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S.I. No. 224 of 2005

European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations 2005

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EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) (NO. 2) REGULATIONS, 2005

I, Mary Coughlan, 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 further effect to Council Directive No 91/414/EEC of 15 July 1991 [1] and of giving full effect to Commission Regulation (EC) No 1112/2002 of 20 June 2002 [2] and Commission Regulation (EC) No 2229/2004 of 3 December 2004[3] hereby make the following Regulations:

Citation

1 (1) These Regulations may be cited as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations, 2005.

(2) The European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 2003 (S.I. No 83 of 2003),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 2003 (S.I. No 357 of 2003),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations, 2003 (S.I. No 702 of 2003),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 2004 (S.I. No 197 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations, 2004 (S.I. No 498 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 3) Regulations, 2004 (S.I. No 580 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 4) Regulations, 2004 (S.I. No 581 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 5) Regulations, 2004 (S.I. No 650 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 6) Regulations, 2004 (S.I. No 651 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 7) Regulations, 2004 (S.I. No 710 of 2004),

the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 2005 (S.I. No 176 of 2005) and

[1] O.J. No. L230 19/08/1991 p1

[2] O.J. No. L168 27/06/2002 p14

[3] O.J. No. L379 24/12/2004 p13

these Regulations may be cited together as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 2003 to 2005.

2 (1) In these Regulations -

"the principal Regulations" means the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 2003, (S.I. No. 83 of 2003);

(2) 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 a Schedule of the Principal Regulations.

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

3 Regulation 2(1) of the Principal Regulations is amended by substituting for the definitions "notified" and "register of plant protection products" the following -

" 'notified' in the case of a plant protection product on the market on or before the 2nd December 1985 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 and as to the producer or 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, a plant protection product containing a macro-organism, or a plant protection product containing only active substances listed in Annex I of Commission Regulation (EC) No 1112/2002 of 20 June 2002 means -

a) the packaging, including any label or container used with the package,

b) basic documentation and 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;

'register of plant protection products' means a list established under paragraph (5) of Regulation 21;"

4 The Principal Regulations are amended by substituting for Regulation 4 the following -

" 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 it has been included in the register of plant protection products and 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."

5 The Principal Regulations are amended by substituting for Regulations 5 the following: -

"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 Regulation 11 (2) (a) and (b), and Regulation 25 of the Regulations of 2001,

and

(b) considered to comply with Regulations 11 (1), 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 or that is notified in accordance with these Regulations may subject to the provisions of the Regulations of 2001, be placed on the market 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 specified period not exceeding 12 months may be granted if -

(a) (i) the active substances in the plant protection product are 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 Member State responsible for its evaluation on behalf of the Commission is available to the Minister,

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

(iv) in the case of a plant protection product intended for one or more minor uses an acceptable daily intake (ADI) value and/or an acute reference dose (ARfD) has been established for each relevant active substance,

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

(c) the plant protection product has been authorized or granted an extension in field of application for the proposed use or uses in another Member State and a copy of the certificate of authorization or extension and of the approved label in that Member State for the plant protection product is provided to the Minister,

(d) the proposed uses of the plant protection product are –

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

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

(iii) uses considered for the purposes of granting the authorization or extension in field of application referred to in subparagraph (c),

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

(5) An authorization for a specified period granted in accordance with paragraph 4 may on application made be renewed for further periods of up to 12 months."

6 The Principal Regulations are amended by substituting for Regulations 8, 9, 10, 11, 12 and 13 the following:

"8 (1) An application for authorization shall be made by or on behalf of the person responsible for first placing the plant protection product 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 product and each active substance therein and standards for each such active substance, as well as for

(i) impurities and formulants of toxicological or environmental significance, and

(ii) 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 carried out under agricultural, plant health and environmental conditions

(a) relevant to use of the plant protection product in question,

(b) representative of those prevailing where the product is intended to be used, and

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 dossier complying with Annex II to the Directive of 1991 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.

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 as a constituent of a plant protection product before 25 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 as a constituent of a plant protection product before 25 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 1876[4]

[4] 1876, c. 77

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.

(5) The Commission shall be informed of each instance in which an application for authorization of a plant protection product is being considered and an active substance concerned is considered to be listed in Annex I, that has been produced by a person or manufacturing process other than those specified in the dossier on the basis of which the active substance was first included in Annex I.

(6) In each instance referred to in paragraph (5), all data regarding the identity and impurities of the active substance concerned shall be transmitted to the Commission.

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 (4) and (5) and without prejudice to Council Directive 90/313/EEC of 7 June 1990[5], 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.

(4) Confidentiality shall not apply to -

(a) the name and content of an active substance;

(b) 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.

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 before 25 July 1993 and not subsequently

[5] O.J. No. L158 28/6/1990, p. 56

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 together with 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.

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 elaborated 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."

7 The Principal Regulations are amended by substituting for Regulation 15 the following:

"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 as a constituent of a plant protection product before 25 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 can satisfy 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) Where authorization for a provisional period is granted, the other Member States and the Commission shall immediately be informed of the assessment carried out and of the terms of each authorization granted.

(4) Notwithstanding paragraph (2), where on expiry of an authorization for a provisional period, 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 of a duration consistent with the period provided in accordance with the final paragraph of Article 8(1) of the Directive of 1991."

8 The Principal Regulations are amended by substituting for Regulations 18 and 19 the following:

"18(1) Subject to Regulation 19 (7), during the period to 25 July 2003 or other period laid down in accordance with Article 8(2) of the Directive of 1991, Commission Regulation (EC) No. 2076/2002 of 20 November 2002[6] or Commission Decision of 2003/565/EC of 25 July 2003[7], 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 as a constituent of a plant protection product before 25 July 1993 and was included in the register of plant protection products.

[6] O.J. No. L 319 23/11/2002, p. 3
[7] O.J. No. L 192 31/7/2003, p. 40

(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;

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

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. An authorization, whether or not for a provisional period, shall where necessary be extended for the period necessary for the provision of such further information or to complete 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 an authorization if it is established that on the basis of developments in scientific and technical knowledge that 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.

(8) 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.

(9) Following the review of an active substance in accordance with Article 8 (2) of the Directive of 1991, the Minister shall -

(a) within 6 months of the completion of each such review, where a decision is taken not to include an active substance in Annex I,

(i) in the case of plant protection products containing the active substance and included on the register of plant protection products prior to 1 October 1994, cancel each notification accepted and each clearance and permission to market granted in accordance with the Regulations of 2001,

(ii) cancel each authorization granted in accordance with Regulation 18 and each permission granted in accordance with Regulation 5 (3), for each plant protection product containing the active substance;

(b) within 6 months of the completion of each such review, where a decision is taken to include an active substance in Annex I,

(i) in the case of a plant protection product containing the active substance included on the register of plant protection products prior to 1 October 1994 -

(I) cancel each relevant notification accepted, and each clearance and permission to market granted in accordance with the Regulations of 2001, for each plant protection product containing the active substance concerned, where in accordance with Regulation 10, information referred to in Regulation 8 (3), may not be used to support its authorization, unless the information concerned is provided in accordance with subparagraph (c),

(II) modify each notification accepted, and each clearance and permission to market granted in accordance with the Regulations of 2001, for each plant protection product concerned, such that the conditions and restrictions associated with inclusion of the active substance in Annex I are complied with,

(ii) in the case of an authorization granted in accordance with Regulation 18 and a permission granted in accordance with Regulation 5 (3), for a plant protection product containing the active substance,

(I) cancel the authorization or permission to market, as appropriate, where in accordance with Regulation 10, information referred to in Regulation 8 (3), may not be used to support the authorization or permission, unless the information concerned is provided in accordance with subparagraph (c),

(II) modify the authorization or permission to market for each product concerned, such that the conditions and restrictions associated with inclusion of the active substance in Annex I are complied with; and

(c) where a decision is taken to include an active substance in Annex I, in the case of plant protection products containing only that active substance or containing that active substance and other active substance all of which are included in Annex I -

(i) require persons marketing a plant protection products containing the active substance and included on the register of plant protection products prior to 1 October 1994, to make application for its authorization in accordance with these Regulations, at a time specified by the competent authority,

(ii) in the case of an authorization granted in accordance with Regulation 18 or permission granted in accordance with Regulation 5 (3) for a plant protection product containing the active substance, require persons marketing the product concerned to make application for its authorization in accordance with these Regulations, at a time specified by the competent authority,

(iii) in cases referred to in subparagraphs (i) and (ii), subject to the provisions of paragraph (13), examine, and authorize, or not, each plant protection product concerned in accordance with these Regulations, by the date specified by the Commission, provided that it has the necessary scientific and technical resources at its disposal.

(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."

9 The Principal Regulations are amended by substituting for Regulation 21 the following:

"21 The Minister shall draw up and maintain a list of the plant protection products that may be placed on the market and used in the State and shall on an annual basis communicate that list to the competent authorities of the other Member States and to the Commission."

10 The Principal Regulations are amended by substituting for Regulations 24, 25, 26, 27 and 28 the following:

"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

(a) 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, and

the 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 1990[8].

(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.

[8] O.J. No. L117 8/5/1990, p. 15

(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 (9) and (10), 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 a period 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 (8) 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.

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 the provisions of Regulation 24 in relation to tests and experiments that comply with the requirements of paragraph (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. The conditions and restrictions specified for each trials permit shall be such that -

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

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

(c) it is 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) may be 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.

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 to Regulation 31.

(2) Following application made, the Minister may grant an exemption from paragraph (1) if he or she 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, 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.

27 (1) The Minster may from time to time specify the maximum levels of residues of plant protection products which may be contained in specified controlled products.

(2) The maximum levels of residues of plant protection products specified in accordance with paragraph (1) shall be those elaborated pursuant to Regulation 13 (1) (c), Regulation 15 or Regulation 18 (3) (b) and shall remain in force until replaced by -

(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 in accordance with Directive 76/895/EEC[9],Directive 86/362/EEC[10], Directive 86/363/EEC[11], Directive 90/642/EEC[12], or Directive 91/132/EEC[13] amending Directive 74/63/EEC[14].”

[9] O.J. No. L340 9/12/1976, p.26
[10] O.J. No. L221 7/8/1986, p.36
[11] O.J. No. L221 7/8/1986, p. 43
[12] O.J. No. L350 14/12/1990, p. 71

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 27;

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."

11 The Principal Regulations are amended by substituting for Regulation 33 the following:

"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 (4).

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[13] O.J. No. L66 13/3/1991, p. 16
[14] O.J. No. L38 11/2/1974, p. 31

(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 (6) 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 (6), 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 a controlled product at the time of its seizure under these Regulations."

12 The Principal Regulations are amended by substituting for Regulation 36 the following:

"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 October in the year on which it falls due. Where payment of an annual fee due is not made within 60 days of the date due, a late fee determined by the Minister shall be paid.

(c) The Minister may revoke the notification, permission to market or authorization of a plant protection product where an annual fee due is not paid by the date due and shall remove the plant protection product concerned from the register of plant protection products. The Minster may re-instate a notification, permission to market or authorization of a plant protection product on payment of all late fees outstanding.

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

(3) 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."

13 The Principal Regulations are amended by substituting for Regulation 39 the following:

"39(1) An authorized officer appointed under the Regulations mentioned in Regulation 38 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 38 and in force immediately before the commencement of these Regulations continues in force after such commencement as if granted under these Regulations."

14 The Principal Regulations are amended by substituting for the Schedule the following Schedule:

"SCHEDULE

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,

(iii) for gases, as a percentage by volume,

(iv) 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

(a) 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) in accordance with Article 16 (5) of the Directive of 1991, additional phrases deemed necessary for the protection of human beings, animals or the environment, where appropriate selected from those specified from time to time by the Minister,

(d) 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 of 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.

3 A label and packaging of a plant protection product shall not bear indications such as "*non-toxic*", "*harmless*", or other similar indication. 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 The Commission and the competent authorities of the other Member States shall be informed of each additional phrase specified in accordance with paragraph 1 (11) (c) and the reasons for its specification,

5 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.

6 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.

7 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.

8 Notwithstanding the provisions of paragraph 1 (9), (10) and (11), where it can be demonstrated that there would be a reduction in environmental impact for plant protection products classified as dangerous for the environment, they shall be labelled in accordance with provisions to be included in Parts A or B of Annex V to the Directive of 1999.

9 Notwithstanding the provisions of 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.

10 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.

11 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.

12 Where paragraph 11 is relied upon for the labelling of a plant protection product, the Commission and the other Member States shall be forthwith informed thereof. ”

Given under my Official,

this 21st day of April 2005

L.S.

Mary Coughlan

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 amend the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 2003 (S.I. No. 83 of 2003).

The amendments specify certain information and records to be compiled and where appropriate to be provided to the other Member States and to the Commission, specify the procedures to be followed following inclusion of existing active substances in Annex I, clarify the requirements concerning the granting parallel import approval for plant protection products and make particular provision for the authorization of plant protection products for minor uses and correct a number of typographical errors.

The amendments also make provision for the continued placing on the market and use, pending review, of plant protection products containing active substances specified in Commission Regulation (EC) No 1112/2002 of 20 June 2002 and included in the 4th stage of EU review programme for active substances used in plant protection.