Statutory Instrument 2003 No. 3241

The Plant Protection Products Regulations 2003

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STATUTORY INSTRUMENTS

2003 No. 3241

PESTICIDES, ENGLAND AND WALES

The Plant Protection Products Regulations 2003

Made	*10th December 2003*
Laid before Parliament	*10th December 2003*
Coming into force	*31st December 2003*

ARRANGEMENT OF REGULATIONS

1. Title, extent and commencement
2. Interpretation
3. Prohibitions
4. Applications concerning active substances
5. Standard approvals
6. General requirements for granting standard approvals
7. Provisional approvals
8. Emergency approvals
9. Approvals for research and development
10. Extensions of approved use
11. Mutual recognition of approvals
12. Provisional restrictions and prohibitions
13. Applications, reviews, revocations and modifications
14. Notification of information on potentially dangerous effects
15. Data protection
16. Duplication of experiments
17. Confidentiality
18. Packaging
19. Labelling
20. Seizure and disposal of plant protection products
21. General offences
22. Penalties
23. General defence of due diligence
24. Enforcement
25. Service of documents
26. Transitional provisions
27. Disapplication
28. Revocations

1. Instruments amending Council Directive 91/414/EEC

2. Non-confidential information

3. Labelling

4. Transitional provisions

5. Revocations

The Secretary of State for Environment, Food and Rural Affairs and the National Assembly for Wales being designated[1] for the purposes of section 2(2) of the European Communities Act 1972[2] in relation to the common agricultural policy of the European Community, acting jointly (the National Assembly for Wales acting in relation to Wales only), in exercise of the powers conferred upon them by that section, hereby make the following Regulations:

Title, extent and commencement

1. These Regulations may be cited as the Plant Protection Products Regulations 2003, extend to England and Wales, and come into force on 31st

December 2003.

Interpretation

2. - (1) In these Regulations -

"the 1985 Act" means the Food and Environment Protection Act 1985[3];

"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 Secretary of State, 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 England and Wales and "approved" shall be construed accordingly;

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

"contravenes" includes "fails to comply with";

"the Directive" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market[4], as amended by the instruments listed in Schedule 1;

"the EEA" means the European Economic Area established under the EEA Agreement;

"the EEA Agreement" means the Agreement on the EEA signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993;

"EEA State" means a State which is a Contracting Party to the EEA Agreement;

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

"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;

"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 any active substance which is not an old active substance;

"old active substance" means any active substance which was on the market -

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

(b) in any other state within the EEA, on or before 26th July 1993;

"placing on the market" means any supply, whether in return for payment or not, within England and Wales, including importation into England and Wales from outside the EEA, other than a supply for storage followed by consignment from the EEA or disposal, and "place on the market" shall be construed accordingly;

"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 excluding 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, otherwise than as a nutrient;

(c) preserve plant products, in so far as such substances or products 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 1986 Regulations" means the Control of Pesticides Regulations 1986[5];

"the relevant competent authorities" means the authorities appointed in the member States, other than the United Kingdom, 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 includes 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 Regulations have the same meaning as in the Directive.

(2) In these Regulations -

(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 the Annex so numbered of the Directive.

Prohibitions

3. - (1) No person shall 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) No person shall use any plant protection product unless -

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

(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) No person shall place on the market any new active substance unless -

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

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

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

(5) Nothing in this regulation shall impede the production, storage or movement within England and Wales of a plant protection product intended for use in another EEA State, 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) above 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 Secretary of State, the relevant competent authorities and the Commission a dossier which satisfies the requirements of Annex II, a declaration that the active substance 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.

(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) above shall submit the application to the Secretary of State, the relevant competent authorities and the Commission.

(4) This regulation applies to any person whose principal place of business in Great Britain is situated in England or Wales.

Standard approvals

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

(2) The Secretary of State 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 Secretary of State may renew the approval for a provisional period while she undertakes the verification mentioned in paragraph (2) above.

(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.

(5) By way of derogation from paragraph (4) above, and 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) above (except for that identifying the active substance) if the active substance is already included in Annex I at the time of the application, there being taken into account the conditions of inclusion in that Annex, and 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 Secretary of State shall not approve a plant protection product under regulation 5 unless the requirements set out in paragraphs (2) to (7) below are satisfied in relation to it.

(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 Secretary of State under paragraph (7) below or by the Commission under Article 4(1)(f) are not exceeded.

(4) The Secretary of State, 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), she has determined are appropriate.

(5) The Secretary of State, 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 Secretary of State, 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 Secretary of State 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 Secretary of State shall ensure that compliance with the requirements set out in paragraphs (2) to (7) above 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 Secretary of State 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)

below 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 Secretary of State 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) above have been satisfied the Secretary of State shall immediately inform the relevant competent authorities and the Commission of her 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 Secretary of State shall withdraw the provisional approval.

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

(6) The Secretary of State 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 England and Wales.

(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 Secretary of State 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) No person shall 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 regulation 5, 7, 8 or 11 unless an approval for trial purposes has been granted by the Secretary of State under this regulation in respect of that product.

(2) Subject to paragraph (3) below, any person who wishes to obtain an approval under this regulation shall submit an application to the Secretary of State 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) above shall not apply if the Secretary of State 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) below.

(5) If the proposed experiments or tests referred to in paragraph (1) above are liable to have harmful effects on human or animal health or to have an unacceptably adverse influence on the environment, the Secretary of State may either prohibit them or permit them subject to such conditions as she 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[6].

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

(a) paragraph (1) above; or

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

shall be guilty of an offence.

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 Secretary of State for the approved use of a plant protection product in England and Wales to be extended to purposes other than those for which the approval of that product was granted.

(2) The Secretary of State shall grant an extension of the approved use of a plant protection product when she 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) she 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 of use granted under this regulation shall be for such a period, not exceeding 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 of use granted under this regulation 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, and

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

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

(2) An applicant for an approval under this regulation must substantiate the comparability requirement with documentary evidence.

(3) To the extent that she is satisfied that the comparability requirement is met, the Secretary of State 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 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 and 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 requirement.

(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.

(8) In this regulation "the comparability requirement" means the requirement that the agricultural, plant health and environmental (including climatic) conditions relevant to the use of the plant protection product in the EEA State in which it has been authorised to be placed on the market and used must be comparable to those in the United Kingdom.

Provisional restrictions and prohibitions

12. - (1) Where the Secretary of State reasonably considers that a product which she has approved, or is required to approve, under regulation 11 constitutes a risk to human or animal health or the environment, she may provisionally restrict or prohibit its sale or use in England and Wales 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) above 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 regulation 5, 7, 8 or 11 shall be made to the Secretary of State by or on behalf of the person responsible for first placing it on the market in England and Wales.

(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 within the EEA;

(b) the applicant's principal place of business in Great Britain shall be situated in England or Wales;

(c) the application shall be in English;

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

(3) The Secretary of State 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) above the Secretary of State 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 necessary to complete the review and provide such further information.

(5) Without prejudice to any decision already taken pursuant to regulation 11, the Secretary of State, 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 Secretary of State revokes an approval or extension of use under paragraph (5) above, she 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[7] as amended[8] 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) below, the Secretary of State, 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 Secretary of State may modify an approval or an extension of use under paragraph (7) above 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) above, or modifying an approval or extension of use under paragraph (7)(a) above, the Secretary of State shall notify the holder of the approval or extension of use of her intention to revoke or modify the approval or extension of use (and of her grounds for doing so) and shall allow him such opportunity (if any) to make representations as the Secretary of State shall consider reasonable having regard to the reason why she thinks the revocation or modification is required.

(10) Where, in the case of a revocation or modification referred to in paragraph (9) above, the Secretary of State does not allow any opportunity to make representations, she shall notify the holder in question as soon as is reasonably practicable of her 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 Secretary of State, 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) above shall be guilty of an offence.

Data protection

15. - (1) Subject to paragraph (2) below, the Secretary of State shall not make use of any information provided in accordance with Annex II 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.

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

(3) Subject to paragraph (4) below, the Secretary of State 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 Secretary of State may make use of such information in the

circumstances provided for in Article 13(4).

(5) The Secretary of State, following examination of an application for approval of a plant protection product under regulation 5 or 7, shall inform the Commission of instances where she 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) Notwithstanding regulation 5(4), and without prejudice to regulation 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 Secretary of State -

(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 Secretary of State, 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 approvals and the person intending to make the application 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 Secretary of State 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 approvals of the same product cannot reach an agreement on the sharing of information, the Secretary of State may direct that person and holders of previous approvals located within England and Wales to share the information with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilising 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) above; or

(b) fails to comply with a direction made by the Secretary of State under paragraph (4) above,

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) above; or

(b) fail to comply with a direction made by the Secretary of State under paragraph (4) above,

shall be guilty of an offence.

Confidentiality

17. - (1) Subject to paragraphs (2) and (4) below, 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 Secretary of State shall treat any information submitted by that applicant as confidential to the extent that in the opinion of the Secretary of State that information contains industrial or commercial secrets.

(2) The Secretary of State shall not treat as confidential the information specified in Schedule 2 and, once the application has been granted, the Secretary of State may make that information available to any person for inspection.

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

(4) This regulation -

(a) is without prejudice to the provisions of the Environmental Information Regulations 1992[9], and

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

Packaging

18. - (1) No person shall 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) above shall be guilty of an offence.

Labelling

19. - (1) No person shall place on the market a plant protection product unless -

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

(b) he has complied with any requirement made by the Secretary of State under paragraph 7 of that Schedule.

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

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 equivalent provision in relation to that plant protection product, the Secretary of State shall have the power -

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

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

(c) to require the holder of the approval, or any other person appearing to the Secretary of State to be the owner or the person in charge of the plant protection product, to take such remedial action as appears to the Secretary of State 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 plant protection product from the market in England and Wales.

(2) If any plant protection product has been imported into England and Wales in contravention of these Regulations, the Secretary of State may, by notice in writing served on the person appearing to her to be the owner, the

importer or the person in charge of the product, require that it shall be exported from England and Wales within such period as the Secretary of State reasonably 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 causes or permits any person -

(a) to make a statement which the former knows to be false in a material particular;

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

(c) intentionally to fail to disclose any material particular,

he 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;

{/d3} 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) Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and be liable to be proceeded against and punished accordingly.

(4) Where the affairs of a body corporate are managed by its members, paragraph (3) above shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(5) In paragraphs (3) and (4) above references to a "body corporate" include references to a partnership in Scotland and, in relation to such partnership, any reference to a director or other officer of a body corporate is a reference to a partner.

(6) 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 England and Wales.

(7) It shall be a defence in proceedings for an offence under section 8(b) of the Protection of Animals Act 1911[10] (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) above, 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) above 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;

(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) Any document required or authorised under these Regulations to be served by the Secretary of State on any person may be served -

(a) by delivering it to him or by leaving it at his proper address or by sending it by post to him at that address;

(b) if the person is a body corporate, by serving it in accordance with sub-paragraph (a) above on the secretary of that body; or

(c) if the person is a partnership, by serving it in accordance with sub-

paragraph (a) above on a partner or a person having control or management of the partnership business.

(2) For the purpose of this regulation and section 7 (which relates to the service of documents by post) of the Interpretation Act 1978[11] in its application to this regulation, the proper address of any person on whom a document is to be served shall be his last known address, except that -

(a) in the case of service on a body corporate or its secretary, it shall be the address of the registered or principal office of the body;

(b) in the case of service on a partnership or a partner or a person having the control or management of a partnership business, it shall be the address of the principal office of the partnership;

and for the purpose of this paragraph the principal office of a company registered outside England and Wales or of a partnership carrying on business outside England and Wales includes its principal office within England and Wales.

(3) If a person to be served under these Regulations with any document has specified to the Secretary of State an address within Great Britain other than his proper address (as determined under paragraph (2) above) as the one at which he or someone on his behalf will accept documents of the same description as that document, that address shall also be treated as his proper address for the purposes of this regulation and for the purposes of section 7 of the Interpretation Act 1978 in its application to this regulation.

(4) In this regulation "secretary", in relation to a local authority within the meaning of the Local Government Act 1972[12], means the proper officer within the meaning of that Act.

Transitional provisions

26. Schedule 4 shall have effect.

Disapplication

27. - (1) The 1986 Regulations shall not apply to any plant protection product the placing on the market and use of which are, or under Schedule 3 have become, subject to the prohibitions specified in regulation 3(1) and (2).

(2) The 1986 Regulations shall not apply to any plant protection product which is approved under regulation 9.

(3) The Farm and Garden Chemicals Regulations 1971[13] shall not apply to any plant protection product to the extent that regulation 19 applies to it.

(4) In this regulation "pesticides", "sale", "supply" and "use" have the same meanings as in the 1986 Regulations.

Revocations

28. The Regulations set out in Schedule 5 are revoked in relation to England and Wales.

Signed on behalf of the National Assembly for Wales

D. Elis-Thomas
Presiding Officer, National Assembly for Wales

10th December 2003

Alun Michael
Minister of State, Department for Environment, Food and Rural Affairs

4th December 2003

SCHEDULE 1

Regulation 2

INSTRUMENTS AMENDING COUNCIL DIRECTIVE 91/414/EEC

Instruments	*Active substances added to Annex I*
Commission Directive 93/71/EEC; [14]	None
Commission Directive 94/37/EC; [15]	None
Commission Directive 94/79/EC; [16]	None
Commission Directive 95/35/EC; [17]	None
Commission Directive 95/36/EC; [18]	None
Commission Directive 96/12/EC; [19]	None
Commission Directive 96/46/EC;	None

[20]	
Commission Directive 96/68/EC; [21]	None
Council Directive 97/57/EC; [22]	None
Commission Directive 2000/80/EC; [23]	lambda-cyhalothrin, imazalil, azoxystrobin, kresoxim-methyl, spiroxamine, azimsulfuron, fluroxypyr, metsulfuron-methyl, triasulfuron, esfenvalerate, prohexadione-calcium and bentazone
Commission Directive 2001/21/EC; [24]	amitrole, diquat, pyridate and thiabendazole
Commission Directive 2001/28/EC; [25]	fenhexamid
Commission Directive 2001/36/EC; [26]	None
Commission Directive 2001/47/EC; [27]	Paecilomyces fumosoroseus
Commission Directive 2001/49/EC; [28]	flupyrsulfuron-methyl
Commission Directive 2001/87/EC; [29]	acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl
Commission Directive 2001/99/EC; [30]	glyphosate and thifensulfuron-methyl
Commission Directive 2001/103/EC; [31]	2,4-dichlorophenoxy acetic acid
Commission Directive 2002/18/EC; [32]	isoproturon

Commission Directive 2002/37/EC; [33]	ethofumesate
Commission Directive 2002/48/EC; [34]	iprovalicarb, prosulfuron and sulfosulfuron
Commission Directive 2002/64/EC; [35]	cinidon-ethyl, cyhalofop-butyl, famoxadone, florasulam, metalaxyl-M and picolinafen
Commission Directive 2002/81/EC; [36]	flumioxazine
Commission Directive 2003/5/EC; [37]	deltamethrin
Commission Directive 2003/23/EC; [38]	imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl, cyazofamid
Commission Directive 2003/68/EC; [39]	trifloxstrobin, carfentrazone-ethyl, mesotrione, fenamidone, isoxaflutole
Commission Directive 2003/82/EC; [40]	None
As from 1st January 2004 amended by:	
Commission Directive 2003/31/EC; [41]	2,4-DB, maleic hydrazide, cyfluthrin, beta-cyfluthrin, iprodione, linuron, pendimethalin
Commission Directive 2003/79/EC; [42]	coniothyrium minitans
Commission Directive 2003/84/EC; [43]	flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate, silthiofam
As from 1st April 2004	

amended by:	
Commission Directive 2003/39/EC; [44]	propyzamide, propineb
As from 1st June 2004 amended by:	
Commission Directive 2003/70/EC; [45]	mecoprop, mecoprop-P, propiconazole
As from 1st August 2004 amended by:	
Commission Directive 2003/81/EC; [46]	molinate, thiram, ziram

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[47] as amended[48]; 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[49] as amended[50].

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

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 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 edition[51] as read with A Guide to IUPAC Nomenclature of Organic Compounds (recommendations 1993)[52];

(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 below, 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 or not the product is restricted to a certain category of user.

2. The requirements specified in paragraphs (l), (m) and (n) of paragraph 1 above 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. In no circumstances may the label of the packaging of a plant protection product 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 the approval 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 Secretary of State may require additional phrases to be clearly and indelibly marked on packaging where this is deemed by her to be necessary for the protection of human beings, animals or the environment and where she makes such a requirement she shall do so in writing by notice served on persons holding approvals for the plant protection products concerned.

7. The Secretary of State may require any of the persons referred to in paragraph 1(b) above at any time to provide her 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 1986 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 1986 Regulations shall continue to apply,

to a relevant plant protection product.

2. Notwithstanding paragraph 1 above, and subject to paragraphs 3 and 4 below, regulations 1, 2 and 9 and (insofar as they relate to approvals granted under regulation 9) regulations 13(2) and (5) to (8), 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 1986 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(a) of the 1986 Regulations which was in force on 13th November 1997 shall continue to be subject to the 1986 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 Secretary of State shall notify the pesticide approval holder of that decision and shall take the action described in paragraph 9(1) below.

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 Secretary of State shall notify the pesticide approval holder of that fact and the pesticide approval holder shall, within such period as the Secretary of State may determine and notify to the pesticide approval holder, provide information to the Secretary of State 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 Secretary of State the information required under paragraph (1) above, the pesticide approval holder may continue to place on the market and use the relevant plant protection product until such time as the Secretary of State notifies him of her decision that she 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 Secretary of State to reach a decision, the Secretary of State 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 Secretary of State to enable her to reach a decision.

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

8. - (1) Where the Secretary of State has determined that the information provided by the approval holder under paragraph 7 above 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 she shall notify the pesticide approval holder of that fact and the pesticide approval holder shall, within such period as the Secretary of State may determine and 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 holder may continue to place on the market and use the relevant plant protection product until such time as the Secretary of State notifies him of her decision to grant or refuse an approval under regulation 5.

(3) Where the pesticide approval holder fails to provide adequate information to enable the Secretary of State to consider the application, the Secretary of State 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 Secretary of State to enable her to consider the application.

Revocation of pesticide approval

9. - (1) The Secretary of State shall, at the same time as she notifies a pesticide approval holder of a decision mentioned in paragraph 6, 7(4) or 8(2) above, revoke the pesticide approval.

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

(3) Where the Secretary of State revokes a pesticide approval under sub-paragraph (1) or (2) above, she may revoke that approval -

(a) completely;

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

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

(4) When revoking an approval in the manner mentioned in paragraph (b) of sub-paragraph (3) above, the Secretary of State shall -

(a) subject to sub-paragraph (b) below, 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 1986 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 paragraph (c) of sub-paragraph (3) above, the Secretary of State shall -

(a) subject to sub-paragraphs (b) and (c) below, 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 1986 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 1986 Regulations for a period, not exceeding one year following the end of the period of provisional approval granted under sub-paragraph (b) above, 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 Secretary of State has revoked a pesticide approval in relation to any plant protection product under paragraph 9(1) or (2) above 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 Secretary of State has revoked a pesticide approval in relation to any plant protection product in the manner specified in paragraph 9(4) above, 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) above.

(3) Where the Secretary of State has revoked a pesticide approval in relation to any plant protection product in the manner specified in paragraph 9(5) above, 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) above.

Notifications

11. Any notification given by the Secretary of State 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 1986 Regulations;

"pesticide approval holder" means any person who holds a current pesticide approval;

"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 1986 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 meanings as in the 1986 Regulations.

SCHEDULE 5

Regulation 28

REVOCATIONS

The following Regulations are hereby revoked:

The Plant Protection Products Regulations 1995	S.I. 1995/887
The Plant Protection Products (Amendment) Regulations 1997	S.I. 1997/7
The Plant Protection Products (Amendment)(No.2) Regulations 1997	S.I. 1997/2499
The Plant Protection Products (Amendment)(No.3) Regulations 2002	S.I. 2002/2874
The Plant Protection Products (Amendment) Regulations 2003	S.I. 2003/1787

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and replace the Plant Protection Products Regulations 1995 (S.I. 1995/887) insofar as they extend to England and Wales.

The Regulations, which consolidate the 1995 Regulations (as amended) with modifications, continue to implement in Great Britain Council Directive 91/414/EEC (OJ No. L230, 19.8.91, p.1 to be read with corrigenda published in OJ 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 2003/5/EC and also implement Commission Directives 2003/23/EC, 2003/68/EC, 2003/31/EC, 2003/79/EC, 2003/84/EC, 2003/39/EC, 2003/70/EC, 2003/81/EC and 2003/82/EC which amend the 1991 Directive and which were not covered by the 1995 Regulations - see Schedule 1.

Directives 91/414/EEC and 93/71/EEC were extended to the European Economic Area ("the EEA") by Decision No. 7/94 of the EEA Joint Committee (OJ No. L160, 28.6.94, p.1), which amended the European Economic Area Agreement (see Decision 94/1 ECSC, EEC; OJ No. L1, 3.1.94, p.1).

The Directive (as extended to the EEA) establishes an authorisation system whereby plant protection products (defined in the 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 Directive by that EEA State (or, subject to qualifications, by another EEA State). The 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 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) 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 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 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 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 Directive described above by providing for the authorisation system in England and Wales under the operation of the Secretary of State. 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 Secretary of State 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 Secretary of State 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 Directive for use in another EEA State are made to the Secretary of State by the persons responsible for first placing the products on the market in England and Wales (regulations 5 to 8, 11 and 13). Similarly, applications for approvals for trial purposes are made to the Secretary of State (regulation 9). The provisions of the 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 of the 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 local authorities) authorised by the Secretary of State, 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 1986 (S.I. 1986/1510) will continue to apply) are contained in regulations 26 and 27 and Schedule 4.

Instruments which are revoked in relation to England and Wales are set out in Schedule 5 (regulation 28).

A compliance cost assessment has not been prepared in respect of these Regulations as they have no impact on the costs of business.

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 2PX or via the website www.pesticides.gov.uk.

Notes:

[1] S.I. 1972/1811 and, in the case of the National Assembly for Wales, S.I. 1999/2788.back

[2] 1972 c. 68.back

[3] 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.back

[4] OJ No. L230 19.8.91, p.1.back

[5] S.I. 1986/1510, amended by S.I. 1997/188, 2001/880.back

[6] OJ No. L106, 17.4.2001, p.1.back

[7] OJ No. L33 8.2.79, p.36.back

[8] Last amended by Council Regulation 807/2003/EC (OJ No. L122, 16.5.2003, p.36).back

[9] S.I. 1992/3240, amended by 1998/1447.back

[10] 1911 c. 27 (1 & 2 Geo 5).back

[11] 1978 c. 30.back

[12] 1972 c. 70.back

[13] S.I. 1971/729.back

[14] OJ No. L221, 31.8.93, p.27, (as read with corrigenda published in OJ No. L170, 25.6.92, p.40).back

[15] OJ No. L194, 29.7.94, p.65.back

[16] OJ No. L354, 31.12.94, p.16, (as read with corrigenda published in OJ No. L280, 23.11.95, p.58).back

[17] OJ No. L172, 22.7.95, p.6.back

[18] OJ No. L172, 22.7.95, p.8.back

[19] OJ No. L65, 15.3.96, p.20.back

[20] OJ No. L214, 23.8.96, p.18.back

[21] OJ No. L277, 30.10.96, p.25.back

[22] OJ No. L265, 27.9.97, p.87.back

[23] OJ No. L309, 9.12.2000, p.14.back

[24] OJ No. L69, 10.3.2001, p.17.back

[25] OJ No. L113, 24.4.2001, p.5.back

[26] OJ No. L164, 20.6.2001, p.1.back

[27] OJ No. L175, 28.6.2001, p.21.back

[28] OJ No. L176, 29.6.2001, p.61.back

[29] OJ No. L276, 19.10.2001, p.17.back

[30] OJ No. L304, 21.11.2001, p.14.back

[31] OJ No. L313, 30.11.2001, p.37.back

[32] OJ No. L55, 26.2.2002, p.29.back

[33] OJ No. L117, 4.5.2002, p.10.back

[34] OJ No. L148, 6.6.2002, p.19.back

[35] OJ No. L189, 18.7.2002, p.27.back

[36] OJ No. L276, 12.10.2002, p.28.back

[37] OJ No. L8, 14.1.2003, p.7.back

[38] OJ No. L81, 28.3.2003, p.39.back

[39] OJ No. L177, 16.7.2003, p.12.back

[40] OJ No. L228, 12.9.2003, p.11.back

[41] OJ No. L101, 23.4.2003, p.3.back

[42] OJ No. L205, 14.8.2003, p.16.back

[43] OJ No. L247, 30.9.2003, p.20.back

[44] OJ No. L124, 20.5.2003, p.30.back

[45] OJ No. L184, 23.7.2003, p.9.back

[46] OJ No. L224, 6.9.2003, p.29.back

[47] OJ No. P196, 16.8.67, p.1 (OJ/SE 1967 p.234).back

[48] Last amended by Council Regulation (EC) No. 806/2003 (OJ No. L122,

16.5.2003, p.1).back

[49] OJ No. L200, 30.7.1999, p.1.back

[50] Amended by Commission Directive 2001/60/EC (OJ No. L226, 22.8.2001, p.5).back

[51] By J Rigaudy and S P Klesney, published by Pergamon (ISBN 0-08022-3699).back

[52] 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.back

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