

## SCHEDULE 1

Regulation 2

INSTRUMENTS AMENDING COUNCIL DIRECTIVE [91/414/EEC](#)

## PART I

## Instruments in force

<i>Instruments</i>	<i>Active substances added to Annex I</i>
Commission Directive <a href="#">93/71/EEC</a> (1)	None
Commission Directive <a href="#">94/37/EC</a> (2)	None
Commission Directive <a href="#">94/79/EC</a> (3)	None
Commission Directive <a href="#">95/35/EC</a> (4)	None
Commission Directive <a href="#">95/36/EC</a> (5)	None
Commission Directive <a href="#">96/12/EC</a> (6)	None
Commission Directive <a href="#">96/46/EC</a> (7)	None
Commission Directive <a href="#">96/68/EC</a> (8)	None
Council Directive <a href="#">97/57/EC</a> (9)	None
Commission Directive <a href="#">2000/80/EC</a> (10)	lambda-cyhalothrin, imazalil, azoxystrobin, kresoxim-methyl, spiroxamine, azimsulfuron, fluroxypyr, metsulfuron-methyl, triasulfuron, esfenvalerate, prohexadione-calcium and bentazone
Commission Directive <a href="#">2001/21/EC</a> (11)	amitrole, diquat, pyridate and thiabendazole
Commission Directive <a href="#">2001/28/EC</a> (12)	fenhexamid
Commission Directive <a href="#">2001/36/EC</a> (13)	None
Commission Directive <a href="#">2001/47/EC</a> (14)	<i>Paecilomyces fumosoroseus</i>
Commission Directive <a href="#">2001/49/EC</a> (15)	flupyrsulfuron-methyl
Commission Directive <a href="#">2001/87/EC</a> (16)	acibenzolar s methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen ethyl

(1) O.J. No. L 221, 31.8.93, p.27, (as read with corrigenda published in O.J. No. L 4, 6.1.96, p.16).

(2) O.J. No. L 194, 29.7.94, p.65.

(3) O.J. No. L 354, 31.12.94, p.16, (as read with corrigenda published in O.J. No. 280, 23.11.95, p.58).

(4) O.J. No. L 172, 22.7.95, p.6.

(5) O.J. No. L 172, 22.7.95, p.8.

(6) O.J. No. L 65, 15.3.96, p.20.

(7) O.J. No. L 214, 23.8.96, p.18.

(8) O.J. No. L 277, 30.10.96, p.25.

(9) O.J. No. L 265, 27.9.97, p.87.

(10) O.J. No. L 309, 9.12.00, p.14.

(11) O.J. No. L 69, 10.3.01, p.7.

(12) O.J. No. L 113, 24.4.01, p.5.

(13) O.J. No. L 164, 20.6.01, p.1.

(14) O.J. No. L 175, 28.6.01, p.21.

(15) O.J. No. L 176, 29.6.01, p.61.

(16) O.J. No. L 276, 19.10.01, p.17.

*Status: This is the original version (as it was originally made).*

<i>Instruments</i>	<i>Active substances added to Annex I</i>
Commission Directive <a href="#">2001/99/EC</a> (17)	glyphosate and thifensulfuron methyl
Commission Directive <a href="#">2001/103/EC</a> (18)	2,4-dichlorophenoxy acetic acid
Commission Directive <a href="#">2002/18/EC</a> (19)	isoproturon
Commission Directive <a href="#">2002/37/EC</a> (20)	ethofumesate
Commission Directive <a href="#">2002/48/EC</a> (21)	iprovalicarb, prosulfuron and sulfosulfuron
Commission Directive <a href="#">2002/64/EC</a> (22)	cinidon-ethyl, cyhalofop-butyl, famoxadone, florasulam, metalaxyl-M and picolinafen
Commission Directive <a href="#">2002/81/EC</a> (23)	flumioxazine
Commission Directive <a href="#">2003/5/EC</a> (24)	deltamethrin
Commission Directive <a href="#">2003/23/EC</a> (25)	imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl, cyazofamid
Commission Directive <a href="#">2003/31/EC</a> (26)	2,4-DB, maleic hydrazide, cyfluthrin, beta-cyfluthrin, iprodione, linuron, pendimethalin
Council Regulation (EC) No. <a href="#">806/2003</a> (27)	None
Commission Directive <a href="#">2003/39/EC</a> (28)	propyzamide, propineb
Commission Directive <a href="#">2003/68/EC</a> (29)	trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone, isoxaflutole
Commission Directive <a href="#">2003/70/EC</a> (30)	mecoprop, mecoprop-P, propiconazole
Commission Directive <a href="#">2003/79/EC</a> (31);	<i>coniothyrium minitans</i>
Commission Directive <a href="#">2003/81/EC</a> (32)	molinolate, thiram, ziram
Commission Directive <a href="#">2003/82/EC</a> (33)	None
Commission Directive <a href="#">2003/84/EC</a> (34)	flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate, silthiofam
Commission Directive <a href="#">2003/112/EC</a> (35)	paraquat

(17) O.J. No. L 304, 21.11.01, p.14.

(18) O.J. No. L 313, 30.11.01, p.37.

(19) O.J. No. L 55, 26.2.02, p.29.

(20) O.J. No. L 117, 4.5.02, p.10.

(21) O.J. No. L 148, 6.6.02, p.19.

(22) O.J. No. L 189, 18.7.02, p.27.

(23) O.J. No. L 276, 12.10.02, p.28.

(24) O.J. No. L 8, 14.1.03, p.7.

(25) O.J. No. L 81, 28.3.03, p.39.

(26) O.J. No. L 101, 23.4.03, p.3.

(27) O.J. No. L 122, 16.5.03, p.1, (as read with corrigenda published in O.J. No. L 138, 5.6.2003, p.49).

(28) O.J. No. L 124, 20.5.03, p.30.

(29) O.J. No. L 177, 16.7.03, p.12 (as amended by Commission Directive [2004/65/EC](#), O.J. No. L 125, 28.4.2004, p.43).

(30) O.J. No. L 184, 23.7.03, p.9.

(31) O.J. No. L 205, 14.8.03, p.16 (as amended by Commission Directive [2004/63/EC](#), O.J. No. L 125, 28.4.2004, p.41).

(32) O.J. No. L 224, 6.9.03, p.29.

(33) O.J. No. L 228, 12.9.03, p.11.

(34) O.J. No. L 247, 30.9.03, p.20 (as amended by Commission Directive [2004/64/EC](#), O.J. No. L 125, 28.4.2004, p.42).

(35) O.J. No. L 321, 6.12.03, p.32.

<i>Instruments</i>	<i>Active substances added to Annex I</i>
Commission Directive <a href="#">2003/119/EC</a> (36)	mesosulfuron, propoxycarbazone and zoxamide
Commission Directive <a href="#">2004/20/EC</a> (37)	chlorpropham
Commission Directive <a href="#">2004/30/EC</a> (38)	benzoic acid, flazasulfuron and pyraclostrobin
Commission Directive <a href="#">2004/58/EC</a> (39)	alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham
Commission Directive <a href="#">2004/60/EC</a> (40)	quinoxifen
Commission Directive <a href="#">2004/62/EC</a> (41)	mepanipyrim
Council Directive <a href="#">2004/66/EC</a> (42)	None
Commission Directive <a href="#">2004/71/EC</a> (43)	<i>Pseudomonas chlororaphis</i>
Commission Directive <a href="#">2004/99/EC</a> (44)	acetamiprid and thiacloprid
Council Directive <a href="#">2005/25/EC</a> (45)	None

## PART II

### Instruments coming into force on 1st October 2005

<i>Instruments</i>	<i>Active substances added to Annex I</i>
Commission Directive <a href="#">2005/2/EC</a> (46)	<i>Ampelomyces quisqualis</i> and <i>Gliocladium catenulatum</i>
Commission Directive <a href="#">2005/3/EC</a> (47)	imazosulfuron, laminarin, methoxyfenozide and s-metolachlor

## PART III

### Instrument coming into force on 1st December 2005

<i>Instrument</i>	<i>Active substances added to Annex I</i>
Commission Directive <a href="#">2005/34/EC</a> (48)	etoxazole and tepraloxydim

(36) O.J. No. L 325, 12.12.03, p.41.

(37) O.J. No. L 70, 9.3.04, p.32.

(38) O.J. No. L 77, 13.3.04, p.50.

(39) O.J. No. L 120, 24.4.04, p.26.

(40) O.J. No. L 120, 24.4.04, p.39 (as amended by Commission Directive [2004/97/EC](#), O.J. No. L 301, 28.9.2004, p.53).

(41) O.J. No. L 125, 28.4.04, p.38.

(42) O.J. No. L 168, 1.5.04, p.35.

(43) O.J. No. L 127, 29.4.04, p.104.

(44) O.J. No. L 309, 6.10.04, p.6.

(45) O.J. No. L 90, 8.4.05, p.1.

(46) O.J. No. L 20, 22.1.05, p.15.

(47) O.J. No. L 20, 22.1.05, p.19.

(48) O.J. No. L 125, 18.5.05, p.6.

## SCHEDULE 2

Regulation 17

## NON-CONFIDENTIAL INFORMATION

1. The name and content of the active substance and the name of the plant protection product.
2. The name of other substances which are regarded as dangerous under–
  - (a) Council Directive [67/548/EEC](#) on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(**49**) as amended(**50**); and
  - (b) Council Directive [1999/45/EC](#) concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations(**51**) as amended(**52**).
3. Physico chemical data concerning the active substance and plant protection product.
4. Any ways of rendering the active substance or plant protection product harmless.
5. A summary of the results of the tests to establish the efficacy and harmlessness to humans, animals, plants and the environment of the active substance or the plant protection product.
6. Recommended methods and precautions to reduce handling, storage, transport, fire or other hazards.
7. The methods of analysis referred to in regulation 6(4) and (5) and Article 5(1).
8. Methods of disposal of the product and of its packaging.
9. Decontamination procedures to be followed in the case of accidental spillage or leakage.
10. First aid and medical treatment to be given in the case of injury to persons.

## SCHEDULE 3

Regulation 19

## LABELLING

1. The packaging containing the plant protection product shall be marked clearly and indelibly with the following information–
  - (a) the trade name or designation of the plant protection product;
  - (b) the name and address of the holder of the approval and the approval number of the plant protection product and, if different, the name and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market;
  - (c) the name and the amount of each active substance; the name must be–
    - (i) the same as that listed in Annex I to Council Directive [67/548/EEC](#)(**53**) as amended, if any;
    - (ii) the common name given by the International Organization for Standardization, if any; or

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(49) O.J. No. L 196, 16.8.67, p.1 (O.J./S.E. 1967 p.234).

(50) Last amended by Commission Directive [2004/73/EC](#) (O.J. No. L 152, 30.4.04, p.1).

(51) O.J. No. L 200, 30.7.99, p.1.

(52) Last amended by Council Directive [2004/66/EC](#) (O.J. No. L 168, 1.5.04, p.35).

(53) O.J. No. P 196, 16.08.67, p.1.

- (iii) its chemical designation according to the rules of the International Union of Pure and Applied Chemistry contained in the Nomenclature of Organic Chemistry, 1979 edition(54) as read with A Guide to IUPAC Nomenclature of Organic Compounds (recommendations 1993)(55);
- (d) the net quantity of plant protection product given in legal units of measurement;
- (e) the formulation batch number or some means of identifying it;
- (f) the particulars required for the product in Articles 10 to 12 of Council Directive 1999/45/EC(56) as amended;
- (g) the nature of any special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those given in Annex IV;
- (h) safety precautions for the protection of humans, animals or the environment, in the form of standard phrases selected as appropriate from those given in Annex V;
- (i) the type of action of the plant protection product;
- (j) the type of preparation;
- (k) the uses for which the plant protection product has been approved and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used;
- (l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the approval;
- (m) where necessary, the safety interval for each use between application and–
  - (i) sowing or planting of the crop to be protected;
  - (ii) sowing or planting of succeeding crops;
  - (iii) access by humans or animals;
  - (iv) harvesting; and
  - (v) use or consumption;
- (n) particulars of possible phytotoxicity, varietal susceptibility and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of–
  - (i) the crop in question; or
  - (ii) subsequent crops;
- (o) if accompanied by a leaflet, as provided for in paragraph 2 below, the sentence “Read accompanying instructions before use”;
- (p) directions for safe disposal of the plant protection product and of the packaging;
- (q) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years; and
- (r) whether the product is restricted to a certain category of user and, if so, which.

2. The requirements specified in paragraphs (l), (m) and (n) of paragraph 1 above may be indicated on a separate leaflet accompanying the package if the space available on the package is too small and in such a case the leaflet shall be regarded as part of the label for the purposes of these Regulations.

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(54) By J Rigaudy and S P Klesney, published by Pergamon (ISBN 0 08022-3699).

(55) By R Panico, W H Powell and J C Richer, published by Blackwell Science (ISBN 0-63203-4882). Corrections published in Pure Appl. Chem., vol. 71, No. 7, pp.1327 1330, 1999.

(56) O.J. No. L 200, 30.07.99, p.1.

3. The label of the packaging of the plant protection product must not bear the indications “non toxic”, “harmless” or similar indications.

4. Information to the effect that the plant protection product may be used when bees or other non target species are active, or when crops or weeds are in flower, or other such phrases to protect bees or other non-target species, may be given on the label if and only if the approval relates explicitly to use during the season for bees or other specified organisms and presents minimal risk to them.

5. Labels shall be in English.

6. At any time the Scottish Ministers may require additional phrases to be clearly and indelibly marked on packaging where this is deemed by them to be necessary for the protection of human beings, animals or the environment and where they make such a requirement they shall do so in writing by notice served on persons holding approvals for the plant protection products concerned.

7. The Scottish Ministers may require any of the persons referred to in paragraph 1(b) above at any time to provide them with samples, models or drafts of the packaging, labelling and leaflets referred to in this Schedule.

#### SCHEDULE 4

Regulation 27

#### TRANSITIONAL PROVISIONS

##### **Application of these Regulations and of the 1986 Regulations to relevant plant protection products**

1. Notwithstanding regulation 3(1) and (2) and subject to the remaining provisions of this Schedule—

- (a) these Regulations shall not apply; and
- (b) the 1986 Regulations shall continue to apply,

to a relevant plant protection product.

2. Notwithstanding paragraph 1 above, and subject to paragraphs 3 and 4 below, regulations 1, 2 and 9 and (insofar as they relate to approvals granted under regulation 9) regulations 13(2) and (5) to (10), 14, 17 and 20 to 28 shall apply to a relevant plant protection product.

3. Regulation 9 shall not apply to a relevant plant protection product to which any of the exemptions provided in regulation 3(2)(a) to (c) and (e) to (j) of the 1986 Regulations applies.

4. Notwithstanding regulation 28(2), a pesticide approval in respect of a relevant plant protection product given in the form of an experimental permit under regulation 5(2)(a) of the 1986 Regulations which was in force on 13th November 1997 shall continue to be subject to the 1986 Regulations and shall continue in force until the date of expiry of the approval or earlier revocation under those Regulations.

##### **Effect of Annex I decisions on the placing on the market and use of relevant plant protection products which are not approved pesticides**

5. Where in relation to a relevant plant protection product which is not an approved pesticide it is decided under Article 6—

- (a) that the relevant active substances of that product should be included in Annex I, or
- (b) that any of the relevant active substances of that product should not be included in Annex I,

the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2).

**Effect of a refusal to include an active substance in Annex I on relevant plant protection products which are approved pesticides**

6. Where, in relation to a relevant plant protection product which is an approved pesticide, it has been decided under Article 6 that any of its relevant active substances should not be included in Annex I, the Scottish Ministers shall notify the pesticide approval holder of that decision and shall take the action described in paragraph 9(1) below.

**Effect of a decision to include active substances in Annex I on relevant plant protection products which are approved pesticides**

7.—(1) Where, in relation to any relevant plant protection product which is an approved pesticide, it has been decided under Article 6 that its relevant active substances should be included in Annex I, the Scottish Ministers shall notify the pesticide approval holder of that fact and the pesticide approval holder shall, within such period as the Scottish Ministers may reasonably determine and notify to the pesticide approval holder, provide information to the Scottish Ministers to show:

- (a) that the relevant active substances contained in the plant protection product comply with the conditions of Annex I inclusion; and
- (b) that the pesticide approval holder has access to a dossier satisfying the requirements of Annex II.

(2) After having submitted to the Scottish Ministers the information required under paragraph (1) above, the pesticide approval holder may continue to place on the market and use the relevant plant protection product until such time as the Scottish Ministers notify the pesticide approval holder of their decision that they are or are not satisfied that the information provided shows that the relevant active substances comply with the conditions of Annex I inclusion and that the approval holder has access to a dossier satisfying the requirements of Annex II.

(3) Where the pesticide approval holder fails to provide adequate information to enable the Scottish Ministers to reach a decision, the Scottish Ministers shall notify the pesticide approval holder of that failure and the pesticide approval holder shall, within such reasonable period as may be specified in the notification, submit further information to the Scottish Ministers to enable them to reach a decision.

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

8.—(1) Where the Scottish Ministers have determined that the information provided by the approval holder under paragraph 7 above shows that the relevant active substances comply with the conditions of Annex I inclusion and that the approval holder has access to a dossier satisfying the requirements of Annex II they shall notify the pesticide approval holder of that fact and the pesticide approval holder shall, within such period as the Scottish Ministers may reasonably determine and notify to the pesticide approval holder, make an application for an approval of the relevant plant protection product under regulation 5.

(2) The pesticide approval shall continue to have effect until such time as the Scottish Ministers notify the approval holder of their decision to grant or refuse an approval under regulation 5.

(3) Where the pesticide approval holder fails to provide adequate information to enable the Scottish Ministers to consider the application, the Scottish Ministers shall notify the pesticide approval holder of that failure and the pesticide approval holder shall, within such reasonable period

as may be specified in the notification, submit further information to the Scottish Ministers to enable them to consider the application.

### **Revocation of pesticide approval**

**9.—(1)** The Scottish Ministers shall, at the same time as they notify a pesticide approval holder of a decision mentioned in paragraphs 6, 7(4) or 8(2) above, revoke the pesticide approval.

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

(3) Where the Scottish Ministers revoke a pesticide approval under sub paragraphs (1) or (2) above, they may revoke that approval—

- (a) completely;
- (b) in the manner specified in sub paragraph (4) below; or
- (c) in the manner specified in sub paragraph (5) below.

(4) When revoking an approval in the manner mentioned in paragraph (b) of sub paragraph (3) above, the Scottish Ministers shall—

- (a) subject to sub paragraph (b) below, revoke that approval in so far as it authorises the advertisement, sale, storage, supply and use of that product; and
- (b) in the form of a provisional approval granted under regulation 5 of the 1986 Regulations for a period not exceeding one year commencing with the date of that revocation, authorise—
  - (i) the storage of that product by any person; and
  - (ii) the advertisement, sale, supply and use of that product by any person other than the pesticide approval holder or the pesticide approval holder's employees or agents.

(5) When revoking an approval in the manner mentioned in paragraph (c) of sub paragraph (3) above, the Scottish Ministers shall—

- (a) subject to sub paragraphs (b) and (c) below, revoke that approval in so far as it authorises the advertisement, sale, supply, storage and use of that product;
- (b) in the form of a provisional approval granted under regulation 5 of the 1986 Regulations for a period not exceeding one year commencing with the date of that revocation, authorise the advertisement, sale, storage, supply and use of that product by any person; and
- (c) in the form of a provisional approval granted under regulation 5 of the 1986 Regulations for a period, not exceeding one year following the end of the period of provisional approval granted under sub paragraph (b) above, authorise—
  - (i) the storage of that product by any person; and
  - (ii) the advertisement, sale, supply and use of that product by any person other than the pesticide approval holder or the pesticide approval holder's employees or agents.

### **Effect of revocation on the placing on the market and use of the product**

**10.—(1)** Where the Scottish Ministers have revoked a pesticide approval in relation to any relevant plant protection product under paragraph 9(1) or (2) above completely, the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2) forthwith.

(2) Where the Scottish Ministers have revoked a pesticide approval in relation to any relevant plant protection product in the manner specified in paragraph 9(4) above, the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2) on the expiry of the period of the provisional approval granted under paragraph 9(4)(b) above.

(3) Where the Scottish Ministers have revoked a pesticide approval in relation to any relevant plant protection product in the manner specified in paragraph 9(5) above, the placing on the market and use of that product shall become subject to the prohibitions specified in regulation 3(1) and (2) on the expiry of the period of the provisional approval granted under paragraph 9(5)(c) above.

### **Notifications**

11. Any notification given by the Scottish Ministers under this Schedule shall be in writing.

### **Interpretation**

12. For the purposes of this Schedule—

“approved pesticide” means a pesticide which is the subject of a pesticide approval;

“pesticide approval” means approval of a pesticide given under regulation 5 of the 1986 Regulations;

“pesticide approval holder” means any person who holds a current pesticide approval;

“relevant active substance” means an active substance contained in a relevant plant protection product which is an approved pesticide;

“relevant plant protection product” means any plant protection product—

(a) which is a pesticide, or substance, preparation or organism prepared or used for any of the purposes mentioned in regulation 3(1)(b) of the 1986 Regulations, and

(b) at least one of whose active ingredients is an old active substance; and

“active ingredient”, “advertisement”, “organism”, “pesticide”, “preparation”, “sale”, “storage”, “substance”, “supply” and “use” have the same meanings as in the 1986 Regulations.