STATUTORY RULES OF NORTHERN IRELAND

2004 No. 126

PESTICIDES

Plant Protection Products Regulations (Northern Ireland) 2004

Made - - - -	*19th March 2004*
Coming into operation	*5th May 2004*

The Department of Agriculture and Rural Development, being a Department designated(**1**) for purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to the common agriculture policy of the European Community, in exercise of the powers conferred on it by the said section 2(2) and of every other power enabling it in that behalf, hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Plant Protection Products Regulations (Northern Ireland) 2004 and shall come into operation on 5th May 2004.

Interpretation

2.—(1) In these Regulations –

"the 1985 Act" means the Food and Environment Protection Act 1985(**3**);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"member State" means member State of the European Communities;

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

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

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

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

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

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

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

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

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

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

(**4**) O.J. No. L230, 19.8.91, p. 1

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

(d) destroy undesired plants; or

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

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

"the 1987 Regulations" means the Control of Pesticides Regulations (Northern Ireland) 1987(**5**);

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

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

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

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

(2) In these Regulations –

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

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

(3) The Interpretation Act (Northern Ireland) 1954(**6**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Prohibitions

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

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

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

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

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

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

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

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

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

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

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

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

(**6**) 1954 c. 33 (N.I.)

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

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

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

(5) Nothing in these Regulations shall impede the production, storage or movement within Northern Ireland of a plant protection product intended for use in another EEA State, provided that –

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

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

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

Applications concerning active substances

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

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

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

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

Standard approvals

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

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

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

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

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

(b) for each active substance in the plant protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II.

(5) By way of derogation from paragraph (4), and without prejudice to the provisions of regulation 15(1) to (4), an applicant for approval of a plant protection product under this regulation shall be exempted from supplying the information required under paragraph (4)(b) (except for that identifying the active substance) if the active substance is already included in Annex I at the time of

the application, there being taken into account the conditions of inclusion in that Annex, and does not differ significantly in degree of purity and nature of impurities from the composition registered in the dossier accompanying the original application for inclusion of the active substance in Annex I.

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

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

General requirements for granting standard approvals

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

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

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

(a) is sufficiently effective;

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

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

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

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

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

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

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

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

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

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

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

(8) The Department shall ensure that compliance with the requirements set out in paragraphs (2) to (7) is achieved by official or officially recognised tests and analyses carried out under agricultural,