

S.I. No. 83 of 2003

EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) REGULATIONS 2003

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**EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE
MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS)
REGULATIONS 2003**

I, Joe Walsh, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving effect to Council Directive 91/414/EEC of 15 July 1991¹, the Corrigendum to Council Directive 91/414/EEC², Council Directive 97/57/EC of 22 September 1997³, Commission Directive 93/71/EEC of 27 July 1993⁴, the Corrigendum to Commission Directive 93/71/EEC⁵, Commission Directive 94/37/EC of 22 July 1994⁶, Commission Directive 94/79/EC of 21 December 1994⁷, the Corrigendum to Commission Directive 94/79/EEC⁸, Commission Directive 95/35/EC of 14 July 1995⁹, Commission Directive 95/36/EC of 14 July 1995¹⁰, Commission Directive 96/12/EC of 8 March 1996¹¹, Commission Directive 96/46/EC of 16 July 1996¹², Commission Directive 96/68/EC of 21 October 1996¹³, Commission Directive 2000/80/EC of 4 December 2000¹⁴, Commission Directive 2001/21/EC of 5 March 2001¹⁵, Commission Directive 2001/28/EC of 20 April 2001¹⁶, Commission Directive 2001/47/EC of 25 June 2001¹⁷, Commission Directive 2001/49/EC of 28 June 2001¹⁸, Commission Directive 2001/87/EC of 12 October 2001¹⁹, Commission Directive 2001/99/EC of 20 November 2001²⁰, Commission Directive 2001/36/EC of 16 May 2001²¹, Commission Directive 2001/103/EC of 28 November 2001²², Commission Directive 2002/18/EC of 22 February 2002²³, Commission Directive 2002/37/EC of 3 May 2002²⁴, Commission Directive 2002/48/EC of 30 May 2002²⁵, Commission Directive 2002/64/EC of 15 July 2002²⁶, and Commission Directive 2002/81/EC of 10 October 2002²⁷ hereby make the following regulations:

²⁷ O.J. No. L276 of 12 10 2002 p28

²⁶ O.J. No. L189 of 18 7 2002 p20

²⁵ O.J. No. L148 of 6 6 2002 p19

²⁴ O.J. No. L117 of 4 5 2002 p10

²³ O.J. No. L55 of 26 2 2002 p29

²² O.J. No. L313 30 11 2001 p37

²¹ O.J. No. L164 20 6 2001 p1

²⁰ O.J. No. L304 21 11 2001 p14

¹⁹ O.J. No. L276 19 10 2001 p17

¹⁸ O.J. No. L176 29 6 2001 p61

¹⁷ O.J. No. L175 28 6 2001 p21

¹⁶ O.J. No. L113 24 4 2001 p5

¹⁵ O.J. No. L69 10 3 2001 p17

¹⁴ O.J. No. L309 9 12 2000 p14

¹³ O.J. No. L227 30 10 1996 p25

¹² O.J. No. L214 3 8 1996 p18

¹¹ O.J. No. L65 15 3 1996 p20

¹⁰ O.J. No. L172 22 7 1995 p8

⁹ O.J. No. L172 22 7 1995 p6

⁸ O.J. No. L280 23 11 1995 P58

⁷ O.J. No. L354 31 12 1994 p16

⁶ O.J. No. L194 29 7 1994 p65

⁵ O.J. No. L4 6 1 1996 p16

⁴ O.J. No. L221 31 8 1993 p27

³ O.J. No. L265 27 9 1997 p87

² O.J. No. L170 25 6 1992 p40

¹ O.J. No. L230 19 8 1991 p1

Citation

1 These Regulations may be cited as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations 2003.

Interpretation

2 (1) In these Regulations —

"actual conditions of use" in relation to good agriculture practice includes any stage in the production, storage, transport and distribution of plants and plant products;

"aircraft" includes hovercraft;

"authorized officer" means a person appointed in writing under Regulation 29;

"Commission" means the Commission of the European Communities;

"designated analyst" means any appropriately qualified person who is authorized in writing under Regulation 30;

"Directive of 1967" means Council Directive 67/548/EEC of 27 June, 1967²⁹, as amended and adapted;

²⁹ O.J. No. L196/1 16/8 1967

"Directive of 1991" means Council Directive No. 91/414/EEC of 15 July 1991;

"Directive of 1992" means Council Directive 92/32/EC of 30 April 1992³⁰;

³⁰ O.J. No. L154/1 5/6/1992

"Directive of 1999" means Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999³¹ and the corrigendum to Directive 1999/45/EC³²;

³² O.J. No. L6/70 10/1/2002

³¹ O.J. No. L200/1 30/7/1999

"essential use" means a use of a plant protection product for which there is no practical alternative available or for which there are an insufficient number of suitable alternatives available;

"good agricultural practice" in the use of a plant protection product, means safe use of the plant protection product under actual conditions necessary for its effective action, in accordance with an authorization granted pursuant to these Regulations, encompassing a range of levels of application up to the highest level of use for which an authorization has been granted, applied in a manner which leaves a residue which is the smallest practicable;

"good plant protection practice" in the use of plant protection products, means their responsible use in accordance with the guidelines issued from time to time by the Minister,

"insufficient number of suitable alternatives", in relation to essential use means insufficient to avoid the imposition of selective pressure for the development of resistant populations of harmful organisms;

'ISO.' means the International Organisation for Standardisation;

'IUPAC Rules' means the chemical nomenclature rules adopted by the International Union of Pure and Applied Chemistry;

"maximum residue level" is the maximum content of residual traces of a plant protection product contained in a product to which a plant protection product has been applied;

"Member State" means a Member State of European Communities;

"Minister" means the Minister for Agriculture and Food;

"notified" means the packaging, including any label or container used with the package, and basic information as to the nature and composition of any such plant protection product on the market on or before the 2nd December 1985 and the manufacturer of each plant protection product which has been submitted and approved by the Minister under the Regulations of 2001, and cognate words shall be construed accordingly,

"notified" in the case of an adjuvant for use with a plant protection product or a plant protection product containing a macro-organism means

- a) the packaging, including any label or container used with the package,
- b) basic documentation,
- c) information as to the nature and composition of any such adjuvant or plant

protection product,

and as to the producer or manufacturer of each such adjuvant or plant protection product, has been submitted to and been approved by the Minister and cognate words shall be construed accordingly,

"officially recognized testing facilities and organizations" for the purposes of these Regulations, means testing facilities and organizations which carry out officially recognised tests and analyses,

"officially recognized tests and analyses" for the purposes of these Regulations, means experiments, studies, tests and analyses carried out in accordance with methodologies and to a standard accepted from time to time by the Minister and issued as guideline documentation,

"parallel import approval" means an approval granted by the Minister for the importation, distribution, sale and use of a plant protection product deemed identical to a product on the register of plant protection products that may be placed on the market and used in accordance with these regulations,

"permission to market" means a permission granted by the Minister to place on the market and use a plant protection product;

"register of plant protection products" means a list established under Regulation 21;
"Regulations of 2001" means the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001 (S.I. No. 624 of 2001);

"safe use, in relation to good agricultural practice", means taking into account public and occupational health and environmental considerations;

"trials authorization" means an authorization granted in accordance with Regulation 24

"trials permit" means a permit granted in accordance with Regulation 25

(2) A word or expression that is used in the Directive of 1991 or in or Commission Directive or Regulation of the European Communities mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive or Regulation concerned

(3) In these Regulations, unless otherwise indicated -

(a) a reference to a Regulation is a reference to a Regulation of these Regulations,

(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs,

(c) a reference to a Schedule is a reference to the Schedule to these Regulations.

(4) A reference to a Directive is to the Directive as amended or extended.

Application

3. (1) Subject to paragraph (2), these Regulations apply to the production, storage or movement of a plant protection product

(2) These Regulations do not apply to a plant protection product intended for use in another Member State and Regulations 32 and 33 are complied with.

Placing on the market

4. (1) A person shall not place a plant protection product on the market, cause or permit another person to place a plant protection product on the market, use the product or cause or permit another person to use the product unless these Regulations are complied with.

(2) A person shall not place a plant protection product on the market if -

(a) the net quantity of a plant protection product in a container is less than the quantity stated on the container, or

(b) a fastening or container used to package the plant protection product has been tampered with.

Exemptions from certain provisions.

5 (1) A plant protection product referred to in Regulation 3 (1) (a) of the Regulations of 2001, classified in accordance with those Regulations is -

(a) exempt from

(i) Regulation 11 (2) (a) and (b), and

(ii) Regulation 25 of the Regulations of 2001.

and

(b) considered to comply with —

(i) Regulation 11 (1), and

(ii) Regulations 12 and 13 of the Regulations of 2001, where it has been authorized under these Regulations.

(2) A plant protection product referred to in Regulation 3 (1) (a) of the Regulations of 2001 that is on the market before the making of these Regulations may continue to be placed on the market under the Regulations of 2001, until:-

(a) approval of the record of the studies conducted and the information, documentation and materials submitted for approval under Regulation 11 (2) (a) or (b) of the Regulations of 2001 has been refused and clearance under those Regulations has been refused, or

(b) it is authorized or is refused an authorization under these Regulations.

(3) Notwithstanding Regulations 8, 13 and 18, in the case of a plant protection product which is not on the market before these Regulations come into effect, permission may be granted by the Minister on approval of an accurate record of studies, information, supporting documentation and materials, as set out from time to time by the Minister, to market and use such a plant protection product, where application is made and -

(a) the plant protection product is similar in terms of its active substance or active substances to one or more plant protection products placed on the market in accordance with these Regulations, and the proposed uses of the plant protection product are encompassed by those of the product or products with which comparison is made.

(b) the plant protection product contains at least one active substance not present in a plant protection product authorized in accordance with these Regulation.

(c) at least one active substance in the plant protection product is included in the review programme for existing active substances pursuant to Article 8.2 of the Directive of 1991 and has not yet been included in Annex I.

(d) none of the active substances in the plant protection product have been refused inclusion in Annex I.

(e) the plant protection product warrants the same or a less severe hazard classification than the plant protection product or products referred to in subparagraph (a).

(f) the plant protection product is considered to involve no greater risk for man, animals or for the environment than the plant protection product or products referred to in subparagraph (a), and

(g) where comparison is made with two or more plant protection products used as a tank mix, the approved label for one of the products must include a recommendation for such tank-mixing.

unless the periods specified in Regulation 10 have not yet expired for information referred to in Regulation 8 (3) (a) and (b).

(4) Notwithstanding Regulations 13 and 18, in the case of a plant protection product for which an application for authorization has been made under Regulation 8. authorization for a period not exceeding 12 months may be granted if -

(a) (i) the active substance in the plant protection product is included in Annex I to the Directive of 1991,

(ii) a detailed assessment of the data referred to in Regulation 8 (4) (a) and (b) prepared by the competent authority of the other Member State responsible for its evaluation on behalf of the Commission is available to the Minister, or

(iii) a detailed assessment comparable to that referred to in subparagraph (ii) prepared by another Member State is available to the Minister.

(b) an active substance in a plant protection product has not been refused inclusion in Annex I to the Directive of 1991.

(c) the plant protection product has been authorized for use in another Member State and a copy of the certificate of authorization and of the approved label in that Member State for the plant protection product is provided to the Minister.

(d) a proposed use of a plant protection product is —

(i) a use considered for the purposes of including an active substance in Annex I to the Directive of 1991, or

(ii) a use considered for assessment as referred to in subparagraph (a),

(e) in the opinion of the Minister there is a reasonable expectation that an authorization will be granted under Regulation 13 or 18 before expiry of the authorization, and

(f) at least one of the uses for which authorization is sought is considered, in the opinion of the Minister, to be an essential use.

Use of plant protection products

6 A person shall only use a plant protection product -

(a) in compliance with conditions established under Regulations 13, 15, 18 and 19 and stated on the label, as appropriate,

(b) in compliance with conditions established under Regulation 16, as appropriate,

(c) in the case of plant protection products on the market before these Regulations come into effect and pending their authorization in accordance with these Regulations, in compliance with the conditions specified on the labelling, approved following the granting of clearance, permission to market or accepted for their notification, as appropriate.

(d) in accordance with the principles of good plant protection practice, and

(e) where possible, in accordance with the principles of integrated control.

Marketing of active substances

7. (1) A person shall only place an active substance on the market where -

(a) it is classified, packaged and labelled under the Directive of 1967, and

(b) where the active substance was not on the market before 25 July 1993 a dossier has been forwarded to the Member States and the Commission, in accordance with Article 6 of the Directive of 1991, with the declaration that the active substance is intended for a use specified in Article 2(1) of that Directive.

(2) This Regulation shall not apply to an active substance contained in a plant protection product intended for use for trial purposes in accordance with Regulations 25 and 26.

Application for authorization

8 (1) An application for authorization shall be made by or on behalf of the person responsible for first placing it on the market.

(2) An applicant for an authorization shall be established in a Member State.

(3) An application shall be in such form and contain such information as the Minister may require.

(4) An application for authorization of a plant protection product shall include -

a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III of the Directive of 1991.

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 of the Directive of 1991,

c) samples of the packaging and models, drafts or samples of labelling and leaflets referred to in Regulations 22 and 23

d) samples of the plant protection products and each active substance therein in it and analytical standards for each such active substance.

i. for impurities and formulants of toxicological or environmental significance, and

ii. for transformation products of the active substance included in the residue definition, and

e) any other matter that the Minister may require.

(5) The tests and analyses conducted for the purposes of compiling dossiers referred to in paragraph (4) (a), shall be

a. carried out under agricultural, plant health and environmental conditions relevant to use of the plant protection product in question and

b. representative of those prevailing where the product is intended to be used.

c. and shall be officially recognized tests and analyses

(6) Notwithstanding paragraph (3) and subject to Regulation 10 (?)-

(a) an applicant is exempt from supplying information required under paragraph 4 (b), except for that identifying the active substance, if the active substance is already listed in Annex I to the Directive of 1991, taking into account the conditions of inclusion in Annex I to the Directive of 1991, and does not differ significantly in degree of purity and nature of impurities, from the composition registered in the Annex II to the Directive of 1991 dossier accompanying the original application, and

(b) in the case of a plant protection product already authorized in another Member State, at the request of an applicant, who must substantiate the claim to comparability with documentary evidence, an applicant shall be exempted from repeating tests and analyses already carried out in connection with the authorization of the product, to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned.

(7) Subject to Regulation 10, an application for authorization of a plant protection product in accordance with Regulation 13 (2), taking account of the agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product in the regions concerned, shall be supported with a claim as to the comparability of the regions concerned and shall be supported with documentary evidence to support any such claim.

(8) The Minister shall not consider an incomplete application.

Limiting of testing involving vertebrate species

9. (1) Notwithstanding Regulations 8 and 10, an applicant for authorization of a plant protection product shall, before carrying out experiments involving vertebrate animals, enquire of the Minister -

(a) whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorization has been granted, and

(b) as to the name and address of the authorization holder.

(2) If the Minister is satisfied on the basis of documentary evidence provided that the prospective applicant intends to apply for authorization on his or her own behalf and that the other information specified in Regulation 8 (4) is available to him or her for use on his or her behalf, the Minister shall provide the name and address of any holder of a previous relevant authorization and shall at the same time inform that holder of the name and address of the applicant.

(3) The holder of a previous authorization and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

(4) If data is to be submitted with a view to inclusion in Annex I to the Directive of 1991 of an active substance on the market after 24 July 1993, the Minister shall encourage applicants to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.

(5) If application is made for the inclusion in Annex I to the Directive of 1991 of an active substance on the market after 24 July 1993, an applicant shall take all reasonable steps to reach agreement on -

(a) sharing of relevant data and information, and

(b) submission collectively of all the data and information concerned.

(6) This Regulation is in addition to and not in substitution for the Cruelty to Animals Act 1876³³

³³ 1876, c. 77).

Proprietary rights to data

10 (1) Information contained in a dossier referred to in Regulation 8 (4) (b) shall not be used to the benefit of another applicant unless -

(a) the applicant has agreed with the first applicant that use may be made of the information and the first applicant has submitted written confirmation of the agreement, or
(b) 10 years have elapsed from the first inclusion in Annex I to the Directive of 1991 of an active substance first placed on the market in a Member State as a constituent of a plant protection product after 24 July 1993, or

(c) 10 years have elapsed from the date of first marketing within the territory of the State of an active substance as a constituent of a plant protection product which was on the market before 25 July 1993, and

(d) Subject to paragraph (2), 5 years have elapsed from the date of decision in the case of further information that is generated specifically for and is necessary -

(i) for first inclusion of an active substance in Annex I to the Directive of 1991, or

(ii) to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I to the Directive of 1991.

(2) If the period of 5 years provided for in paragraph (1)(d) expires before the periods provided for in paragraphs (1) (b) and (c) the period of 5 years shall be extended so as to expire on the same date as those periods.

(3) Information contained in a dossier referred to in Regulation 8 (4) (a) shall not be used to the benefit of another applicant unless -

(a) the applicant has agreed with the first applicant that use may be made of the information and the first applicant has submitted written confirmation of the agreement.

(b) 10 years have elapsed from the first authorization or marketing of the plant protection product in any Member State, where authorization follows the inclusion in Annex I to the Directive of 1991 of any active substance contained in the product, or

(c) 10 years have elapsed from the date of first marketing within the territory of the State of a plant protection product where such marketing precedes inclusion in Annex I to the Directive of 1991 of any active substance contained in the product.

(4) Paragraphs (1), (2) and (3) apply to data and information submitted under the Regulations of 2001.

Confidentiality

11 (1) An applicant for authorization of a plant protection product, who claims that certain information submitted in accordance with Regulation 8, includes information involving industrial or commercial secrets, may apply for the information to be treated as confidential.

(2) An application shall identify the information concerned and shall include a statement justifying the application that it be treated as confidential.

(3) Subject to paragraphs (5) and without prejudice to Council Directive 90/313/EEC of 7 June 1990³⁴, the Minister shall ensure that information referred to in paragraph (1) is treated as confidential where he or she shall accepts that such treatment is justified.

³⁴ O.J. No. L158/56 23/6 1990

(4) Confidentiality shall not apply to -

(b) the name and content of an active substance:

(c) the name of the plant protection product.

- (c) the name of any other substance which is regarded as dangerous under the Directive of 1967 or the Directive of 1999.
 - (d) physico-chemical data concerning the active substance and plant protection product.
 - (e) any method of rendering the active substance or plant protection product harmless.
 - (f) a summary of the results of tests to establish the efficacy of the substance or product and harmlessness to humans, animals, plants or the environment,
 - (g) any recommended method and precautions to reduce handling, storage, transport, fire or other hazards,
 - (h) any method of analysis accepted under Article 4(1)(c) and (d) and 5(1) of the Directive of 1991,
 - (i) any method of disposal of a product or its packaging,
 - (j) any decontamination procedure to be followed in the case of accidental spillage or leakage, or
 - (k) first aid and medical treatment to be given in the case of injury to persons.
- (5) If an applicant discloses previously confidential information, he or she shall inform the Minister of the fact.

Consideration of applications.

12 (1) The Minister shall consider a completed application for authorization of a plant protection product and inform the applicant within a reasonable period, of his or her decision to authorize the product or refuse the application.

(2) In the case of applications involving one or more active substances not on the market in a Member State as a constituent of a plant protection product after 24 July 1993 and not subsequently included in Annex I to the Directive of 1991, the Minister shall, without undue delay, assess the information provided to determine if the requirements specified in Regulation 8 (4) have been satisfied.

(3) For each such application referred to in Paragraph (2) believed to satisfy the requirements of Annex II to the Directive of 1991, the Minister shall require the applicant to forward the dossier to the other Member States and to the Commission together with a dossier complying with Annex III to the Directive of 1991 on at least one preparation containing that active substance.

(4) If, under paragraph (3), an applicant is required to forward a dossier believed to satisfy Annex II to the Directive of 1991 a dossier complying with Annex III to the Directive of 1991 on at least one preparation containing the active substance, the Minister shall, under Article 6.3 of the Directive of 1991, request the Commission to establish whether the dossier satisfies Annex II and Annex III to the Directive of 1991, under the procedure provided for in that Article.

Granting of authorizations

13 (1) Subject to Regulation 19 and paragraph (3) the Minister shall only authorize the placing on the market and use of any plant protection product where -

- (a) each active substance contained in the product is listed in Annex I to the Directive of 1991 and any condition laid down therein is fulfilled.
- (b) following application of Annex VI to the Directive of 1991, Article 4 (1) (b), (c), (d) and (e) of the Directive of 1991 are satisfied,
- (c) where relevant, maximum residue levels in the agricultural products referred to in the authorization have been established and notified to the Commission, and
- (d) its packaging and labelling satisfy Regulations 22 and 23;

(2) Subject to paragraphs (3) and (4), if a plant protection product, authorized under the Directive of 1991 in another Member State, contains only active substances

included in Annex I to the Directive of 1991, at the request of the applicant, the Minister, to the extent that Annex VI to the Directive of 1991 has been adopted under Article 23 of the Directive of 1991, may authorize the placing on the market and use of the product, if it has been established to the satisfaction of the Minister that the agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned.

(3) The Minister may impose conditions and restrictions on use to avoid exposure of consumers to risks of dietary contamination in excess of the acceptable daily intake of a residue of a plant protection product and to take account of differences in dietary patterns.

(4) An authorization granted under this Regulation may, with the agreement of the applicant, be subject to changes in the conditions of use in order to render, in the regions concerned, any non-comparable agricultural, plant health or environmental (including climatic) conditions irrelevant for the purpose of comparability.

(5) The Minister may attach such conditions and restrictions to an authorization, as are, in his or her opinion, necessary and relevant to ensure:

- (a) compliance with Article 4 (1)(b) of the Directive of 1991, and
- (b) that maximum residue levels are not exceeded.

(6) An authorization granted under this Regulation shall be valid for a period not exceeding 10 years.

Refusal to recognize comparability

14 (1) Where the Minister does not accept that claims as to comparability, with respect to the agricultural, plant health and environmental (including climatic) conditions relevant to use of the product in the regions concerned, made in accordance with Regulation 8 (6) (b), are justified, and has required the repetition of one or more tests and analyses, he or she shall notify the Commission of the grounds on which the repetition of tests or analysis is required.

(2) Where the Minister does not accept that claims as to comparability, with respect to the agricultural, plant health and environmental (including climatic) conditions relevant to use of the product in the regions concerned, made in accordance with Regulation 8 (7) are justified, and has refused to authorize a plant protection product in accordance with Regulation 13 (2), it shall notify the Commission of the grounds on which the application was refused.

(3) Where a decision different from that of the Minister is made pursuant to Article 10 (3) of the Directive of 1991, he or she shall without delay accept the tests and analyses or authorize the placing of the plant protection product on the market, subject in the latter case to any terms which the above decision may set.

Authorization for provisional periods

15. (1) Notwithstanding Regulation 13 (1) (a) and subject to Regulation 19, a person may apply, under Regulation 8 for an authorization for a provisional period for the placing on the market and use of a plant protection product containing an active substance not listed in Annex I to the Directive of 1991 and not available on the market after 24 July 1993.

(2) The Minister may grant an authorization to which paragraph (1) refers for a period not exceeding three years, if -

(a) following application of Article 6 (2) and (3) of the Directive of 1991, it is found that the dossier on the active substance satisfies Annexes II and III of the Directive of 1991 in relation to the projected uses.

(b) the active substance satisfies Article 5 (1) of the Directive of 1991 and that the plant protection product may, in the opinion of the Minister, be expected to satisfy Regulation 13 (1) (b) and (c); and

(c) its packaging and labelling satisfy Regulations 22 and 23.

(3) Notwithstanding paragraph (2), where on expiry of the authorization, a decision has not been taken concerning the inclusion of an active substance in Annex I to the Directive of 1991, the Minister may grant a further period of provisional authorization.

Extension of the field of application of a plant protection product

16. (1) An official or scientific body involved in agricultural activities, a professional agricultural organisation or a professional user may request that the field of application of a plant protection product included on the register of plant protection products, be extended to purposes other than those covered by the authorization, clearance, permission to market or notification concerned

(2) Subject to paragraph (4), the Minister may grant an extension of the field of application of a product included in the register of plant protection products, where -

(a) an application for an extension of the field of its application is made in a form and containing documentation and information, as the Minister may require from time to time,

(b) the Minister has established that the conditions referred to in Article 4 (1) (b) (iii), (iv) and (v) of the Directive of 1991, are satisfied, and

(c) the extension of the field of application relates to one or more minor uses.

(3) The Minister shall post on the official Pesticide Control Service internet site or by other means, information on the extended use of the plant protection product.

(4) An extension expires on the same date as the authorization, permission to market, clearance or notification for the plant protection product to which it relates.

Information on potentially harmful effects

17. (1) A person to whom an authorization, an extension or a permission to market under has been granted, shall immediately notify the Minister of all new information on potentially dangerous effects of a plant protection product or of residues of an active substance contained in a plant protection product on human or animal health, ground water or the environment.

(2) A person who makes notification under paragraph (1) shall immediately notify the information provided to the other Member States and to the Commission.

Authorization of certain plant protection products on the market before 25 July 1993

18. (1) Subject to paragraph (3) and Regulation 19 (7), before 25 July 2003, an application may be made to the Minister for authorization of a plant protection product under Regulation 8 in respect of a product containing an active substance not listed in Annex I to the Directive of 1991 that was on the market before 25 July 1993.

(2) Pending the review of the active substances under Article 8 (2) of the Directive of 1991, an application made under paragraph (1) shall be examined by the Minister who will decide thereon within a reasonable period.

(3) In deciding on an application under paragraph (1), the Minister shall only authorize the placing on the market and use of a plant protection product if -

(a) following application of Annex VI to the Directive of 1991, the requirements of Article 4 (1) (b), (c), (d) and (e) of the Directive of 1991 are satisfied,

(b) where relevant, a maximum residue level in the agricultural products referred to in the authorization has been notified to the Commission, and

(c) its packaging and labelling satisfy Regulations 22 and 23;

Renewal, alteration and cancellation of authorizations

19 (1) Where an application is made for the renewal of an authorization using forms as specified from time to time by the Minister and is supported with the

documentation specified in Regulation 8 (4) and where relevant, the documentation specified in Regulation 8 (6) (b), the authorization shall be renewed where the Minister has verified that the requirements of Regulation 13 (1) are still satisfied. Renewal shall be granted for the period necessary for such verification, where an application for such renewal has been made.

(2) Where an application is made for the renewal of an extension of the field of application of an authorization using forms as specified from time to time by the Minister and is supported with the documentation specified in Regulation 16 (2) (a), an extension shall be renewed where the Minister has verified that the requirements of Regulation 16 (2) are still satisfied. Renewal shall be granted for the period necessary for such verification, where an application for such renewal has been made.

(3) An authorization may be reviewed at any time by the Minister and he or she shall require the holder of the authorization concerned, or party to whom an extension of the field of application was granted, to submit further information necessary for completion of the review.

(4) Where an application is made by the holder of an authorization for its modification using a form as determined from time to time by the Minister and is supported with a statement as to the reasons for the proposed modification and with the documentation specified in Regulation 8, an amendment to the authorization may be granted where the Minister has verified that the requirements of Regulation 13 (1), Regulation 15 (2) and Regulation 18 (3), as appropriate, are still satisfied.

(5) Where an application is made by the holder of an authorization for its revocation using a form as determined from time to time by the Minister and is supported with a statement as to the reasons for revocation, the Minister shall revoke the authorization.

(6) Without prejudice to decisions taken pursuant to Regulation 13 (2), the Minister may:

(a) revoke an authorization if he or she is of the opinion that -

(i) the requirements for obtaining the authorization are not, or are no longer, satisfied;

or

(ii) false or misleading particulars were supplied concerning the facts on the basis of which the authorization was granted,

or

(b) modify 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.

(7) Following the evaluation of a dossier referred to in Article 6 (3) of the Directive of 1991, the Minister shall, within 6 months -

(a) where it has been decided that the active substance does not satisfy the requirements specified in Article 5 (1) of the Directive of 1991, cancel any authorization granted in accordance with Regulations 13 or 15 (2) for plant protection products containing the active substance, and

(b) where it has been decided to include the active substance in Annex I of the Directive of 1991, modify any authorization granted in accordance with Regulations 13 or 15 (2) and modify any extension of the field of application of any authorization granted in accordance with Regulation 16, for each plant protection product containing the active substance, such that the conditions and restrictions associated with inclusion of the active substance in Annex I of the Directive are complied with.

(9) If the Minister has reason to consider that a plant protection product has been authorized under Regulation 13 (1) or (2) or Regulation 15 (2), constitutes a risk to human or animal health or the environment, he or she shall provisionally restrict or prohibit the use

and/or sale of that product and immediately inform the Commission and the other Member States of the action and the reasons for the action.

(10) Following the adoption of a reduced maximum residue level or the adoption of a maximum residue level at or about the limit of quantification for the residue concerned, the Minister shall where necessary modify or revoke authorizations, extensions of the field of application, permissions to market, or notifications granted under these Regulations, or clearances, permissions to market, or notifications granted under the Regulations of 2001, to ensure that the approved uses for relevant products are encompassed by the uses considered for the establishment of any such maximum residue level.

(11) If an authorization is revoked under this Regulation, the Minister shall immediately inform the holder of the authorization of its revocation.

(12) The Minister may grant a period for the disposal, storage, placing on the market and use of existing stocks.

Emergency authorization

20 Notwithstanding Regulations 13, 15 and 18, the Minister may authorize for a period not exceeding 120 days the placing on the market of a plant protection product not complying with those Regulations for limited and controlled use if, in his or her opinion, it is necessary because of an unforeseeable danger that cannot be contained by other means;

Information exchange

21 The Minister shall draw up an annual list of the plant protection products authorized in the State.

Packaging

22. (1) The packaging of a plant protection product together with a fastening or container used in the packaging shall -

- (a) be designed and constructed so that its contents cannot escape.
- (b) not be susceptible to adverse attack by the contents.
- (c) not be liable to form dangerous compounds with the contents.
- (d) be strong and solid throughout to resist loosening and meet the normal stresses and strains of handling, and

(e) in the case of a container fitted with replaceable fastening devices, be designed so that the packaging can be refastened repeatedly without the contents escaping.

(2) The packaging of a plant protection product shall not have -

- (a) either a shape or graphic decoration likely to attract or arouse the active curiosity of children or mislead consumers, or
- (b) a presentation or a designation used for foodstuffs, animal feedingstuffs, medicinal products or cosmetic products.

(3) The packaging of any plant protection product that is placed on the market shall

—
(a) be fitted with a child-resistant fastening conforming with the technical specifications provided in Part (A) of Annex IV to the Directive of 1999, and

(b) carry a tactile warning of danger conforming to the technical specifications provided in Part B of Annex IV to the Directive of 1999,

where the criteria specified in Annex IV to the Directive of 1999 taking account of the technical specifications comprising Annex IX to Directive of 1967 as amended by the Directive of 1992 and adapted by Commission Directives 91/410/EEC and 2000/32/EC) are satisfied or where although not dangerous it may nevertheless present a specific hazard.

(4) A package containing a plant protection product shall be closed with a distinctive seal in such a way that when the package is opened for the first time the seal is irreparably damaged.

(5) Where the packaging of a plant protection product includes an inner liner, except where the liner is used as a seal to protect rodenticidal baits, or is a water soluble sachet contained in a sealed foil sachet, it shall not be detachable from the rest of the packaging unless it complies with paragraph (1).

(6) Subparagraphs (a), (b) (c) and (d) of paragraph (1) shall be satisfied if the packaging of a plant protection product complies with the requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air.

Labelling

23. The packaging of a plant protection product or label attached to the packaging, shall comply with the Schedule.

Trials authorizations

24. (1) A person shall not place a plant protection product on the market for use in experiment or tests or use the product in experiments and tests, other than under a trials authorisation where -

- (a) the testing or experimentation is for research or development purposes, and
- (b) the tests or experiments concerned involve any release into the environment of an
 - i. unauthorized plant protection product, or
 - ii. authorized plant protection product for an unauthorized use, andthe experiments and tests are carried out in a manner as the Minister may require from time to time

(2) This Regulation, in relation to authorization of plant protection products for trials purposes, shall not apply to experiments or tests covered by Part B of Council Directive No. 90/220/EEC of 23 April 1990³⁵.

³⁵ O.J. No. L117/15 8/5/1990

(3) An application for a trials authorization shall be made in a form as set out from time to time by the Minister and shall be made by or on behalf of the person responsible for, or on whose behalf, the research and development is to be conducted, subject to the person concerned being established in a Member State.

(4) An application for a trials authorization shall be submitted to the Minister at least 45 days before the date on which it is intended that the trial commence and shall be supported with a dossier containing such information as the Minister may from time to time require.

(5) The tests and analyses conducted for the purposes of compiling dossiers referred to in paragraph (4), shall be carried out under agricultural, plant health and environmental conditions relevant to use of the plant protection product in question and representative of those prevailing where the product is intended to be used, and where relevant, shall be officially recognized tests and analyses where they are carried out in the State.

(6) Notwithstanding paragraph (5) and subject to Regulation 10 an applicant need not supply the information relevant to the active substance, except for that identifying the active substance, if -

- (a) it is listed in Annex I to the Directive of 1991,
- (b) a plant protection product containing the active substance is authorized for a provisional period under Regulation 15.

(c) a plant protection product containing the active substance is authorized under Regulation 18, or

(d) a plant protection product containing the active substance has been granted a clearance under the Regulations of 2001.

(7) The Minister shall examine every application received for a trials authorization and shall decide thereon.

(8) The Minister shall not authorize the placing on the market and use of any plant protection product for trials purposes unless it is satisfied that when used in accordance with the conditions and restrictions specified in paragraphs (10) and (11), it has no harmful effect on human or animal health and no unacceptable influence on the environment.

(9) Restrictions on use, necessary in order to avoid harmful effects on human or animal health that may arise -

(a) through exposure of consumers of treated products to risks of dietary contamination -

(i) in excess of the Acute Reference Dose (ArfD) of the residues concerned,

(ii) in excess of the Acceptable Daily Intake (ADI) level of the residues concerned, or

(iii) due to residues for which the health risks associated with exposure have yet to be established.

(b) through direct exposure of workers and other persons —

(i) in excess of the Acceptable Operator Exposure Level (AOEL) for the active substance concerned, or

(ii) due to exposure to an active substance for which the health risks associated with exposure have yet to be established.

shall, where appropriate, be attached to a trials authorization.

(10) In granting a trials authorization the Minister shall attach any further conditions to the authorization as are necessary and relevant to avoid any harmful effect on human, animal health or the environment, to include -

(a) particular packaging and labelling requirements.

(b) restrictions as to the quantity that may be placed on the market and used for trials purposes.

(c) restrictions as to the area or areas that may be treated, and

(d) conditions necessary to ensure that the use for trials purposes is controlled and subject to official supervision.

(11) A trials authorization -

(a) shall be valid for of 12 months,

(b) may be varied as to any conditions and restrictions attached, where application for such variation is made using forms as determined from time to time by the Minister, and the Minister is satisfied that the provisions of paragraph (9) shall be complied with under the changed conditions or restrictions, and

(c) may be renewed for further fixed periods of 12 months, where application for renewal is made in a form as set out from time to time the Minister.

(12) Experiments and tests conducted in accordance with the conditions and restrictions set out in the trials authorization shall be considered to have been conducted by officially recognized testing facilities or organizations, for the purposes of these Regulations.

(13) Regulations 6, 7, 8, 12, 13, 15, 16 and 18 do not apply to a plant protection product authorized for trial purposes under this Regulation.

Trials permits

25 (1) Subject to paragraph (2), and notwithstanding Regulation 24, the Minister may grant a trials permit to a person involved in research and development, for a

particular premises to conduct tests and experiments using plant protection products for which for which a trials authorization has not been granted, or for the use of an authorized plant protection products in a manner not yet authorized, where -

(a) application is made by the person using forms as determined from time to time by the Minister, and

(b) the Minister is satisfied that the requirements specified in paragraph (3) are satisfied.

(2) A person that holds a trials permit is exempt from (6), where they are conducted in accordance with the conditions and restrictions of the trials permit specified pursuant to paragraphs (4) and (5).

(3) A trials permit shall not be granted for particular premises or sites, unless the applicant -

(a) owns, or has exclusive control of premises or sites suitable for conducting trials and experiments,

(b) owns, or has available, equipment and other facilities, necessary for conducting trials and experiments, at each such premises or site, and

(c) holds, or an employee of his or hers holds, appropriate professional qualifications.

(4) Each trials permit granted shall be subject to the condition that -

(a) tests and experiments conducted in accordance with the trials permit shall be carried out as required from time to time by the Minister,

(b) unless the tests and experiments are conducted by an organization or laboratory accredited in accordance with European Standards EN 45002 and EN 45003 to carry out such tests and experiments in accordance with European Standard EN 45001.

(5) Each trials permit granted shall be subject to conditions and restrictions such that the use of plant protection products in tests and experiments conducted in accordance with the trials permit has no harmful effect on human or animal health and no unacceptable influence on the environment including:

(a) restrict its validity to the premises stated in the trials permit,

(b) restrict its validity to tests and experiments conducted under the direct supervision of the professionally qualified personnel referred to in the trials permit, and

(c) being conditional on an authorization for trials purposes being obtained, in each instance in which trials or experiments other than those conforming to the requirements of paragraph (6) are to be conducted.

(6) A trials permits shall not be valid for tests and experiments involving plant protection products unless -

(a) the conditions and manner of use are encompassed by an existing authorization for a plant protection product containing the same active substance or substances.

(b) use is restricted to crops other than food or feed crops,

(c) the nature of the use or of the active substance is such that residues at harvest are precluded, or

(d) food, feed and forage crops are destroyed by burning or burying to preclude consumption by humans or animals.

(7) A trials permit -

(a) shall be granted for fixed periods of 12 months,

(b) may be varied as to any conditions and restrictions attached, where application for such variation is made using forms as determined from time to time by the Minister, and the Minister is satisfied that the provisions of paragraph (3) will be complied with under the changed conditions or restrictions.

(c) may be renewed for a further fixed periods of 12 months, where application for such renewal is made using forms as determined from time to time by the Minister, and

(d) revoked by the Minister where a condition or restriction of the trials permit is breached.

(8) Experiments and tests conducted in accordance with the conditions and restrictions associated with a trials permit, are hereby deemed to have been conducted by officially recognized testing facilities or organizations, for the purposes of these Regulations.

Notification of imports and exports

26. (1) Subject to paragraph (2), a person shall not import a plant protection product into the State unless three days notice in advance of the intended importation has been received by the Minister in a form as set out from time to time by him or her stating-

(a) the brand name of the plant protection product,

(b) the place at which the plant protection product is to be brought into the State,

(c) the date on which the plant protection product is to be brought into the State.

(d) the number of packs that comprise the consignment,

(e) the pack size (given by reference to volume or weight) of the consignment or, in case the consignment comprises more than one pack size, the pack size (so given) of each such pack, and

(f) the destination to which the plant protection product is consigned or, in lieu thereof, an address at which it may be examined, sampled, tested or inspected pursuant.

(2) The Minister may grant an exemption from paragraph (1) if he or she is satisfied that where, following application, the Minister is satisfied that a plant protection product imported and intended for use within the State, in the first instance following importation will be transferred to nominated warehouse or storage facilities pending distribution and sale to end-users, the Minister may grant an exemption from paragraph (1) if-

(a) the importer has provided the name and address of each premises at which plant protection product will be stored following importation, prior to sale,
and

(b) the importer notifies by 31 January in each year details of all imports during the previous year to the Minister using a form as set out from time to time by him or her.

(3) If a plant protection product is exported from the State, the exporter shall notify by 31 January each year details of the export using a form as set out from time to time by the Minister.

Provisional maximum residue levels

27 The maximum levels of residues of a plant protection are

(a) provisional maximum levels established by the Community in accordance with Article 4 (1) (f) of the Directive of 1991, or

(b) maximum levels established by Directive 76/895/EEC³⁶, Directive 86/362/EEC³⁷, Directive 86/363/EEC³⁸, Directive 90/642/EEC³⁹, or Directive 91/132/EEC⁴⁰ amending Directive 74/63/EEC⁴¹.

⁴¹ O.J. No. L38/31 11/2/1974

⁴⁰ O.J. No. L66/16 13/3/1991

³⁹ O.J. No. L350/71 14/12/1990

³⁸ O.J. No. L221/43 7/8/1986

³⁷ O.J. No. L221/36 7/8/1986

³⁶ O.J. No. L340/26 9/12/1976

Products containing residues

28 (1) A person shall not place on the market any product, if -

(a) that product contains within it or on it a residue of a plant protection product,
and

(b) the level of such residue exceeds the maximum specified in relation to the product in accordance with Regulation 28 (1);

and such products shall be referred to as controlled products.

(2) A person who contravenes the provisions of paragraph (1) shall be guilty of an offence.

Appointment of authorized officer

29 (1) The Minister may appoint such and so many persons as he or she thinks fit to be authorized officers for the purpose of these Regulations.

(2) An authorized officer shall be furnished with a certificate of his or her appointment as an authorized officer and when exercising any power conferred on him or her by these Regulations shall, if requested by any person affected, produce the certificate to that person.

Appointment of designated analyst

30 (1) The Minister may appoint such and so many persons as he or she thinks fit to be designated analysts for the purpose of these Regulations

(2) A designated analyst shall be furnished with a certificate of his or her appointment by the Minister to carry out analyses as required by these Regulations.

Search and inspections

31 (1) Subject to paragraph (2), an authorized officer may for the purpose of insuring that these Regulations are being complied with -

(a) at all reasonable times, enter any premises or a place where he or she has reason to believe there is a plant protection product or a controlled product and inspect the premises or place.

(b) require any person in charge of the premises or place or connected with any equipment or other device at that premises or place to produce to him or her any books, documents or records and in the case of such information in a non-legible form to reproduce it in permanent legible form relating to the plant protection product or controlled product and to give to him or her such information as he or she may reasonably require in relation to the plant protection product or controlled product,

(c) inspect and take copies of, or take extracts from, any such books, documents or records including in the case of information in a non-legible form a copy of or extract from such information in permanent legible form,

(d) there or at any other place, carry out such examinations, inspections or tests of the plant protection product or controlled product found on the premises or at the place as the officer considers appropriate and, if the officer so thinks fit, remove or have removed any plant protection product or controlled product, equipment or other device and retain it for a reasonable period to facilitate such examination, testing or inspection,

(e) examine any procedure connected with the manufacture, placing on the market, processing, storage, usage or transportation of a plant protection product,

(f) take, without payment, such samples of a plant protection product or of a controlled product or of any other substance as the officer may reasonably require and carry

out or have carried out on such samples there or elsewhere such checks, analysis and inspections as he or she considers necessary,

(g) secure for later inspection the premises or place or part of it.

(h) if accompanied by -

(I) a member of the Garda Síochána in uniform, or

(II) an officer of the Revenue Commissioners in uniform authorized by them to exercise powers conferred by the Customs Acts or the statutes which relate to the duties of excise,

stop any vehicle which the authorized officer reasonably suspects to contain any plant protection product or controlled product to which these Regulations apply.

(2) An authorized officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (5) authorising such entry.

(3) An authorized officer, where he or she considers it necessary, may be accompanied by a member of the Garda Síochána when performing any powers conferred on an authorized officer by this Regulation.

(4) A member of the Garda Síochána not in uniform, when exercising any such power, shall, if so requested by any person affected, produce evidence in writing that he or she is such a member or officer.

(5) If a judge of the District Court is satisfied, on the sworn information of an authorized officer that there are reasonable grounds for suspecting that there is a plant protection product or controlled product on any premises or at any place or that there is any apparatus or other equipment required by him or her for inspection or tests, under this Regulation held in any premises or at any place, the judge may issue a warrant authorising an authorized officer, accompanied, if appropriate, by other authorized officers or by a member or members of the Garda Síochána at any time or times within one month from the date of issue of the warrant, on production of the warrant requested, to enter those premises or part of it, if need be by reasonable force, and exercise all or any of the powers conferred on an authorized officer under this Regulation.

(6) A person who without reasonable excuse fails to comply with any request or requirement made by an authorized officer under this Regulation is guilty of an offence.

(7) A person who obstructs or interferes with an authorized officer in the exercise of his or her powers under this Regulation or gives an authorized officer information which is false or misleading is guilty of an offence.

(8) A person guilty of an offence under this Regulation is liable on summary conviction to a fine not exceeding €3,000.

Sampling

32 (1) Where a sample is taken the authorized officer concerned shall take such samples in accordance with

(a) the methods described in the manual on the development and use of the Food and Agriculture Organization of the United Nations Plant Production and Protection Paper 149. Fifth Edition specifications for plant protection products as updated from time to time, and

(b) (i) in accordance with Commission Directive 2002/63/EC of 11 July 2002⁴³,

⁴³ O.J. No. L187/30 16/7/2002

(ii) or the Joint Food and Agriculture Organisation of the United Nations and World Health Organization Food Standards Programme. Codex Alimentarius Commission, recommended method of sampling for the determination of Pesticide Residues (Volume 2a,

Codex Alimentarius, "Pesticide Residues in Food, Methods of Analysis and Sampling" 2nd edition, Rome, 2000), where relevant, and

(iii) in accordance with other internationally accepted procedures.

(c) divide the sample into 2 or more parts, each of which he or she shall seal and mark,

(d) give one part thereof to a designated analyst for analysis in accordance with paragraph (2),

(e) leave with, or send by registered post to, the person in charge of the plant protection product or controlled product or his or her agent, a second part thereof, and

(f) where there is more than one defendant, leave with, deliver to, or send by registered post to each such defendant, a further part thereof.

(2) Where a designated analyst receives a sample from an authorized officer he or she shall analyse it in accordance with a validated method of analysis.

(3) In any proceedings for an offence under these Regulations -

(a) the result of any test, examination or analysis of, or any report on, a sample taken pursuant to this Regulation shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided (as required by paragraph (1)) was left with, or sent by registered post to, the defendant or his agent,

(b) evidence of the presence of a plant protection product to which the Regulations apply, in or on equipment used for application of the pesticide, is evidence, until the contrary is proved, of the use of the plant protection product by the owner or person in possession of the equipment.

(c) evidence of the presence of a residue of a plant protection product to which the Regulations apply, in or on agricultural produce, soil, compost, surfaces or other materials which may have been treated with or exposed to the plant protection product, is evidence, until the contrary is proved, of the use of the plant protection product by the owner, occupier or person in possession, as the case may be,

(d) a certificate in a form as set out from time to time by the Minister showing the results of an analysis is sufficient evidence until the contrary is shown of the facts certified to in the certificate in relation to

(i) the presence in a plant protection product of any active substance, impurity or formulating ingredient, and the level of any such presence, or

(ii) the presence of a residue of a plant protection product and the level of such residues in any controlled product, and

(iii) a document purporting to be such a certificate shall be considered, until the contrary is shown, to be such a certificate.

(4) The presence of a plant protection product or controlled product, to which these Regulations apply, on any premises, including any stores, where the business of marketing such a plant protection product or a controlled product is conducted, is sufficient evidence until the contrary is shown that the plant protection product in question is or was being placed on the market by the owner or the person in possession of the product or substance on such premises.

(5) If any person -

(a) tampers with any plant protection product so as to procure that any sample of it taken pursuant to these Regulations does not correctly represent the plant protection product, or

(b) tampers with any controlled product so as to procure that any sample of it taken pursuant to these Regulations does not correctly represent the product sampled, or

(c) tampers or interferes with any sample taken pursuant to these Regulation.
he or she is guilty of an offence.

Seizure, retention, removal and

33 (1) An authorized officer may by a notice in writing given to the owner or to the person in apparent charge or control of a plant protection product or of a controlled product seize and detain the plant protection product or controlled product.

(2) An authorized officer may, in respect of a plant protection product or a controlled product seized under paragraph (1). -

(a) require things specified in the notice to be done in relation to the plant protection product or the controlled product before an authorized officer releases it, and

(b) in the case of a plant protection product, either -

(i) require the disposal of the plant protection product by the person to whom the notice is given, in a manner specified in the notice and at the expense of the owner, or

(ii) indicate the authorized officer's intention of disposing of the plant protection product at the expense of the owner,

such disposal to be, in either case, such as will prevent the said plant protection product from being placed on the market or used, and

(c) in the case of a controlled product require the disposal of the product by the owner, or person in apparent charge or control of the product, in a manner and within a time specified in the notice and at the expense of the owner, such disposal to be such as will prevent the product being used for human or animal consumption,

and in case a notice given under this paragraph requires specified things to be done in relation to a plant protection product or controlled product, the authorized officer shall retain control of the plant protection product or controlled product to which the notice relates until the requirements of the notice have been complied with.

(3) An authorized officer may destroy or otherwise dispose of any plant protection product or a controlled product seized and detained by him or her under Paragraph (1), with the consent of the owner or person in charge of the product or substance or upon the granting of an order under paragraph (6).

(4) An authorized officer who has seized and detained any product or substance may on giving notice in writing to the owner or person in charge of the product or substance apply to a judge of the District Court in whose district court the product or substance was seized for an order directing that the product or substance be destroyed or otherwise disposed of as being a product or substance which is a danger to human or animal health or the environment.

(5) Where a notice is given under this Regulation, a person shall not, without the consent of the authorized officer by whom the notice was given sell, move, dispose of or otherwise interfere with the plant protection product or controlled product in any way pending compliance with the requirements of the notice.

(6) Any person who is aggrieved by a notice given under paragraph (2), in relation to a plant protection product, which either requires the plant protection product to which it relates to be disposed of or indicates an intention to dispose of such a plant protection product may, not later than the expiration of a period of seven days beginning on the date of the notice, appeal against the notice to the District Court in the District Court District in which the notice has been served.

(7) Disposal of a plant protection product pursuant to a notice given under paragraph (2) shall not take place until -

(a) the period during which an appeal under paragraph (4) may be taken against the notice has expired, or

(b) an appeal under that paragraph is determined or withdrawn.

(8) (a) Where an appeal is made to the District Court under paragraph (4), that court, if it is satisfied that -

(i) the plant protection product to which the relevant notice under this Regulation relates is one to which Regulation 3 applies, and

(ii) if the plant protection product was released, it might be placed on the market or used for purposes not authorized in accordance with these Regulations, and

(iii) there has been a failure to comply with the provisions of these Regulations - shall order that the plant protection product be disposed of in the manner specified in the notice, or in such other manner as may be specified in the court's order and which, in the opinion of the court, will prevent the plant protection product from being used or placed on the market.

(b) Where an order made by the District Court under this paragraph requires the plant protection product to which it relates to be disposed of by an authorized officer, the cost of such disposal shall be recoverable by the Minister as a simple contract debt in any court of competent jurisdiction from the person who was either the owner or in apparent charge or control of the product at the time of its seizure under this Regulation.

(9) Notwithstanding paragraph (2) and the requirements of these Regulations in relation to plant protection products, the method of disposal specified by the authorized officer in a notice given under paragraph (2) may include its use subject to such conditions as the Minister may specify in order to minimize any unacceptable risk to man, animals or the environment that might arise from such use.

(10) In the case of a notice given under paragraph (2) which indicates an intention to dispose of a plant protection product, the ownership of such a plant protection product shall, in the absence of an appeal by the owner against the notice to the District Court, vest in the Minister on the expiration of a period of 7 days beginning on the date of the notice. In the event of an appeal by the owner against the notice to the District Court, ownership of the plant protection product shall vest in the Minister if the court makes an order under paragraph (6) that requires the plant protection product to be disposed of by an authorized officer.

(11) In the case of a notice under paragraph (2) which requires the disposal at the expense of the owner of a plant protection product which has been seized under this Regulation and where there has been a failure to pay, the cost of such disposal shall be recoverable by the Minister as a simple contract debt in any court of competent jurisdiction from the person who was either the owner or in apparent charge or control of the plant protection product at the time of its seizure under this Regulation.

(12) Where there has been failure to comply with a requirement of a notice given under paragraph (2) with respect to a controlled product, an authorized officer who in pursuance of this Regulation has seized any controlled product may, on giving notice in writing to the owner, or the person in apparent charge or control of such product of his intention to do so, apply to the District Court in the District Court district in which the notice has been served for an order directing that the controlled product be disposed of (by destruction or otherwise) in a manner, specified in the order, that will prevent its being used for human or animal consumption.

(13) Where an application is made under paragraph (12) to the District Court for an order directing the disposal of a controlled product, the Court, if it is satisfied that -

(i) the controlled product to which the notice relates contains within it or on it a residue of a plant protection product in excess of the maximum specified in relation to that product in accordance with Regulation 27,

(ii) if such product were released, it might be put into circulation contrary to Regulation 28, and

(iii) such product if consumed would constitute a danger to human or animal health,

shall order that the product be disposed of (by destruction or otherwise) in a manner, specified in the order that will prevent its being used for human or animal consumption.

(14) Where an order is made by the District Court under paragraph (12), the order may provide that the controlled product to which it relates be disposed of in the manner specified in the notice given under paragraph (2), or in such other manner as may be specified in the Court's order and which, in the opinion of the Court, will prevent the product being used for human or animal consumption.

(15) Where an order made by the District Court under paragraph (12) requires that a product to which it relates be disposed of by an authorized officer, the cost of disposing of the relevant product pursuant to and in accordance with the order shall be recoverable by the Minister as a simple contract debt in any court of competent jurisdiction from the person who was either the owner, or in apparent charge or control of the product, at the time it was seized.

(16) A judge of the District Court to whom an application is made under paragraph (4) shall, if satisfied that such product or substance does not comply with these Regulations or the Directive of 1991 and is a danger to human or animal health or the environment, order that it be destroyed or otherwise disposed of after such a period, not exceeding 14 days, as may be specified in the order, as being a product or substance which is a danger to human or animal health or to the environment.

(17) In the case of a notice under paragraph (1) requiring specific actions or disposal under paragraph (2), all costs incurred shall be the liability of the owner of a plant protection product or a controlled product and where there has been a failure to pay, the cost of such disposal shall be recoverable by the Minister as a simple contract debt in any court of competent jurisdiction from the person who was either the owner or in apparent charge or control of the plant protection product or or a controlled product at the time of its seizure under these Regulations.

General Offences

34 (1) A person who fails to comply with any Regulation under these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €3,000, or to imprisonment for a term not exceeding 6 months, or to both.

(2) (a) A person shall not forge or utter knowing it to be forged -

(i) a record purporting to be established and maintained under these Regulation or a document purporting to be an extract therefrom (hereafter in this Regulation referred to as "a forged record"), or

(ii) a dispatch document purporting to be issued or given under this Regulation (hereafter in this Regulation referred to as "a forged document").

(b) A person shall not alter with intent to defraud or deceive, or utter knowing it to be so altered —

(i) a record purporting to be established and maintained under these Regulation or a document purporting to be an extract therefrom (hereafter in these Regulation referred to as "an altered record"), or

(ii) a dispatch document purporting to be issued or given under these Regulation (hereafter in this Regulation referred to as "an altered document").

(c) A person shall not have, without lawful authority, in his or her possession a forged record, forged document, altered record or altered document.

(d) A person, in purported compliance with these Regulations, shall not give information that he or she knows to be false or misleading.

Prosecutions and specific rules of evidence

35. (1) An offence under these Regulations may be prosecuted by the Minister.

(2) In proceedings for an offence under these Regulations evidence that claims have been made that a product -

(a) protects plants or plant products against harmful organisms or prevents the action of such organisms,

(b) influences the life processes of plants, other than as a nutrient, (e.g. growth regulators),

(c) preserves plant products,

(d) destroys undesired plants, or

(e) destroys parts of plants, checks or prevents undesired growth of plants,

shall, until the contrary is shown, be sufficient evidence that it is a plant protection product.

(3) (a) In any proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or any report on, a sample taken shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided was left with, delivered to, or sent by registered post to the defendant or his or her agent.

(b) In any proceedings for an offence under these Regulations, evidence of the presence of a plant protection product in or on equipment capable of use for application of the pesticide, shall be evidence, until the contrary is proved, of the use of the plant protection product by the owner or person in possession of the equipment.

(c) In any proceedings for an offence under these Regulations, evidence of the presence of a residue of a plant protection product, in or on agricultural produce, in soil or compost or in or on surfaces or other materials which may have been treated with or exposed to the plant protection product, shall be evidence, until the contrary is proved, of the use of the plant protection product by the owner, occupier or person in possession, as the case may be.

(d) In any proceedings for an offence under these Regulations, a certificate showing the results of analysis shall, until the contrary is shown, be sufficient evidence of the facts certified to therein in relation to -

(i) the presence in a plant protection product of any active substance, impurity or formulating ingredient and the level of any such presence, or

(ii) the presence of a residue of a plant protection product and the level of such residues in any controlled product, and

a document purporting to be such a certificate shall be such a certificate.

(e) The presence of a plant protection product on any premises (including any stores), shall, until the contrary is shown, be sufficient evidence that the plant protection product in question is or was being placed on the market or used by the owner and by the occupier of such premises.

Fees

36 (1) An application for authorization of a plant protection product or any other service provided or act done under these Regulations shall be accompanied by such fee or part thereof as the Minister may, from time to time, determine.

(2) (a) The Minister shall not consider an application unless it is accompanied by the appropriate fee.

(b) If the Minister determines that a fee or part of a fee is to be paid on an annual basis, the fee or part thereof shall be paid no later than 1 September in the year on which it falls due.

(3) A fee under this Regulation shall be paid in the manner that the Minister may from time to time determine.

(4) A person shall not place a thing in respect of which a fee is payable on the market unless he or she has paid the appropriate fee or fees.

Reduction in fees

37. (1) A person who makes a claim for a reduction or a refund of fees shall -

(a) produce, at the request of an authorized officer, any records, books or other documents that are in his or her possession or under his or her control which substantiate such a claim, and

(b) permit the authorized officer to inspect and take extracts from such records, books or other documents and give to the authorized officer any information which is within his or her knowledge or under his or her control and which such officer may reasonably require for the purpose of verifying the claim, and

(c) afford to such an officer such facilities and assistance as are reasonably necessary for inspecting the stock of the relevant plant protection product if the authorized officer considers such inspection is necessary for the purpose of verifying the claim.

(2) The Minister may, on application, reduce a fee or refund part of a fee.

(3) An application for reduction or refund of a fee shall be in such form and contain such particulars as the Minister may require.

Revocations

38. The following are revoked -

(1) European Communities (Authorization, Placing on the Market. Use and Control of Plant Protection Products) Regulations 1994 (S.I. No. 139 of 1994).

(2) European Communities (Authorization, Placing on the Market. Use and Control of Plant Protection Products) (Amendment) Regulations 1995 (S.I. No. 200 of 1995).

(3) European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations 1996 (S.I. No. 159 of 1996).

(4) European Communities (Authorization. Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations 1997 (S.I. No. 290 of 1997),

(5) European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (Number 2) Regulations 1997 (S.I. No. 466 of 1997).

(6) European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 4) Regulations 1999 (S.I. No. 461 of 1999).

(7) European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations 2001 (S.I. No. 141 of 2001), and

(8) European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 4) Regulations 2001 (S.I. No. 623 of 2001).

Savers

40. (1) An authorized officer appointed under the Regulations mentioned in Regulation 39 and holding office immediately before the commencement of these Regulations continues in office after such commencement as if appointed under these Regulations;

(2) Any authorization, permission to place on the market, trials authorization or trials permit granted under any Regulation mentioned in Regulation 39 and in force

immediately before the commencement of these Regulations continues in force after such commencement as if granted under these Regulations.

Regulation 23

1 The following shall be stated clearly and in an indelible form on all packaging and on a label on, or attached to, the packaging in the Irish language or in the English language or in both languages -

(1) the phrases and inscriptions set out in Annex V to the Directive of 1999, and
(2) the inscription - "To avoid risks to man and the environment, comply with the instructions for use".

(3) the trade name or designation of the plant protection product,

(4) (a) the name and address of the holder of the authorization or permission to market,

(b) 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, and

(c) the registration number allocated by the Minister to the plant protection product.

(5) (a) the name of each active substance as given in the list contained in Annex I to the Directive of 1967, if not included therein, its ISO common name or if an ISO name has not yet been assigned, its chemical designation according to IUPAC rules, and

(b) the amount of each active substance so contained expressed for plant protection products that are —

(i) solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pas at 20 °C), as a percentage by weight.

(ii) for other liquids, as a percentage by weight and in grams per litre at 20 °C, for gases, as a percentage by volume.

(iii) for acids, their amides, esters and salts, on an acid equivalent basis.

(6) the net quantity of plant protection product.

(7) the formulation batch number or some means of identifying it,

(8) the chemical name of each substance present in the preparation, excluding active substances, under the designations listed in Annex I to the Directive of 1967 or under an internationally recognised chemical nomenclature if its designation is not included in that Annex, under the following detailed rules

(a) for preparations classified as very toxic, toxic or harmful under Regulation 9 of the Regulations of 2001 and subject to subparagraph (e), the name of every very toxic, toxic or harmful substance present in concentrations equal to, or greater than, the lowest limit laid down for the substances concerned in Annex I to the Directive of 1967, or failing that in Part B of Annex IX of the Regulations of

(b) for preparations classified as corrosive under Regulation 9 of the Regulations of 2001 and subject to subparagraph (e), the name of every corrosive substance present in concentrations equal to, or greater than, the lowest limit laid down for the substances concerned in Annex I to the Directive of 1967, or failing that in Part B of Annex IX of the Regulations of 2001

(c) subject to subparagraph (e), the name of every substance that has given rise to the classification of the preparation in one or more of the following danger categories as set out in Annex IV of the Directive of 1967-

(i) carcinogen category 1, 2 or 3.

(ii) mutagen category 1, 2 or 3.

(iii) toxic for reproduction category 1, 2 or 3.

(iv) very toxic, toxic or harmful due to non-lethal effects after a single exposure,

- (v) toxic or harmful due to severe effects after repeated or prolonged exposure, or
- (vi) sensitising,
- (d) the name of every substance that has given rise to the classification of the preparation in one or more of the following danger categories, where the name of the substance must be included on the label under subparagraphs (a), (b) or (c) as set out in Annex to the Directive of 1967—
 - (i) explosive,
 - (ii) oxidising,
 - (iii) extremely flammable,
 - (iv) highly flammable,
 - (v) flammable
 - (vi) irritant, or
 - (vii) dangerous for the environment,
- (e) unless more are necessary to identify the substances primarily responsible for the major health hazards that gave rise to the classification and choice of corresponding phrases under subparagraphs (a) to (b), a maximum of four chemical names shall suffice,
- (9) (a) subject to subparagraph (b) the danger symbols and indications of the dangers specified in Annex II to the Directive of 1967,
 - (b) where more than one danger symbol must be assigned to a preparation the obligation to apply the symbol -
 - i. T shall make use of the symbols C and X optional unless otherwise specified in Annex I to the Directive of 1991 to the Directive of 1991,
 - ii. C shall make use of the symbol X optional,
 - iii. E shall make use of the symbols F and O optional,
 - iv. Xn shall make use of the symbol Xi optional,
 - (c) the danger symbols shall be printed in black on an orange-yellow background.
- (10) (a) subject to subparagraphs (b), (c) and (d), risk phrases selected from those included in Annex III to the Directive of 1967.
 - (b) unless more are necessary to identify the principal hazards, a maximum of six risk phrases shall suffice to describe the risks, for this purpose, the combined phrases listed in Annex III to the Directive of 1967 shall be regarded as single phrases,
 - (c) in the case of plant protection products classified dangerous in more than one danger category, the risk phrases selected shall cover all of the principal hazards identified.
 - (d) the risk phrases "extremely flammable" or "highly flammable" need not be used where they describe an indication of danger, used under paragraph (a),
- (11) (a) subject to subparagraph (b), safety phrases selected from those included in Annex IV to the Directive of 1967
 - (b) unless more are necessary to provide appropriate safety advice, a maximum of six safety phrases shall suffice listed from those included in Annex IV to the Directive of 1967,
 - (c) where it is physically impossible to include the advice on the label or package itself, the package shall be accompanied by safety advice on the use of the plant protection product,
- (12) first-aid information for use in the event of accidental exposure or ingestion.
- (13) 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 to the Directive of 1991,
- (14) 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 to the Directive of 1991,

- (15) the type of action of the plant protection product,
- (16) the type of preparation,
- (17) the uses for which the plant protection product has been included on the register of plant protection products and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used;
- (18) directions for use and the dose rate, expressed in metric units, for each use,
- (19) where necessary, the safety interval for each use between application and -
 - (a) sowing or planting of the crop to be protected.
 - (b) sowing or planting of succeeding crops,
 - (c) access by humans or animals,
 - (d) harvesting, and
 - (e) use or consumption,
- (20) particulars of possible phytotoxicity, varietal susceptibility and any other direct or indirect adverse side effects on plants or products or plant origin together with the intervals to be observed between application and sowing or planting of a crop or subsequent crops,
- (21) if accompanied by a leaflet, the sentence "*Read accompanying instructions before use*".
- (22) directions for safe disposal of the plant protection product and of packaging,
- (23) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years, and
- (24) where relevant, the category of users to which supply is restricted.

2 Notwithstanding paragraph 1. the information specified in paragraph 1 (18), (19) and (20) may be included on a separate leaflet accompanying the package if the space available on the package is too small and the leaflet shall be regarded as part of the label. A label and packaging of a plant protection product shall not bear indications such as "*non-toxic*", "*harmless*", or other similar indication.

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

4 Where the information stated in paragraph 1 appears on a label, the label shall be firmly affixed to one or more surfaces of the packaging so that those particulars can be read horizontally when the package is set down normally.

5 The colour and presentation of each label or packaging where the information specified in paragraph 1 is printed on the package, shall be such that the danger symbol and its background stand out clearly from it.

6 The information stated in paragraph 1 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

7 Notwithstanding paragraph 1 (10) and (11) where the contents of a package do not exceed 125 millilitres -

(a) in the case of a plant protection product classified as highly flammable, oxidising or irritant, with the exception of a product assigned the phrase R41, or classified as dangerous for the environment and assigned the symbol N, the labelling need not include the relevant risk and safety phrases, and

(b) in the case of a plant protection product classified as flammable, or dangerous for the environment but not assigned the N symbol, the labelling need not include the relevant safety phrases.

8 Notwithstanding paragraph 1, the requirements in relation to the information to be included on packaging or on a label attached to packaging shall be satisfied -

(a) in the case of an outer package containing one or more inner packages, if the outer package is labelled under international rules on the transport of dangerous goods and the inner package or packages are labelled under paragraph 1, and

(b) in the case of a single package -

(i) if such a package is labelled under international rules on the transport of dangerous goods and with paragraph 1 (3), (4), (6), (8), (10) and (11),

(ii) for products classified under Regulation 10 of the Regulations of 2001, paragraph 2 (a) shall apply in relation to the property in question when it has not been so identified on the label, or

(iii) where appropriate, for particular types of packaging such as mobile gas cylinders, the specific requirements referred to in Annex VI to the Directive of 1967 are complied with.

9 Where packaging -

(a) is either too small or is unsuitable to enable all the information required by paragraph 1 to be shown on the container itself or on a label or on attached thereto,

(b) containing a plant protection product classified as being harmful, extremely flammable, highly flammable, flammable, irritant or oxidising and the quantity so contained is small and presents no danger to persons handling the plant protection product or any other person,

(c) containing a plant protection product classified as being dangerous for the environment in such small quantities that there is no reason to fear any danger to the environment, or

(d) containing a plant protection product not mentioned in subparagraph (b) or (c) and the quantity so contained is small and presents no danger to persons handling the plant protection product or any other person,

the labelling required under paragraph 1 shall be in a manner that for the time being stands approved of for the purposes of this paragraph by the Minister and which he or she considers appropriate, subject to the symbols, indications of danger, risk phrases and safety phrases used being those specified under paragraph 1.

GIVEN under my Official Seal,

4th March, 2003.

Joe Walsh

Minister for Agriculture and Food

Explanatory Note

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations which consolidate and replace the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001 (S.I. No. 139 of 1994, S.I. No. 200 of 1995, S.I. No. 159 of 1996,

S.I. No. 290 of 1997, S.I. No. 466 of 1997, S.I. No. 461 of 1999, S.I. No. 141 of 2001, S.I. No. 623 of 2001), also give effect to Commission Directive 2001/36/EC of 16 May 2001, Commission Directive 2001/103/EC of 28 November 2001, Commission Directive 2002/18/EC of 22 February 2002, Commission Directive 2002/37/EC of 3 May 2002, Commission Directive 2002/48/EC of 30 May 2002, Commission Directive 2002/64/EC of 15 July 2002 and Commission Directive 2002/81/EC of 10 October 2002.

The Regulations specify the data requirements for plant protection products containing micro-organisms and for active substances that are micro-organisms, and include the active substances, 2,4-D, isoproturon, ethofumesate, iprovalicarb, prosulfuron, sulfosulfuron, cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M and picolinafen in Annex I to the Directive of 1991 to the Directive of 1991 (*i.e.* in the list of active substances authorized for use in plant protection products).

The amendments made introduce additional definitions, revise the requirements concerning permissions to market, and those concerning extensions in the field of application of plant protection products, make provision for the granting of authorizations for specified periods, amend the packaging and labelling requirements to provide consistency with the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001 (S.I. No. 624 of 2001), amend the control arrangements specified under the Regulations, and allow for amendments to application and annual fees.

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