STATUTORY RULES OF NORTHERN IRELAND

2005 No. 526

PESTICIDES

Plant Protection Products Regulations (Northern Ireland) 2005

Made - - - -	*29th November 2005*
Coming into operation -	*26th January 2006*

ARRANGEMENT OF REGULATIONS

The Department of Agriculture and Rural Development, being a Department designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to the common agricultural policy of the European Community, in exercise of the powers conferred on it by the said section 2(2) and of every other power enabling it in that behalf, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Plant Protection Products Regulations (Northern Ireland) 2005 and shall come into operation on 26th January 2006.

Interpretation

2.—(1) In these Regulations—

"the 1985 Act" means the Food and Environment Protection Act 1985(**c**);

"active substance" means any substance or micro-organism, including a virus, having general or specific action against harmful organisms or on plants, parts of plants or plant products;

"animals" means animals belonging to species normally fed and kept or consumed by man;

"approval" in relation to a plant protection product means an administrative act under these Regulations by which the Department, following an application submitted by an applicant, approves the placing on the market or use of that plant protection product in the whole or any part of Northern Ireland;

"the Commission" means the Commission of the European Communities;

"the Department" means the Department of Agriculture and Rural Development;

"the Directive" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market(**d**), as amended—

(a) by the instruments in force listed in Part I of Schedule 1, and

(b) by the instruments coming into force listed in Part II of Schedule 1;

"EEA State" means a member State, Norway, Iceland or Liechtenstein;

"the environment" means water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms;

"equivalent provision" in relation to any particular provision in these Regulations means any provision in any other Regulations made for the purposes of implementing the Directive, extending to any other part of the United Kingdom which has equivalent effect to that particular provision;

"harmful organisms" means pests of plants or plant products belonging to the animal or plant kingdom, viruses, bacteria and mycoplasmas and other pathogens;

"integrated control" means the rational application of a combination of biological, biotechnological, chemical, cultural or plant-breeding measures whereby the use of chemical plant protection products is limited to the minimum strictly necessary to maintain harmful organisms below levels above which economically unacceptable damage or loss would occur;

(**a**) S.I. 2000/2812
(**b**) 1972 c. 68; section 2 is subject to Schedule 2 to that Act and is to be read with S.I. 1984/703 (N.I. 3) and S.R. 1984 No. 253
(**c**) 1985 c. 48; section 19 was amended by the Pesticides (Fees and Enforcement) Act 1989 (c. 27); section 2, and by the Pesticides Act 1998 (c. 26), section 2
(**d**) O.J. No. L230, 19.8.91, p. 1

"International Organisation for Standardization" means the institution of that name founded in 1947 and currently having its headquarters at 1 Rue de Varembé, CP 56, 1211 Geneva 20, Switzerland;

"International Union of Pure and Applied Chemistry" means the institution of that name founded in 1919 and currently having its headquarters at 104 T.W. Alexander Drive, Building 19, Research Triangle Park, NC 27709, USA;

"new active substance" means an active substance which is not an old active substance;

"old active substance" means an active substance which was on the market in—

(a) the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and Slovakia, on or before 1st May 2004;

(b) Austria, Finland, Iceland, Norway, Sweden and Liechtenstein, on or before 1st July 1994;

(c) any other EEA State, on or before 26th July 1993;

"placing on the market" means any supply, whether in return for payment or not, within Northern Ireland, including importation into Northern Ireland otherwise than from an EEA State, other than a supply for storage followed by consignment otherwise than to an EEA State or disposal;

"plants" means live plants and live parts of plants including fresh fruit and seeds;

"plant products" means products derived from plants in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, but excludes plants themselves;

"plant protection product" means an active substance or a preparation containing one or more active substances, put up in the form in which it is supplied to the user, intended to—

(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms;

(b) influence (for example, as a growth regulator) the life processes of plants, other than as a nutrient;

(c) preserve plant products, in so far as such active substances or preparations are not subject to provisions of Community law on preservatives;

(d) destroy undesired plants; or

(e) destroy parts of plants or check or prevent the undesired growth of plants;

"preparation" means a mixture or solution composed of two or more substances, of which at least one is an active substance, and which is intended for use as a plant protection product;

"the 1987 Regulations" means the Control of Pesticides Regulations (Northern Ireland)1987(**a**);

"the relevant competent authorities" means the authorities of any member State, other than the United Kingdom, appointed by that member State for the purpose of carrying out the duties of a competent authority under the Directive;

"residue" in relation to a plant protection product means one or more substances present in or on plants or products of plant origin, edible animal products or elsewhere in the environment and resulting from the use of that plant protection product, and including its metabolites and products resulting from its degradation or reaction;

"substance" means any chemical element and its compounds, as they occur naturally or by manufacture, and includes any impurity inevitably resulting from the manufacturing process;

and other terms used in these Regulations and in the Directive shall have the same meaning as in the Directive.

(2) In these Regulations—

(**a**) S.R. 1987 No. 414 as amended by article 21(3) of the Food Safety (Northern Ireland) Order 1991 (Consequential Modifications) Order (Northern Ireland) 1991 (S.R. 1991 No. 203), S.R. 1997 No. 469 and regulation 42 of the Biocidal Products Regulations (Northern Ireland) 2001 (S.R. 2001 No. 422)

(a) any reference to a numbered Article shall be construed as a reference to the Article so numbered in the Directive; and

(b) any reference to a numbered Annex shall be construed as a reference to an Annex so numbered of the Directive;

(3) The Interpretation Act (Northern Ireland) 1954(**a**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Prohibitions

3.—(1) A person shall not place on the market any plant protection product unless—

(a) it has been approved under regulation 5, 7, 8 or 11 or an equivalent provision; and

(b) it is placed on the market in accordance with any requirement or condition which is specified in the approval.

(2) A person shall not use any plant protection product unless—

(a) it has been approved under regulation 5, 7, 8 or 11 or an equivalent provision; and

(b) it is used in accordance with any requirement or condition which is—

(i) specified in the approval or in any extension of use granted under regulation 10 or an equivalent provision; or

(ii) required by the approval or extension of use to be on the labelling;

(c) it is used in accordance with the principles of good plant protection practice; and

(d) whenever possible, it is used in accordance with the principles of integrated control.

(3) A person shall not place on the market any new active substance unless—

(a) that active substance is included in Annex I; or

(b) an application—

(i) has been granted for the inclusion of that active substance in Annex I; or

(ii) has been made for the inclusion of that active substance in Annex I but has not yet been decided in accordance with the procedure in Article 19.

(4) Paragraphs (1), (2) and (3) shall not apply to any plant protection product or active substance which is approved under regulation 9 or an equivalent provision.

(5) Nothing in these Regulations shall impede the production, storage or movement within Northern Ireland of a plant protection product intended for use in an EEA State other than the United Kingdom, provided that—

(a) the product is authorised by the competent authority of that EEA State for use in that EEA State; and

(b) the inspection requirements laid down by that EEA State in order to ensure compliance with Article 3(1) are satisfied.

(6) Any person who contravenes or causes or permits any person to contravene paragraph (1), (2)(a) or (b) or (3) shall be guilty of an offence.

Applications concerning active substances

4.—(1) Any person who applies for the inclusion of a new active substance in Annex I shall submit to the Department, the relevant competent authorities and the Commission a dossier which satisfies the requirements of Annex II, a declaration that the active substances is intended for use in a plant protection product, and a dossier complying with Annex III on at least one preparation containing that active substance.

(**a**) 1954 c. 33 (N.I.)

(2) Where any active substance has been included in Annex I, any person may make an application for variation of the conditions subject to which the active substance was included.

(3) Any person who applies under paragraph (2) shall submit the application to the Department, the relevant competent authorities and the Commission.

(4) This regulation shall apply to any person whose principal place of business in the United Kingdom is situated in Northern Ireland.

Standard approvals

5.—(1) Subject to the following provisions of this regulation and to regulation 6, the Department may approve, for a period not exceeding ten years, the placing on the market and use of any plant protection product.

(2) The Department may renew an approval granted under this regulation after verification that the requirements of regulation 6(2) to (7) continue to be satisfied.

(3) Where an application for renewal of an approval granted under this regulation has been made, the Department may renew the approval for a provisional period while it undertakes the verification mentioned in paragraph (2).

(4) Without prejudice to regulation 11, an applicant for approval of a plant protection product under this regulation shall submit with his application—

(a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III; and

(b) for each active substance in the plant protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II except to the extent that he is exempted from doing so by paragraph (5).

(5) Without prejudice to the provisions of regulation 15(1) to (4), an applicant for approval of a plant protection product under this regulation shall be exempted from supplying the information required under paragraph (4)(b) (except for that identifying the active substance) if the active substance—

(a) is already included in Annex I at the time of the application, there being taken into account the conditions of that inclusion; and

(b) does not differ significantly in degree of purity and nature of impurities from the composition registered in the dossier accompanying the original application for inclusion of the active substance in Annex I.

(6) An approval granted under this regulation shall specify the requirements and conditions relating to the placing on the market and use of the product and such requirements and conditions shall include all those necessary to comply with regulation 6(3)(a) to (e).

(7) Any person who contravenes or causes or permits any person to contravene any requirement or condition of an approval granted under this regulation shall be guilty of an offence.

General requirements for granting standard approvals

6.—(1) The Department shall not approve a plant protection product under regulation 5 unless the requirements set out in paragraphs (2) to (7) are satisfied.

(2) The active substances of the plant protection product shall have been included in Annex I at the time the approval is granted and any conditions laid down in that Annex shall have been fulfilled.

(3) Having regard to current scientific and technical knowledge and upon the appraisal of the dossier submitted for the approval of the product, it shall have been established (pursuant to the uniform principles provided for in Annex VI) that, when used in accordance with regulation 3(2) and having regard to all normal conditions under which it may be used and the consequences of its use, the plant protection product—

(a) is sufficiently effective;

(b) has no unacceptable effects on plants or plant products;

(c) does not cause unnecessary suffering and pain to vertebrates which are to be controlled;

(d) has no harmful effect directly or indirectly on human or animal health (for example, through drinking water, food or feed) or on ground water;

(e) has no unacceptable influence on the environment, having particular regard to—

(i) its fate and distribution in the environment, particularly contamination of water (including drinking water and ground water); and

(ii) its impact on non-target species; and

(f) can be used in such a way that any provisional maximum residue levels determined by the Department under paragraph (7) or by the Commission under Article 4(1)(f) are not exceeded.

(4) The Department, pursuant to the uniform principles provided for in Annex VI, shall have determined the nature and quantity of the active substances of the plant protection product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, applying methods which, until harmonised methods have been adopted under Article 4(1)(c), it has determined are appropriate.

(5) The Department, pursuant to the uniform principles provided for in Annex VI, shall have determined the residues of the plant protection product, resulting from approved uses, which are of toxicological or environmental significance, by applying appropriate methods in general use.

(6) The Department, pursuant to the uniform principles provided for in Annex VI, shall have determined the physical and chemical properties of the plant protection product and shall have adjudged them to be acceptable for the purposes of the appropriate use and storage of the product.

(7) The Department shall have determined provisional maximum residue levels for the agricultural products referred to in the approval and shall have notified them to the Commission.

(8) The Department shall ensure that compliance with the requirements set out in paragraphs (2) to (7) is achieved by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product and representative of those prevailing where the product is intended to be used.

Provisional approvals

7.—(1) The Department may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, approve, for a provisional period not exceeding three years, the placing on the market and use of any plant protection product containing a new active substance which is not included in Annex I, provided that the conditions specified in paragraph (2) are satisfied.

(2) The conditions mentioned in paragraph (1) are—

(a) a dossier on the active substance has been submitted in accordance with regulation 4(1) and satisfies the requirements of Annexes II and III in relation to the projected uses;

(b) the Department has established that the active substance can satisfy the requirements of Article 5(1) and that the plant protection product may be expected to satisfy the requirements of regulation 6(3) to (7).

(3) When the conditions specified in paragraph (2) have been satisfied the Department shall immediately inform the relevant competent authorities and the Commission of its assessment of the dossier and of the terms of the approval, giving at least the information provided for in Article 12(1).

(4) If, following the examination provided for in Article 6(3) of a dossier submitted under regulation 4(1), it is decided, in accordance with the procedure laid down in Article 19, that the active substance does not satisfy the requirements specified in Article 5(1), the Department shall withdraw the provisional approval.

(5) Before the expiry of an approval under paragraph (1) and at the request of the approval holder, the Department may, subject to Article 8(1), extend that approval.

(6) The Department shall ensure that compliance with the requirements set out in regulation 6(2) to (7) is achieved by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product and representative of those prevailing where the product is intended to be used in Northern Ireland.

(7) An approval granted under this regulation shall specify the requirements and conditions relating to the placing on the market and use of the product and such requirements and conditions shall include at least all those necessary to comply with regulation 6(3)(a) to (e).

(8) Any person who contravenes or causes or permits any person to contravene any requirement or condition of an approval granted under this regulation shall be guilty of an offence.

Emergency approvals

8.—(1) For the purpose of addressing a danger falling within Article 8(4), the Department may approve, for a period not exceeding 120 days, the placing on the market and use of any plant protection product not complying with regulation 6 for a limited and controlled use.

(2) An approval granted under this regulation shall specify the requirements and conditions relating to the placing on the market and use of the product.

(3) Any person who contravenes or causes or permits any person to contravene any requirement or condition of an approval granted under this regulation shall be guilty of an offence.

Approvals for research and development

9.—(1) A person shall not carry out any experiment or test for research or development purposes involving the release into the environment of a plant protection product which has not been approved under regulations 5, 7, 8 or 11 unless an approval for trial purposes has been granted by the Department under this regulation in respect of that product.

(2) Subject to paragraph (3), any person who wishes to obtain an approval under this regulation shall submit an application to the Department before the commencement of the experiment or test, together with a dossier containing all the available information, so as to permit an assessment to be made of possible effects on human or animal health or the possible impact on the environment.

(3) Paragraph (2) shall not apply if the Department has granted the applicant the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

(4) An approval granted under this regulation shall specify the requirements and conditions relating to the release into the environment of the product, which shall include a specification of the controlled conditions for carrying out the test, the quantities and area or location in respect of which the approval shall apply and any conditions imposed under paragraph (5).

(5) If the proposed experiments or tests referred to in paragraph (1) are liable to have harmful effects on human or animal health or to have an unacceptably adverse influence on the environment, the Department may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.

(6) This regulation shall not apply to experiments or tests covered by Part B of Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms(**a**).

(7) Any person who contravenes or causes or permits any person to contravene—

(a) paragraph (1); or

(b) any requirement or condition of an approval granted under this regulation,

shall be guilty of an offence.

(**a**) O.J. No. L106, 17.4.2001, p. 1 as last amended by Regulation (EC) No. 1830/2003 of the European Parliament and Council (O.J. No. L268, 18.10.2003, p. 24)

Extensions of approved use

10.—(1) Official or scientific bodies involved in agricultural activities or professional agricultural organisations and professional users may apply to the Department for the approved use of a plant protection product in Northern Ireland to be extended to purposes other than those for which the approval of that product was granted.

(2) The Department shall grant an extension under paragraph (1) when it considers that it is in the public interest and if—

(a) the documentation and information to support the extension have been submitted by the applicant for extension;

(b) the Department has established that the conditions referred to in regulation 6(3)(c), (d) and (e) are satisfied;

(c) the intended use is minor in nature; and

(d) users are fully and specifically informed as to instructions for use.

(3) An extension granted under paragraph (1) shall be for such a period, not extending beyond the expiry of the period for the approved use of the plant protection product, as may be specified in the extension and shall specify the requirements and conditions relating to the extended use of the product.

(4) Any person who contravenes or causes or permits any person to contravene any requirement or condition of an extension granted under paragraph (1) shall be guilty of an offence.

Mutual recognition of approvals

11.—(1) Where—

(a) a plant protection product has been authorised under the Directive to be placed on the market and used in another EEA State,

(b) all the active substances contained in that plant protection product are included in Annex I, and

(c) the agricultural, plant health and environmental (including climatic) conditions relevant to the use of the plant protection product in that other EEA State are comparable to those in Northern Ireland.

any person may apply to the Department for approval of that plant protection product under this regulation.

(2) An applicant for an approval under this regulation must substantiate the comparability condition referred to in paragraph (1)(c) with documentary evidence.

(3) To the extent that it is satisfied that that comparability condition is met, the Department shall not require the repetition of tests and analyses already carried out in connection with the authorisation of the plant protection product in that other EEA State and shall grant the application.

(4) An approval granted under this regulation may specify conditions, resulting from the implementation of other measures in accordance with Community law, relating to the conditions for distribution and use of plant protection products in question that are intended to protect the health of the distributors, users and workers concerned.

(5) An approval granted under this regulation may also specify conditions by way of restrictions on use which arise from differences in dietary patterns between Northern Ireland and the EEA State concerned and which are necessary in order to avoid exposure of consumers of treated products to the risks of dietary contamination in excess of the acceptable daily intake of the residues concerned.

(6) An approval granted under this regulation may, with the agreement of the applicant, specify modifications in the requirements or conditions of use subject to which the plant protection product was authorised in order to render any non-comparable agricultural, plant health or

environmental (including climatic) conditions irrelevant for the purpose of satisfying the comparability condition.

(7) Any person who contravenes or causes or permits any person to contravene any requirement or condition of an approval granted under this regulation shall be guilty of an offence.

Provisional restrictions and prohibitions

12.—(1) Where the Department reasonably considers that a product which it has approved, or is required to approve, under regulation 11 constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit its sale or use in Northern Ireland and shall immediately notify the holder of the approval or the applicant (as the case may be), the relevant competent authorities and the Commission of such action, giving reasons for the decision.

(2) A provisional restriction or prohibition under paragraph (1) shall survive so long as its survival is consistent with Article 11(2).

Applications, reviews, revocations and modifications

13.—(1) An application for approval of a plant protection product under regulations 5, 7, 8 or 11 shall be made to the Department by or on behalf of the person responsible for first placing it on the market in Northern Ireland.

(2) For the purpose of any application for an approval under these Regulations or for an extension of use under regulation 10—

(a) the applicant shall have a permanent office in an EEA State;

(b) the applicant's principal place of business in the United Kingdom shall be situated in Northern Ireland;

(c) the application shall be in English;

(d) samples of the preparation and of its ingredients shall be provided if requested by the Department.

(3) The Department may review an approval granted under regulation 5 or 7 or an extension of use granted under regulation 10 if there are indications that any of the relevant requirements are no longer satisfied.

(4) When reviewing an approval or extension of use under paragraph (3) the Department may require the holder of the approval or extension of use to submit further information necessary for the review and the approval or extension of use may, where necessary, be extended for the period required to provide such further information and complete the review.

(5) Without prejudice to any decision already taken pursuant to regulation 11, the Department, in relation to any approval granted under these Regulations or extension of use granted under regulation 10—

(a) shall revoke the approval or extension of use if it is established that—

(i) the requirements for obtaining the approval or extension of use are not or are no longer satisfied; or

(ii) false or misleading particulars were supplied concerning the facts on the basis of which the approval or extension of use was granted;

(b) may revoke the approval or extension of use if it is established that any requirement or condition which is—

(i) specified in the approval or extension of use; or

(ii) required by the approval or extension of use to be on the labelling,

is not or is no longer satisfied;

(c) may revoke the approval or extension of use at the request of the holder of the approval or the extension of use, who shall state the reasons for such a request.

(6) Where the Department revokes an approval or extension of use under paragraph (5), it shall immediately inform the holder of the approval or extension of use of such revocation and may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks, of a length commensurate with the reason for the revocation, without prejudice to any period provided for by a decision taken under Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances(**a**) or to Article 6(1) or 8(1) or (2).

(7) Without prejudice to any decision already taken pursuant to regulation 11, and subject to paragraph (8), the Department, in relation to any approval granted under these Regulations or extension of use granted under regulation 10—

(a) shall modify the approval or extension of use if it is established that on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified;

(b) may modify the approval or extension of use at the request of the holder of the approval or the extension of use, who shall state the reasons for such a request.

(8) The Department may modify an approval or an extension of use under paragraph (7) if it is established that the relevant requirements continue to be satisfied.

(9) Before revoking an approval or extension of use under paragraph (5)(a) or (b), or modifying an approval or extension of use under paragraph (7)(a), the Department shall notify the holder of the approval or extension of use of its intention to revoke or modify the approval or extension of use (and of its grounds for doing so) and shall allow him such opportunity (if any) to make representations as the Department shall consider reasonable having regard to the reason why it thinks the revocation or modification is required.

(10) Where, in the case of a revocation or modification referred to in paragraph (9), the Department does not allow any opportunity to make representations, it shall notify the holder in question as soon as is reasonably practicable of its grounds for not allowing it.

(11) In this regulation "the relevant requirements" means—

(a) in the case of an approval granted under regulation 5, the requirements of regulation 6(2) to (7);

(b) in the case of an approval granted under regulation 7, the requirements of regulation 6(3) to (7);

(c) in the case of an extension of use granted under regulation 10, the requirements of regulation 6(3)(c), (d) and (e).

Notification of information on potentially dangerous effects

14.—(1) The holder of any approval of a plant protection product granted under these Regulations or the holder of any extension of use of a plant protection product granted under regulation 10 shall immediately notify the Department, the relevant competent authorities and the Commission of all new information on the potentially dangerous effects of that plant protection product, or of residues of an active substance contained in that plant protection product, on human or animal health, ground water or the environment.

(2) Any person who contravenes or causes or permits any person to contravene paragraph (1) shall be guilty of an offence.

Data protection

15.—(1) Subject to paragraph (2), the Department shall not make use of any information provided in accordance with Annex II by an applicant for approval of a plant protection product

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(**a**) O.J. No. L33, 8.2.79, p. 36 as last amended by Regulation (EC) No. 850/2004 of the European Parliament and the Council (O.J. No. L158, 30.4.2004, p. 7)

under regulation 5 or 7 for the benefit of any other applicant for approval of a plant protection product under regulation 5 or 7.

(2) The Department may make use of such information in the circumstances provided for in Article 13(3).

(3) Subject to paragraph (4), the Department shall not make use of any information provided in accordance with Annex III by an applicant for approval of a plant protection product under regulation 5 or 7 for the benefit of any other applicant for approval of a plant protection product under regulation 5 or 7.

(4) The Department may make use of such information in the circumstances provided for in Article 13(4).

(5) The Department, following examination of an application for approval of a plant protection product under regulation 5 or 7, shall inform the Commission of instances where it considers that an active substance as included in Annex I has been produced by a person or manufacturing process other than those specified in the dossier on the basis of which that active substance was first included in Annex I and shall transmit to the Commission all relevant information regarding the identity and impurities of that active substance.

Duplication of experiments

16.—(1) Without prejudice to regulations 5(4) or 11, where an active substance has been included in Annex I—

(a) any person who intends to apply for approval under regulation 5 or 7 of a plant protection product containing that substance, and who intends to use that plant protection product in an experiment involving vertebrate animals, shall enquire of the Department—

(i) whether approval has already been granted for that plant protection product and, if so,

(ii) as to the name and address of any holder of a previous or existing approval,

and shall supply evidence that he intends to apply for approval on his own behalf and that the other information specified in regulation 5(4) is available;

(b) the Department, if satisfied that that person intends to make such an application, shall provide him with the name and address of the holder or holders of previous or existing approvals and at the same time inform the holders of those approvals of the name and address of that person.

(2) The holder or holders of previous or existing approvals of a plant protection product and any person intending to make the application for an approval of the same product shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

(3) Where a person requests any information with a view to inclusion of an old active substance in Annex I, the Department shall encourage holders of such information to co-operate in the provision of the requested information, with a view to limiting the duplication of testing on vertebrate animals.

(4) Where a person who intends to apply for approval of a plant protection product and holders of previous or existing approvals of the same product cannot reach an agreement on the sharing of information, the Department may give such directions about the sharing of the information to that person and those holders of previous or existing approvals located within Northern Ireland as appear to it to be necessary or expedient to avoid duplicate testing on vertebrate animals and such directions shall, in particular, determine both the procedure for utilising the information and the reasonable balance of the interests of the parties concerned.

(5) Any person who—

(a) fails to make enquiries as required in paragraph (1)(a); or

(b) fails to comply with a direction made by the Department under paragraph (4),

shall be guilty of an offence.

(6) Any person who causes or permits any person to—

(a) fail to make enquiries as required in paragraph (1)(a); or

(b) fail to comply with a direction made by the Department under paragraph (4),

shall be guilty of an offence.

Confidentiality

17.—(1) Subject to paragraph (2) and (4), where an applicant for the inclusion of an active substance in Annex I or an applicant for approval of a plant protection product so requests, the Department shall treat any information submitted by that applicant as confidential to the extent that in the opinion of the Department that information contains industrial or commercial secrets.

(2) The Department shall not treat as confidential the information, submitted by an applicant, specified in Schedule 2 and, once his application has been granted, the Department may make that information available to any person for inspection.

(3) If subsequent to the request mentioned in paragraph (1) the applicant discloses any information which is confidential by virtue of this regulation, he shall inform the Department accordingly.

(4) This regulation—

(a) is without prejudice to the provisions of the Environmental Information Regulations 2004(**a**), and

(b) does not prohibit the provision, to any authority responsible for exercising any function under any equivalent provision, of information which the Department considers will assist the authority in exercising it.

Packaging

18.—(1) A person shall not place on the market a plant protection product unless the packaging of that product satisfies the following requirements—

(a) the packaging must be so designed and constructed that its contents cannot escape (unless special safety devices have been prescribed);

(b) the materials constituting the packaging and fastenings must not be susceptible to attack by the contents, or liable to form harmful or dangerous compounds with the contents;

(c) the packaging and fastenings must be strong and solid throughout so as to ensure that they will not come apart and will safely withstand normal handling;

(d) containers with fastening devices must be so designed that the container can be repeatedly refastened so that the contents cannot escape.

(2) Any person who contravenes or causes or permits any person to contravene paragraph (1) shall be guilty of an offence.

Labelling

19.—(1) A person shall not place on the market a plant protection product unless—

(a) the labelling of the packaging in which the product is contained satisfies the requirements specified in paragraphs 1 to 6 of Schedule 3; and

(b) he has complied with any requirement imposed by the Department under paragraph 7 of that Schedule.

(2) Any person who contravenes or causes or permits any person to contravene paragraph (1) shall be guilty of an offence.

(**a**) S.I. 2004/3391

Seizure and disposal of plant protection products

20.—(1) Where there has been a contravention, in relation to any plant protection product, of any prohibition, requirement or condition imposed by or under these Regulations or an equivalent provision, in relation to that plant protection product, any Northern Ireland Department shall have the power—

(a) to seize or dispose of the plant protection product or require the holder of any approval relating to that product, or any other person appearing to that Department to be the owner or the person in charge of that product, to dispose of it;

(b) to seize or dispose of anything treated with the product or require any person appearing to that Department to be the owner or the person in charge of anything so treated to dispose of it;

(c) to require the holder of any approval relating to that product, or any other person appearing to that Department to be the owner or the person in charge of the product, to take such remedial action as appears to that Department to be necessary as a result of the contravention including, where it appears to be necessary as a result of the contravention, recovery of the product from the market in Northern Ireland.

(2) If any plant protection product has been imported into Northern Ireland in contravention of these Regulations, the Department may, by notice in writing served on the person appearing to it to be the owner, the importer or the person in charge of the product, require that it shall be exported from Northern Ireland within such reasonable period as the Department may determine.

(3) Any person who contravenes or causes or permits any person to contravene any requirement imposed under this regulation shall be guilty of an offence.

General offences

21.—(1) Where in relation to an application for an approval under these Regulations, an application for an extension of use under regulation 10 or a requirement or condition specified in such an approval or extension of use, any person—

(a) makes a statement which he knows to be false in a material particular;

(b) recklessly makes a statement which is false in a material particular; or

(c) intentionally fails to disclose any material particular,

he shall be guilty of an offence.

(2) Where in relation to an application for an approval under these Regulations, an application for an extension of use under regulation 10 or a requirement or condition specified in such an approval or extension of use, any person ("the first mentioned person") causes or permits any person—

(a) to make a statement which the first mentioned person knows to be false in a material particular or is reckless as to whether it is false in a material particular; or

(b) to fail to disclose any particular which the first mentioned person knows or believes to be material,

the first mentioned person shall be guilty of an offence.

(3) Any person who—

(a) intentionally obstructs an officer in the performance of any of his functions under regulation 24;

(b) fails to comply with a requirement made or direction given by an officer in the performance of his functions under regulation 24; or

(c) in purporting to give information required by an officer for the performance of any of his functions under regulation 24—

(i) makes a statement which he knows to be false in a material particular;

(ii) recklessly makes a statement which is false in a material particular; or

(iii) intentionally fails to disclose any material particular;

shall be guilty of an offence.

(4) In this regulation "officer" shall have the same meaning as provided for in paragraph 1(c) of Schedule 2 to the 1985 Act, as read with regulation 24.

Penalties

22.—(1) A person guilty of an offence under regulation 3(6), 5(7), 7(8), 8(3), 9(7), 10(4), 11(7), 18(2), 19(2), 20(3) or 21(1) or (2) shall be liable—

(a) on summary conviction, to a fine of an amount not exceeding the statutory maximum; and

(b) on conviction on indictment, to a fine.

(2) A person guilty of an offence under regulation 14(2), 16(5) or (6) or 21(3) shall be liable on summary conviction to a fine of an amount not exceeding level 5 on the standard scale.

(3) Proceedings for any offence under these Regulations may be taken, and the offence may for the purposes of the jurisdiction of the court to try the offences be treated as having been committed, in any place in Northern Ireland.

(4) It shall be a defence in proceedings for an offence under section 22(2)(b) of the Welfare of Animals Act (Northern Ireland) 1972(**a**) (which restricts the placing on land of poison and poisonous substances) for the person charged to show that he acted in accordance with an approval granted under these Regulations and, where appropriate, an extension of use granted under regulation 10.

General defence of due diligence

23.—(1) In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) Without prejudice to the generality of paragraph (1), a person is to be taken to have established the defence provided by that paragraph if he proves—

(a) that he acted under instructions given to him by his employer; or

(b) that he acted in reliance on information supplied by another person without any reason to suppose that the information was false or misleading,

and in either case that he took all such steps as were reasonably open to him to ensure that no offence would be committed.

(3) If in any case the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to an act or omission by another person, other than the giving of instructions to the person charged with the offence by his employer, or to reliance on information supplied by another person, the person charged shall not, without leave of the court, be entitled to rely on that defence unless within a period ending seven clear days before the hearing, he has served on the prosecutor a notice giving such information identifying or assisting in the identification of that other person as was then in his possession.

Enforcement

24.—(1) Section 19 of, and paragraphs 1(c), 2 and 4 to 9 of Schedule 2 to, the 1985 Act (enforcement powers) shall have effect for the purposes of these Regulations as they have effect for the purpose of that Act and as if—

(a) any reference in that section, or in those paragraphs, to that Act or a Part of it were a reference to these Regulations;

(**a**) 1972 c. 7

(b) any reference in that section to a pesticide were a reference to a plant protection product; and

(c) any reference in that section to an offence under section 16(12)(a) of that Act were a reference to an offence to which this regulation applies.

(2) This regulation applies to any offence under regulation 3(6), 5(7), 7(8), 8(3), 9(7), 10(4), 11(7), 14(2), 16(5) or (6), 18(2), 19(2) or 20(3).

Service of documents

25.—(1) For the purpose of these Regulations the address of the principal office of a company registered outside the United Kingdom or of a partnership carrying on business outside the United Kingdom is the address of its principal office within the United Kingdom.

(2) Without prejudice to section 24 of the Interpretation Act (Northern Ireland) 1954, if a person to be served under these Regulations with any document has specified to the Department an address within the United Kingdom (other than an address determined under paragraph (1)) as the one at which he or someone on his behalf will accept documents of the same description as that document, the address so specified shall also be treated as his usual address for the purposes of these Regulations.

Transitional provisions

26. Schedule 4 shall have effect.

Disapplication

27.—(1) The 1987 Regulations shall not apply to any plant protection product the placing on the market and use of which are, or under Schedule 4 have become, subject to the prohibitions specified in regulation 3(1) and (2).

(2) The 1987 Regulations shall not apply to any plant protection product which is approved under regulation 9.

(3) The Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2002(**a**) shall not apply to any plant protection product to the extent that regulation 19 applies to it.

Revocation

28. The Plant Protection Products Regulations (Northern Ireland) 2004(**b**) and the Plant Protection Products (Amendment) Regulations (Northern Ireland) 2004(**c**) are hereby revoked.

(**a**) S.R. 2002 No. 301
(**b**) S.R. 2004 No. 126
(**c**) S.R. 2004 No. 411

Sealed with the Official Seal of the Department of Agriculture and Rural Development on 29th November 2005.

D. Small
A senior officer of the Department of Agriculture and Rural Development

SCHEDULE 1

Regulation 2

INSTRUMENTS AMENDING COUNCIL DIRECTIVE 91/414/EEC

Part I

Instruments in force

Instruments	*Active substances added to Annex I*
Commission Directive 93/71/EEC(**a**);	None
Commission Directive 94/37/EC(**b**);	None
Commission Directive 94/79/EC(**c**);	None
Commission Directive 95/35/EC(**d**);	None
Commission Directive 95/36/EC(**e**);	None
Commission Directive 96/12/EC(**f**);	None
Commission Directive 96/46/EC(**g**);	None
Commission Directive 96/68/EC(**h**);	None
Council Directive 97/57/EC(**i**);	None
Commission Directive 2000/80/EC(**j**);	Azimsulfuron, azoxystrobin, bentazone esfenvalerate, fluroxypyr, imazalil, kresoxim-methyl, lambda-cyhalothrin, metsulfuron-methyl, prohexadione-calcium, spiroxamine and triasulfuron
Commission Directive 2001/21/EC(**k**);	Amitrole, diquat, pyridate and thiabendazole
Commission Directive 2001/28/EC(**l**);	fenhexamid
Commission Directive 2001/36/EC(**m**);	None
Commission Directive 2001/47/EC(**n**);	*Paecilomyces fumosoroseus*
Commission Directive 2001/49/EC(**o**);	Flupyrsulfuron-methyl
Commission Directive 2001/87/EC(**p**);	Acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl
Commission Directive 2001/99/EC(**q**);	Glyphosate and thifensulfuron-methyl
Commission Directive 2001/103/EC(**r**);	2,4-dichlorophenoxy acetic acid
Commission Directive 2002/18/EC(**s**);	Isoproturon
Commission Directive 2002/37/EC(**t**);	Ethofumesate

(**a**) O.J. No. L221, 31.8.93, p. 27 (to be read with Corrigenda published in O.J. No. L4, 6.1.96, p. 16)
(**b**) O.J. No. L194, 29.7.94, p. 65
(**c**) O.J. No. L354, 31.12.94, p. 16 (to be read with Corrigenda published in O.J. No. L280, 23.11.95, p. 58)
(**d**) O.J. No. L172, 22.7.95, p. 6
(**e**) O.J. No. L172, 22.7.95, p. 8
(**f**) O.J. No. L65, 15.3.96, p. 20
(**g**) O.J. No. L214, 23.8.96, p. 18
(**h**) O.J. No. L277, 30.10.96, p. 25
(**i**) O.J. No. L265, 27.9.97, p. 87
(**j**) O.J. No. L309, 9.12.2000, p. 14
(**k**) O.J. No. L69, 10.3.2001, p. 17
(**l**) O.J. No. L113, 24.4.2001, p. 5
(**m**) O.J. No. L164, 20.6.2001, p. 1
(**n**) O.J. No. L175, 28.6.2001, p. 21
(**o**) O.J. No. L176, 29.6.2001, p. 61
(**p**) O.J. No. L276, 19.10.2001, p. 17
(**q**) O.J. No. L304, 21.11.2001, p. 14
(**r**) O.J. No. L313, 30.11.2001, p. 37
(**s**) O.J. No. L55, 26.2.2002, p. 29
(**t**) O.J. No. L117, 4.5.2002, p. 10

Commission Directive 2002/48/EC(**a**);	Iprovalicarb, prosulfuron and sulfosulfuron
Commission Directive 2002/64/EC(**b**);	Cinidon-ethyl, cyhalofop-butyl, famoxadone, florasulam, metalaxyl-M and picolinafen
Commission Directive 2002/81/EC(**c**);	Flumioxazine
Commission Directive 2003/5/EC(**d**);	Deltamethrin
Commission Directive 2003/23/EC(**e**);	Cyazofamid, ethoxysulfuron, foramsulfuron, imazamox, oxadiargyl and oxasulfuron
Commission Directive 2003/31/EC(**f**);	2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide, and pendimethalin
Council Regulation (EC) No. 806/2003(**g**);	None
Commission Directive 2003/39/EC(**h**);	Propyzamide and propineb
Commission Directive 2003/68/EC(**i**);	Carfentrazone-ethyl, fenamidone, isoxaflutole, mesotrione and trifloxystrobin
Commission Directive 2003/70/EC(**j**);	Mecoprop, mecoprop-P and propiconazole
Commission Directive 2003/79/EC(**k**);	*Coniothyrium minitans*
Commission Directive 2003/81/EC(**l**);	molinate, thiram and ziram
Commission Directive 2003/82/EC(**m**);	None
Commission Directive 2003/84/EC(**n**);	Dimethenamid-p, flufenacet, flurtamone, fosthiazate, iodosulfuron, picoxystrobin and silthiofam
Commission Directive 2003/112/EC(**o**);	Paraquat
Commission Directive 2003/119/EC(**p**);	Mesosulfuron, propoxycarbazone and zoxamide
Commission Directive 2004/20/EC(**q**);	Chlorpropham
Commission Directive 2004/30/EC(**r**);	Benzoic acid, flazasulfuron and pyraclostrobin
Commission Directive 2004/58/EC(**s**);	Alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham
Commission Directive 2004/60/EC(**t**);	Quinoxyfen
Commission Directive 2004/62/EC(**u**);	Mepanipyrim
Council Directive 2004/66/EC(**v**);	None
Commission Directive 2004/71/EC(**w**);	*Pseudomonas chlororaphis*

(**a**) O.J. No. L148, 6.6.2002, p. 19
(**b**) O.J. No. L189, 18.7.2002, p. 27
(**c**) O.J. No. L276, 12.10.2002, p. 28
(**d**) O.J. No. L8, 14.1.2003, p. 7
(**e**) O.J. No. L81, 28.3.2003, p. 39
(**f**) O.J. No. L101, 23.4.2003, p. 3
(**g**) O.J. No. L122, 16.5.2003, p. 1 (to be read with Corrigenda published in O.J. No. L138, 5.6.2003, p. 49)
(**h**) O.J. No. L124, 20.5.2003, p. 30
(**i**) O.J. No. L177, 16.7.2003, p. 12 as amended by Directive 2004/65/EC published in O.J. No. L125, 28.4.2004, p. 43
(**j**) O.J. No. L184, 23.7.2003, p. 9
(**k**) O.J. No. L205, 14.8.2003, p. 16 as amended by Directive 2004/63/EC published in O.J. No. L125, 28.4.2004, p. 41
(**l**) O.J. No. L224, 6.9.2003, p. 29
(**m**) O.J. No. L228, 12.9.2003, p. 11
(**n**) O.J. No. L247, 30.9.2003, p. 20 as amended by Directive 2004/64/EC published in O.J. No. L125, 28.4.2004, p. 42
(**o**) O.J. No. L321, 6.12.2003, p. 32
(**p**) O.J. No. L325, 12.12.2003, p. 41
(**q**) O.J. No. L70, 9.3.2004, p. 32
(**r**) O.J. No. L77, 13.3.2004, p. 50
(**s**) O.J. No. L120, 24.4.2004, p. 26
(**t**) O.J. No. L120, 24.4.2004, p. 39 as amended by Directive 2004/97/EC published in O.J. No. L301, 28.9.2004, p. 53
(**u**) O.J. No. L125, 28.4.2004, p. 38
(**v**) O.J. No. L168, 1.5.2004, p. 35
(**w**) O.J. No. L127, 29.4.2004, p. 104

Commission Directive 2004/99/EC(**a**);	Acetamiprid and thiacloprid
Commission Directive 2005/2/EC(**b**);	*Ampelomyces quisqualis* and g*liocladium catenulatum*
Commission Directive 2005/3/EC(**c**);	Imazosulfuron, laminarin, methoxyfenozide and s-metolachlor
Council Directive 2005/25/EC(**d**)	None
Commission Directive 2005/34/EC(**e**)	Etoxazole and tepraloxydim

Part II

Instruments coming into force

Instruments	*Active substances added to Annex I*
From 1st March 2006:	
Commission Directive 2005/53/EC(**f**)	Chlorothalonil, chlorotoluron cypermethrin, daminozide and thiophanate-methyl
From 1st March 2006:	
Commission Directive 2005/54/EC(**g**)	Tribenuron
From 1st May 2006:	
Commission Directive 2005/57/EC(**h**)	MCPA and MCPB
From 1st December 2005:	
Commission Directive 2005/58/EC(**i**)	Bifenazate and milbemectin
From 1st July 2006:	
Commission Directive 2005/72/EC(**j**)	Chlorpyriphos, chlorpyriphos-methyl, mancozeb, maneb and metiram

(**a**) O.J. No. L309, 6.10.2004, p. 6
(**b**) O.J. No. L20, 22.1.2005, p. 15
(**c**) O.J. No. L20, 22.1.2005, p. 19
(**d**) O.J. No. L90, 8.4.2005, p. 1
(**e**) O.J. No. L125, 18.5.2005, p. 5
(**f**) O.J. No. L241, 17.9.2005, p. 51
(**g**) O.J. No. L244, 20.9.2005, p. 21
(**h**) O.J. No. L246, 22.9.2005, p. 14
(**i**) O.J. No. L246, 22.9.2005, p. 17
(**j**) O.J. No. L279, 22.10.2005, p. 63

SCHEDULE 2

Regulation 17

NON-CONFIDENTIAL INFORMATION

1. The name and content of the active substance and the name of the plant protection product.

2. The name of other substances which are regarded as dangerous under—

(a) Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(**a**); and

(b) Council Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations(**b**).

3. Physico-chemical data concerning the active substance and plant protection product.

4. Any ways of rendering the active substance or plant protection product harmless.

5. A summary of the results of the tests to establish the efficacy and harmlessness to humans, animals, plants and the environment of the active substance or the plant protection product.

6. Recommended methods and precautions to reduce handling, storage, transport, fire or other hazards.

7. The methods of analysis referred to in regulation 6(4) and (5) and Article 5.1.

8. Methods of disposal of the product and of its packaging.

9. Decontamination procedures to be followed in the case of accidental spillage or leakage.

10. First aid and medical treatment to be given in the case of injury to persons.

SCHEDULE 3

Regulation 19

LABELLING REQUIREMENTS

1. The packaging containing the plant protection product shall be marked clearly and indelibly with the following information—

(a) the trade name or designation of the plant protection product;

(b) the name and address of the holder of the relevant approval and the approval number of the plant protection product and, if different, the name and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market;

(c) the name and the amount of each active substance; the name must be—

(i) the same as that listed in Annex I to Council Directive 67/548/EEC, if any;

(ii) the common name given by the International Organisation for Standardization, if any; or

(iii) its chemical designation according to the rules of the International Union of Pure and Applied Chemistry contained in the Nomenclature of Organic Chemistry, 1979

(**a**) O.J. No. L196, 16.8.67, p. 1 (O.J./S.E. 1967 p. 234) as last amended by Commission Directive 2004/73/EC (O.J. No. L152, 30.4.2004, p. 1)

(**b**) O.J. No. L200, 30.7.1999, p. 1 as last amended by Council Directive 2004/66/EC (O.J. No. L168, 1.5.2004, p. 35)

edition(**a**) as read with A Guide to IUPAC Nomenclature of Organic Compounds (recommendations 1993)(**b**);

(d) the net quantity of plant protection product given in legal units of measurement;

(e) the formulation batch number or some means of identifying it;

(f) the particulars required for the product in Articles 10 to 12 of Council Directive 1999/45/EC;

(g) the nature of any special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those given in Annex IV;

(h) safety precautions for the protection of humans, animals or the environment, in the form of standard phrases selected as appropriate from those given in Annex V;

(i) the type of action of the plant protection product;

(j) the type of preparation;

(k) the uses for which the plant protection product has been approved and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used;

(l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the approval;

(m) where necessary, the safety interval for each use between application and—

(i) sowing or planting of the crop to be protected;

(ii) sowing or planting of succeeding crops;

(iii) access by humans or animals;

(iv) harvesting; and

(v) use or consumption;

(n) particulars of possible phytotoxicity, varietal susceptibility and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of—

(i) the crop in question; or

(ii) subsequent crops;

(o) if accompanied by a leaflet, as provided for in paragraph 2, the sentence "Read accompanying instructions before use";

(p) directions for safe disposal of the plant protection product and of the packaging;

(q) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years;

(r) whether the product is restricted to a certain category of user and, if so, which.

2. The requirements specified in paragraphs (l), (m) and (n) of paragraph 1 may be indicated on a separate leaflet accompanying the package if the space available on the package is too small and in such a case the leaflet shall be regarded as part of the label for the purposes of these Regulations.

3. The label of the packaging of the plant protection product must not bear the indications "non-toxic", "harmless" or similar indications.

4. Information to the effect that the plant protection product may be used when bees or other non-target species are active, or when crops or weeds are in flower, or other such phrases to protect bees or other non-target species, may be given on the label if and only if the approval

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(**a**) By J Rigaudy and S P Klesney, published by Pergamon (ISBN 0-08022-3699)

(**b**) By R Panico, W H Powell and J-C Richer, published by Blackwell Science (ISBN 0-63203-4882). Corrections published in Pure Appl.Chem., vol. 71, No. 7, pp. 1327-1330, 1999

relates explicitly to use during the season for bees or other specified organisms and presents minimal risk to them.

5. Labels shall be in English.

6. At any time the Department may require additional phrases to be clearly and indelibly marked on packaging where this is deemed by it to be necessary for the protection of human beings, animals or the environment and where it makes such a requirement it shall do so in writing by notice served on persons holding approvals for the plant protection products concerned.

7. The Department may require any of the persons referred to in paragraph 1(b) at any time to provide it with samples, models or drafts of the packaging, labelling and leaflets referred to in this Schedule.

SCHEDULE 4

Regulation 26

TRANSITIONAL PROVISIONS

Application of these Regulations and of the 1987 Regulations to relevant plant protection products

1. Notwithstanding regulation 3(1) and (2) and subject to the remaining provisions of this Schedule—

(a) these Regulations shall not apply; and

(b) the 1987 Regulations shall continue to apply,

to a relevant plant protection product.

2. Notwithstanding paragraph 1, and subject to paragraphs 3 and 4, regulations 1, 2 and 9 and (insofar as they relate to approvals granted under regulation 9) regulations 13(2) and (5) to 13(10), 14, 17 and 20 to 27 shall apply to a relevant plant protection product.

3. Regulation 9 shall not apply to a relevant plant protection product to which any of the exemptions provided in regulation 3(2)(a) to (c) and (e) to (j) of the 1987 Regulations applies.

4. Notwithstanding regulation 27(2), a pesticide approval in respect of a relevant plant protection product given in the form of an experimental permit under regulation 5(2)(a) of the 1987 Regulations which was in force on 23rd December 1997 shall continue to be subject to the 1987 Regulations and shall continue in force until the date of expiry of such approval or earlier revocation under those Regulations.

Effect of Annex I decisions on the placing on the market and use of relevant plant protection products which are not approved pesticides

5. Where in relation to a relevant plant protection product which is not an approved pesticide it is decided under Article 6—

(a) that the relevant active substances of that product should be included in Annex I, or

(b) that any of the relevant active substances of that product should not be included in Annex I,

the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2).

Effect of a refusal to include an active substance in Annex I on relevant plant protection products which are approved pesticides

6. Where, in relation to a relevant plant protection product which is an approved pesticide, it has been decided under Article 6 that any of its relevant active substances should not be included in Annex I, the Department shall notify the pesticide approval holder of that decision and shall take the action described in paragraph 9(1).

Effect of a decision to include active substances in Annex I on relevant plant protection products which are approved pesticides

7.—(1) Where, in relation to any relevant plant protection product which is an approved pesticide, it has been decided under Article 6 that its relevant active substances should be included in Annex I, the Department shall notify the pesticide approval holder of that fact and the pesticide approval holder shall, within such period as the Department shall notify to the pesticide approval holder, provide information to the Department to show:

(a) that the relevant active substances contained in the plant protection product comply with the conditions of Annex I inclusion; and

(b) that he has access to a dossier satisfying the requirements of Annex II.

(2) After having submitted to the Department the information required under paragraph (1) the pesticide approval holder may continue to place on the market and use the relevant plant protection product until such time as the Department notifies him of its decision that it is or is not satisfied that the information provided shows that the relevant active substances comply with the conditions of Annex I inclusion and that the approval holder has access to a dossier satisfying the requirements of Annex II.

(3) Where the pesticide approval holder fails to provide adequate information to enable the Department to reach a decision, the Department shall notify him of that failure and the pesticide approval holder shall, within such reasonable period as may be specified in the notification, submit further information to the Department to enable it to reach a decision.

(4) Where the Department decides that the information provided under paragraph (1) fails to show that the relevant active substances comply with the conditions of Annex I inclusion and that the approval holder has access to a dossier satisfying the requirements of Annex II it shall take the action described in paragraph 9(1).

8.—(1) Where the Department has determined that the information provided by the approval holder under paragraph 7 shows that the relevant active substances comply with the conditions of Annex I inclusion and that the approval holder has access to a dossier satisfying the requirements of Annex II it shall notify the pesticide approval holder of that fact and the pesticide approval holder shall, within such period as the Department shall notify to the pesticide approval holder, make an application for an approval of the relevant plant protection product under regulation 5.

(2) The pesticide approval shall continue to have effect until such time as the Department notifies the approval holder of its decision to grant or refuse an approval under regulation 5.

(3) Where the pesticide approval holder fails to provide adequate information to enable the Department to consider the application, the Department shall notify him of that failure and the pesticide approval holder shall, within such reasonable period as may be specified in the notification, submit further information to the Department to enable it to consider the application.

Revocation of pesticide approval

9.—(1) The Department shall, at the same time as it notifies a pesticide approval holder of a decision mentioned in paragraph 6, 7(4) or 8(2), revoke the pesticide approval.

(2) The Department may, if any pesticide approval holder fails to comply with a notification given under paragraph 7(1) or (3) or 8(1) or (3), revoke the pesticide approval.

(3) Where the Department revokes a pesticide approval under sub-paragraph (1) or (2), it may revoke that approval—

(a) completely;

(b) in the manner specified in sub-paragraph (4); or

(c) in the manner specified in sub-paragraph (5).

(4) When revoking an approval in the manner mentioned in sub-paragraph (3)(b), the Department shall—

(a) subject to head (b), revoke that approval in so far as it authorises the advertisement, sale, storage, supply and use of that product; and

(b) in the form of a provisional approval granted under regulation 5 of the 1987 Regulations for a period not exceeding one year commencing with the date of that revocation, authorise—

(i) the storage of that product by any person; and

(ii) the advertisement, sale, supply and use of that product by any person other than the pesticide approval holder or the pesticide approval holder's employees or agents.

(5) When revoking an approval in the manner mentioned in sub-paragraph (3)(c), the Department shall—

(a) subject to heads (b) and (c), revoke that approval in so far as it authorises the advertisement, sale, supply, storage and use of that product;

(b) in the form of a provisional approval granted under regulation 5 of the 1987 Regulations for a period not exceeding one year commencing with the date of that revocation, authorise the advertisement, sale, storage, supply and use of that product by any person; and

(c) in the form of a provisional approval granted under regulation 5 of the 1987 Regulations for a period, not exceeding one year following the end of the period of provisional approval granted under head (b), authorise—

(i) the storage of that product by any person; and

(ii) the advertisement, sale, supply and use of that product by any person other than the pesticide approval holder or the pesticide approval holder's employees or agents.

Effect of revocation on the placing on the market and use of the product

10.—(1) Where the Department has revoked a pesticide approval in relation to any relevant plant protection product under paragraph 9(1) or (2) completely, the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2) forthwith.

(2) Where the Department has revoked a pesticide approval in relation to any relevant plant protection product in the manner specified in paragraph 9(4), the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2) on the expiry of the period of the provisional approval granted under paragraph 9(4)(b).

(3) Where the Department has revoked a pesticide approval in relation to any relevant plant protection product in the manner specified in paragraph 9(5), the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2) on the expiry of the period of the provisional approval granted under paragraph 9(5)(c).

Notifications

11. Any notification given by the Department under this Schedule shall be in writing.

Interpretation

12. For the purposes of this Schedule—

"approved pesticide" means a pesticide which is the subject of a pesticide approval;

"pesticide approval" means approval of a pesticide given under regulation 5 of the 1987 Regulations;

"pesticide approval holder" in relation to any pesticide means any person who holds the current pesticide approval for that pesticide;

"relevant active substance" means an active substance contained in a relevant plant protection product which is an approved pesticide;

"relevant plant protection product" means any plant protection product—

(a) which is a pesticide, or substance, preparation or organism prepared or used for any of the purposes mentioned in regulation 3(1)(b) of the 1987 Regulations, and

(b) at least one of whose active ingredients is an old active substance; and

"active ingredient", "advertisement", "organism", "pesticide", "preparation", "sale", "storage", "substance", "supply" and "use" have the same respective meanings as in the 1987 Regulations.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and replace the Plant Protection Products Regulations (Northern Ireland) 2004 (S.R. 2004 No. 126) ("the 2004 Regulations").

The Regulations, which replace the consolidated 2004 Regulations amended by the Plant Protection Products (Amendment) Regulations (Northern Ireland) 2004 (S.R. 2004 No. 411) with modifications, continue to implement as respects Northern Ireland Council Directive 91/414/EEC (O.J. No. L230, 19.8.91, p.1 to be read with Corrigenda published in O.J. No. L170, 25.6.92, p. 40) concerning the placing of plant protection products on the market ("the 1991 Directive"). The Regulations continue to implement the Directives amending the 1991 Directive, up to and including Commission Directive 2004/71/EC and also implement Commission Directives 2004/99/EC, 2005/2/EC and 2005/3/EC, Council Directive 2005/25/EC, Commission Directive 2005/34/EC and (with effect from 1st December 2005) Commission Directive 2005/58/EC, (with effect from 1st March 2006) Commission Directives 2005/53/EC and 2005/54/EC, (with effect from 1st May 2006) Commission Directive 2005/57/EC and (with effect from 1st July 2006) Commission Directive 2005/72/EC which amend the 1991 Directive and which were not covered by the 2004 Regulations – see Schedule 1.

The 1991 Directive was extended to the European Economic Area ("the EEA") by Decision No. 7/94 of the EEA Joint Committee (O.J. No. L160, 28.6.94, p. 1), which amended the European Economic Area Agreement (see Decision 94/1 ECSC, EEC; O.J. No. L1, 3.1.94, p. 1).

The 1991 Directive (as extended to the EEA) establishes an authorisation system whereby plant protection products (defined in the 1991 Directive as active substances and preparations containing one or more active substances intended *inter alia* to protect plants against harmful organisms) may not be placed on the market and used in the territory of an EEA State unless they have been authorised under the 1991 Directive by that EEA State (or, subject to qualifications, by another EEA State). The 1991 Directive (as read with adaptations set out in Decision No. 7/94 of the EEA Joint Committee) establishes uniform rules on the conditions and procedures for authorisation, including rules on the mutual recognition of authorisations between EEA States. The purpose of the system is to ensure that wherever they are placed on the market and used within the EEA plant protection products are effective without causing harm to human or animal health and without adversely affecting plants and ground water or the environment in general.

Before a plant protection product can receive a standard authorisation all its active substances must be included in Annex I to the 1991 Directive although the Directive allows provisional authorisation of a product in advance of such inclusion.

The inclusion of active substances which were on the market of EEA States on or before 26th July 1993 (or, as far as Austria, Finland, Iceland, Liechtenstein, Norway and Sweden are concerned, on or before 1st July 1994 and, as far as the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and Slovakia are concerned, on or before 1st May 2004) are subject to a rolling review programme operated by the European Commission in conjunction with the member States of the European Community, although in transitional provisions set out in the 1991 Directive EEA States are permitted to authorise the placing on the market of products containing such substances until they have been reviewed; whereas inclusion of a new active substance in Annex I requires an application by the person intending to place it on the market.

The 1991 Directive also permits authorisations for short periods in the event of emergency and authorisations for releasing plant protection products into the environment for trial purposes. Authorisations are for fixed periods and in the case of standard authorisations they may be renewed on expiry. They may also be modified, or their range of application may be extended, in certain circumstances. Authorisations are subject to special requirements and conditions determined by the EEA State granting the authorisation, the breach of which would occasion automatic revocation. Authorisations carry a general requirement to notify the authorising EEA State of new information on the potentially dangerous effects of the authorised plant protection product or of residues of its active substances.

The 1991 Directive additionally provides certain data protection and confidentiality safeguards for holders of authorisations (whilst providing in certain circumstances for the release of information to other applicants and for the inspection of information by the public) and makes provision for the sharing of information between applicants and holders of previous authorisations of the same plant protection products with a view to limiting the duplication of tests on vertebrate animals. In addition, it prescribes requirements for labelling and packaging with which plant protection products must comply if they are to be placed on the market in the territory of an EEA State.

The Regulations continue to implement the provisions of the 1991 Directive described above by providing for the authorisation system in Northern Ireland under the operation of the Department of Agriculture and Rural Department ("the Department"). In the Regulations authorisations are described as approvals. The Regulations impose a prohibition on the placing on the market and use of plant protection products unless they have been approved by the Department under the Regulations and are placed on the market and used in accordance with any conditions or requirements specified in their approval (regulation 3(1) and (2)). Persons intending to place new active substances on the market must apply to the Department for such substances to be included in Annex I (regulation 3(3) and 4(1)).

Applications for standard, provisional and emergency approvals of plant protection products and applications for approval of plant protection products already authorised under the 1991 Directive for use in another EEA State are made to the Department by the persons responsible for first placing the products on the market in Northern Ireland (regulations 5 to 8, 11 and 13). Similarly, applications for approvals for trial purposes are made to the Department (regulation 9). The provisions of the 1991 Directive concerning extensions of the range of application of approved plant protection products and the provisions requiring the notification of potentially dangerous effects of approved plant protection products are respectively incorporated in regulations 10 and 14.

The data protection, information-sharing and confidentiality provisions derived from the 1991 Directive are set out in regulations 15, 16 and 17 and Schedule 2 and the provisions concerning the labelling and packaging of plant protection products are set out in regulations 18 and 19 and Schedule 3.

The Regulations confer enforcement powers on officers (who for specified purposes may be officers of district councils) authorised by any Northern Ireland Department, including powers to seize and dispose of plant protection products in the event of a breach of a prohibition, requirement or condition imposed by or under the Regulations, to enter on land and to effect certain other controls (regulations 20 and 24). The Regulations make such breaches a criminal offence (see regulations 3, 5, 7, 8, 9, 10, 11, 14, 16, 18 and 19), create certain other types of offence (regulation 21) and prescribe penalties and defences (regulations 22 and 23).

The transitional and consequential provisions (including those specifying the extent to which the Control of Pesticides Regulations (Northern Ireland) 1987 (S.R. 1987 No. 414) will continue to apply) are contained in regulations 26 and 27 and Schedule 4.

A list of competent authorities of the member States of the European Community, to whom certain information and documents are required under the Regulations to be forwarded, can be obtained from the Pesticides Safety Directorate, Room 308, Mallard House, Kings Pool, 3 Peasholme Green, York YO1 7PX or via the website www.pesticides.gov.uk.

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