the authorisation of an unauthorised biocidal product under this regulation, the Executive may authorise, for a period not exceeding 120 days, the placing on the market of an unauthorised biocidal product for a limited and controlled use if such authorisation appears necessary because of an unforeseen danger which cannot be contained by any other means.

(2) The Executive shall immediately inform the Commission and the member States of an authorisation granted in accordance with paragraph (1) and the justification for it.

(3) An authorisation granted under paragraph (1) shall specify such conditions and restrictions relating to the placing on the market and the use of the biocidal product in question as the Executive considers appropriate.

(4) If there is a Commission decision that—

(a) the period in respect of which an authorisation granted pursuant to paragraph (1) may be extended; or

(b) such an authorisation may be renewed,

the Executive may extend that period or renew that authorisation.

(5) Where the Executive extends the period of, or renews, an authorisation under paragraph (4), it shall at the same time specify any conditions referred to in the Commission decision subject to which the period may be extended or the authorisation may be renewed, as the case may be.

(6) In this regulation, "unauthorised biocidal product" means a biocidal product which—

(a) has not been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14; or

(b) has been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14, but which, by virtue of the conditions or restrictions to which the authorisation, or, as the case may be, the registration, is subject, cannot be used to deal with an unforeseen danger referred to in paragraph (1).

Research and development

16.—(1) This regulation shall not apply to the placing on the market of a relevant product for use in an experiment or test in Northern Ireland which may involve or result in the release into the environment of that relevant product.

(2) A person shall not place on the market a relevant product for use in an experiment or test for the purposes of scientific research and development, or process-orientated research and development, unless that person compiles a dossier containing all available information on the possible effects of the relevant product on human or animal health and on the environment.

(3) A person shall not place on the market a relevant product for use in an experiment or test for the purposes of scientific research and development unless that person draws up and maintains a written record of the following information relating to that relevant product, namely—

(a) its identity;

(b) any data on which the information on its label should be based;

(c) the quantity placed on the market; and

(d) the name and address of the person who receives it.

(4) A person, who places on the market a relevant product for use in an experiment or test for the purposes of scientific research and development, which is to be conducted in Northern Ireland, shall provide to the Executive on request the written record and dossier relating to that relevant product which he is required to compile and maintain in accordance with paragraphs (2) and (3).

(5) A person, who intends to place on the market a relevant product for use in an experiment or test for the purpose of process-orientated research and development in Northern Ireland, shall provide to the Executive before the relevant product is placed on the market—

(a) the dossier relating to the relevant product which he is required to compile in accordance with paragraph (2); and

(b) the following information relating to the relevant product namely—

(i) its identity,

(ii) any data on which the information on its label should be based,

(iii) the quantity of the relevant product to be placed on the market, and

(iv) the name and address of the person who is to receive the relevant product.

(6) If an experiment or test referred to in paragraph (2) or (3) is liable to have harmful effects on human or animal health or an unacceptable adverse influence on the environment, the Executive may—

(a) prohibit the experiment or test; or

(b) impose such conditions regarding the conduct of the experiment or test as it considers necessary to prevent such harmful effects or such adverse influence.

(7) A person shall not conduct an experiment or test which the Executive has prohibited under paragraph (6)(*a*).

(8) Where the Executive has imposed conditions regarding the conduct of an experiment or test under paragraph (6)(*b*), the person conducting the experiment or test shall comply with the conditions, or shall ensure that the conditions are complied with.

(9) In this regulation—

(a) "unauthorised biocidal product" means a biocidal product which—

(i) has not been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14, or

(ii) has been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14, but which, by virtue of the conditions or restrictions to which the authorisation, or, as the case may be, the registration is subject, cannot be used in the experiment or test in question;

(b) "relevant product" means—

(i) an unauthorised biocidal product, or

(ii) an active substance intended exclusively for use in a biocidal product.

Experimental authorisation

17.—(1) Subject to the following paragraphs of this regulation, the Executive may authorise a biocidal product, or an active substance intended exclusively for use in a biocidal product, for placing on the market for the purpose of any experiment or test in Northern Ireland which may involve or result in the release into the environment of that biocidal product or active substance, as the case may be.

(2) An authorisation granted under this regulation—

(a) shall contain conditions limiting—

(i) the quantity of biocidal product or active substance, as the case may be, to be used, and

(ii) the area to be treated with that biocidal product or active substance; and

(b) may contain such further conditions, including any conditions necessary to prevent harmful effects on human or animal health or unacceptable adverse influence on the environment, as the Executive considers necessary.

(3) An authorisation granted under this regulation may relate to more than one experiment or test and, if it does so, shall—

(a) be granted to one person;

(b) specify the experiments or tests to which it relates; and

(c) specify the conditions under which those experiments and tests shall be undertaken.

(4) An applicant for an authorisation under this regulation shall submit his application to the Executive together with a dossier setting out, in relation to each experiment or test—

(a) the identity of the biocidal product or active substance in question;

(b) any data on which the information on the label of that biocidal product or active substance should be based;

(c) the quantity of the biocidal product or active substance to be placed on the market;

(d) the name and address of each person who is to receive the biocidal product or active substance in question; and

(e) all available information on the possible effects on human or animal health and on the environment of the biocidal product or active substance concerned.

(5) Subject to regulation 39(2), the Executive shall assess the information provided by the applicant before deciding whether or not to grant an authorisation under this regulation.

Frame-formulations

18.—(1) At the same time the Executive grants an authorisation in respect of a biocidal product under regulation 9 or 13, or grants a registration in respect of a biocidal product under regulation 10 or 14—

(a) it shall, when requested to do so by the applicant for that authorisation or that registration; or

(b) it may, without being requested to do so,

issue a frame-formulation which includes that biocidal product and it shall communicate that frame-formulation to that applicant.

(2) Where an application is made under regulation 9, 10, 13 or 14 in respect of a biocidal product within an issued frame-formulation, the Executive shall take that issued frame-formulation into account in evaluating the dossiers submitted with the application in question.

(3) Where a person makes an application for an authorisation under regulation 9 or 13 and that person has a letter of access in respect of the information relating to the biocidal products within an issued frame-formulation, the Executive shall decide whether or not to grant the authorisation within 60 days of its receiving the application.

(4) In this regulation, "issued frame-formulation" means a frame-formulation issued by the Executive in accordance with paragraph (1).

Revocation of authorisations and registrations

19.—(1) The Executive shall revoke an authorisation granted under regulation 9 or 11 where—

(a) an active substance in the biocidal product to which the authorisation relates—

(i) is removed from Annex I, or

(ii) is removed from Annex IA and that active substance is not included in Annex I; or

(b) a requirement laid down in Annex I or Annex IA in respect of an active substance in the biocidal product to which the authorisation relates is no longer satisfied.

(2) The Executive shall revoke an authorisation—

(a) granted under regulation 9, 11 or 13, where the biocidal product, the subject of the authorisation, no longer satisfies one or more of the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3;

(b) granted under regulation 9, 11, 13, 15 or 17, where false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted.

(3) The Executive shall revoke an authorisation of a biocidal product for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(4) The Executive shall revoke a registration granted under regulation 10 or 12 where—

(a) an active substance in the low-risk biocidal product to which the registration relates is removed from Annex IA; or

(b) a requirement laid down in Annex IA in respect of an active substance in the low-risk biocidal product to which the registration relates is no longer satisfied.

(5) The Executive shall revoke a registration granted under regulation 10 if—

(a) there is a Commission decision referred to in regulation 20(4); and

(b) following a review of the registration in accordance with regulation 20(4), the Executive decides that the biocidal product in question is not a low-risk biocidal product.

(6) The Executive shall revoke a registration granted under regulation 10, 12 or 14 where—

(a) the biocidal product, the subject of the registration, no longer satisfies one or more of the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3;

(b) false or misleading information was supplied concerning the facts on the basis of which the registration was granted.

(7) The Executive shall revoke a registration of a biocidal product for use by the public or for placing on the market for use by the public, where that low-risk biocidal product is classified as toxic or very toxic.

(8) The Executive shall revoke an authorisation granted under regulation 13 where there is a Commission decision that an active substance in the biocidal product to which the authorisation relates shall not be included in Annex I, and no decision is made to include that active substance in Annex IA.

(9) The Executive shall revoke a registration granted under regulation 14 where there is a Commission decision that an active substance in the biocidal product to which the registration relates shall not be included in Annex IA.

(10) The Executive shall revoke an authorisation granted under regulation 15 where a Commission decision does not uphold it.

(11) The Executive may revoke an authorisation granted under regulation 17 if the experiment or test in question is liable to have harmful effects on human or animal health or an unacceptable adverse effect on the environment.

(12) The Executive may revoke an authorisation or registration granted under these Regulations at the written request of the holder, who shall state the reasons for that request.

(13) Before revoking an authorisation or a registration, except following a request made in accordance with paragraph (12), the Executive shall—

(a) give to the holder a notice in writing stating that—

(i) it is considering revoking that authorisation or registration and the reasons why, and

(ii) within a period specified in the notice, the holder may make written representations to the Executive or, if the holder so requests, may make oral representations to the Executive; and

(b) consider any representations which are duly made and not withdrawn.

(14) Before refusing to revoke an authorisation or a registration following a request made in accordance with paragraph (12), the Executive shall—

(a) give to the holder a notice in writing stating that—

(i) it is considering not revoking that authorisation or that registration and the reasons why, and

(ii) within a period specified in the notice, the holder may make written representations to the Executive or, if the holder so requests, may make oral representations to the Executive; and

(b) consider any representations which are duly made and not withdrawn.

(15) When the Executive revokes—

(a) an authorisation or a registration granted under these Regulations in respect of a biocidal product; or

(b) an authorisation granted under regulation 17 in respect of an active substance intended exclusively for use in a biocidal product,

it may grant a period of grace for the disposal, storage, placing on the market or use of existing stocks of the biocidal product to which the authorisation or the registration relates, or the active substance to which the authorisation relates, as the case may be.

(16) The period of grace referred to in paragraph (15) shall be of a length commensurate with the reason for the revocation, but shall be without prejudice to any period provided for in connection with the removal from Annex I or Annex IA of an active substance in the biocidal product in question or the active substance in question, as the case may be.

(17) In this regulation, "holder" means a person to whom an authorisation or a registration has been granted in accordance with these Regulations.

Modification and review of authorisations and registrations

20.—(1) The Executive shall modify the conditions of use, subject to which an authorisation or a registration is granted under these Regulations, where it considers that, on the basis of developments in scientific and technical knowledge, such modification is necessary to protect human or animal health or the environment.

(2) Subject to regulation 39(3), the Executive may modify the conditions of use, subject to which an authorisation or a registration is granted under these Regulations, at the written request of the holder, who shall state the reasons for that request.

(3) The Executive may review an authorisation of a biocidal product granted under regulation 9, 11 or 13 or a registration of a biocidal product granted under regulation 10, 12 or 14 at any time if there are indications that—

(a) the biocidal product in question no longer satisfies one or more of the requirements referred to in paragraphs 1(*a*)–(*d*) or 4(*b*) of Schedule 3;

(b) there is a change in the classification of the biocidal product; or

(c) the conditions or restrictions, subject to which the biocidal product has been authorised or registered, as the case may be, and imposed to ensure that the requirements referred to in paragraphs 1(*a*)–(*d*) or 4(*b*) of Schedule 3 remain satisfied, are no longer appropriate for ensuring that such requirements remain satisfied.

(4) Where a Commission decision confirms the refusal of a member State to register a biocidal product in respect of which the Executive has granted a registration under regulation 10, if considered appropriate by the Standing Committee, the Executive shall review that registration, taking the refusal of the member State into consideration.

(5) Where the Executive reviews an authorisation or a registration under paragraph (3), or a registration under paragraph (4), the Executive—

(a) may extend the authorisation or registration in question for the period necessary to enable it to complete the review; and

(b) may require the holder to provide further information necessary for the review.

(6) Where the Executive requires further information in accordance with paragraph (5), the Executive shall extend the authorisation or registration for the period necessary to enable the holder to provide such information.

(7) In this regulation—

(a) "holder" has the same meaning as it has in regulation 19;

(b) "the conditions of use" means the conditions relating to the use of a biocidal product, including, but without prejudice to the generality of the foregoing, the manner of use and the amounts used; and

(c) "the Standing Committee" means the Standing Committee on Biocidal Products referred to in Article 28(1).

Notification of new information

21.—(1) A person to whom an authorisation or a registration has been granted in accordance with these Regulations shall immediately notify the Executive of any information of which he is aware or may reasonably be expected to be aware concerning—

(a) the biocidal product; or

(b) an active substance contained in the biocidal product,

to which the authorisation or the registration relates, which may affect that authorisation or registration.

(2) The information referred to in paragraph (1) shall include—

(a) new knowledge or information on the effects of that biocidal product, or the active substance which the biocidal product contains, on humans, animals or the environment;

(b) changes in the source or composition of the active substance which the biocidal product contains;

(c) changes in the composition of the biocidal product;

(d) development of resistance to the biocidal product in the harmful organisms which it is intended to control;

(e) changes of an administrative nature; or

(f) changes in the nature of the packaging.

(3) A notification made pursuant to paragraph (1) shall include—

(a) a statement that the notification is made in compliance with this regulation; and

(b) the number of the authorisation or registration relating to the biocidal product with which the notification is concerned.

(4) The Executive shall immediately notify member States and the Commission of any information it receives by virtue of paragraph (1) relating to—

(a) potentially harmful effects for humans, animals or the environment of—

(i) a biocidal product,

(ii) an active substance, an impurity or a co-formulant which a biocidal product contains, or

(iii) a residue of a biocidal product; and

(b) changes in the composition of a biocidal product, including changes in the active substance which a biocidal product contains.

Emergency prohibition or restriction

22.—(1) The Executive may prohibit or restrict the sale or use of a biocidal product which has been authorised or registered under these Regulations, where it has valid reasons to consider that the biocidal product constitutes an unacceptable risk to human or animal health or to the environment.

(2) Where the Executive prohibits or restricts the sale or use of a biocidal product pursuant to paragraph (1), it shall immediately inform the Commission and member States of that prohibition or restriction and of the reasons for it.

(3) A person shall not sell a biocidal product—

(a) whose sale has been prohibited pursuant to paragraph (1); or

(b) in a manner which contravenes any restriction on the sale of that biocidal product imposed pursuant to paragraph (1).

(4) A person shall not use a biocidal product—

(a) whose use has been prohibited pursuant to paragraph (1); or

(b) in a manner which contravenes any restriction on the use of that biocidal product imposed pursuant to paragraph (1).

(5) The Executive shall revoke a prohibition or restriction issued under this regulation where a decision made in accordance with the procedures set out in Article 28(3) does not uphold the prohibition or restriction.