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SCOTTISH STATUTORY INSTRUMENTS

2005 No. 331

PESTICIDES

The Plant Protection Products (Scotland) Regulations 2005

Made - - - -	*8th June 2005*
Laid before the Scottish Parliament - - - -	*9th June 2005*
Coming into force - -	*1st July 2005*

The Scottish Ministers, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**) and of all other powers enabling them in that behalf, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Plant Protection Products (Scotland) Regulations 2005 and shall come into force on 1st July 2005.

(2) These Regulations extend to Scotland only.

Commencement Information

I1 Reg. 1 in force at 1.7.2005, see **reg. 1(1)**

Interpretation

2.—(1) In these Regulations, except where the context otherwise requires–

"the 1985 Act" means the Food and Environment Protection Act 1985(**2**);

"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 humans;

"approval" in relation to a plant protection product means an administrative act under these Regulations by which the Scottish Ministers, following an application submitted by an

(**1**) 1972 c. 68; section 2(2) was amended by the Scotland Act 1998 (c. 46), Schedule 8, paragraph 15(3) the functions of the Minister of the Crown insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act.

(**2**) 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.

applicant, approve the placing on the market or use of that plant protection product in the whole or any part of Scotland, and "approved" shall be construed accordingly;

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

"contravenes" includes "fails to comply with";

"the Directive" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market(**3**), as amended–

(a) by the instruments listed in Part I of Schedule 1 to these Regulations,

(b) from 1st October 2005, by the instruments listed in Part II of Schedule 1 to these Regulations, and

(c) from 1st December 2005, by the instrument listed in Part III of Schedule 1 to these Regulations;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(**3**) O.J. No. L 230, 19.8.91, p.1.

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

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

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

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

(d) destroy undesired plants; or

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

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

"the 1986 Regulations" means the Control of Pesticides Regulations 1986(**4**);

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

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

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

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

(2) In these Regulations–

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

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

(3) A reference in these Regulations to anything done in writing or produced in written form includes a reference to an electronic communication, as defined in the Electronic Communications Act 2000(**5**), which has been recorded and is consequently capable of being reproduced.

Commencement Information

I2 Reg. 2 in force at 1.7.2005, see **reg. 1(1)**

Prohibitions

3.—(1) No person shall place on the market any plant protection product unless–

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

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

(**4**) S.I. 1986/1510, amended by S.I. 1997/188 and 2001/880.
(**5**) 2000 c. 7.

(2) No person shall use any plant protection product unless–

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

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

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

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

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

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

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

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

(b) an application–

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

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

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

(5) Nothing in this regulation shall impede the production, storage or movement within Scotland of a plant protection product intended for use in an EEA State other than the United Kingdom, provided that–

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

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

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

Commencement Information

I3 Reg. 3 in force at 1.7.2005, see **reg. 1(1)**

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 Scottish Ministers, the relevant competent authorities and the Commission a dossier which satisfies the requirements of Annex II, a declaration that the active substance is intended for use in a plant protection product, and a dossier complying with Annex III on at least one preparation containing that active substance.

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

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

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

Commencement Information

I4 Reg. 4 in force at 1.7.2005, see **reg. 1(1)**

Standard approvals

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

(2) The Scottish Ministers 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 Scottish Ministers may renew the approval for a provisional period while they undertake the verification mentioned in paragraph (2) above.

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

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

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

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

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

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

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

(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.

Commencement Information

I5 Reg. 5 in force at 1.7.2005, see **reg. 1(1)**

General requirements for granting standard approvals

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

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