# S.I. No. 623 of 2001

# EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) (No. 4) REGULATIONS, 2001

I, Joe Walsh, Minister for Agriculture, Food and Rural Development, 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<sup>1</sup>, and for the purposes of giving effect to Commission Directive 2000/80/EC of 4 December 2000<sup>2</sup>, Commission Directive 2001/21/EC of 5 March 2001<sup>3</sup>, Commission Directive 2001/28/EC of 20 April 2001<sup>4</sup>, Commission Directive 2001/47/EC of 25 June 2001<sup>5</sup>, Commission Directive 2001/49/EC of 28 June 2001<sup>6</sup>, Commission Directive 2001/87/EC of 12 October 2001<sup>7</sup> and Commission Directive 2001/99/EC of 21 November 2001<sup>8</sup>, hereby make the following Regulations:

- 1. (1) These Regulations may be cited as the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No.4) Regulations, 2001.
  - (2) The European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001 and these Regulations may be cited together as the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001 and shall be construed together as one.
- 2. In these Regulations -

"the Principal Regulations" means the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 (S.I. No. 139 of 1994).

3. Regulation 2 of the Principal Regulations is hereby amended by the substitution of the following definition, in paragraph (1), for the definition of "Annex I":

" " Annex I " (which is set out in the First Schedule) means Annex I to the Directive of 1991 as amended by Commission Directive 2000/80/EC of 4 December 2000<sup>2</sup>, Commission Directive 2001/21/EC of 5 March 2001<sup>3</sup>, Commission Directive 2001/28/EC of 20 April 2001<sup>4</sup>, Commission Directive 2001/47/EC of 25 June 2001<sup>5</sup>, Commission Directive 2001/49/EC of 28 June 2001<sup>6</sup>, Commission Directive 2001/87/EC of 12 October 2001<sup>7</sup> and Commission Directive 2001/99/EC of 21 November 2001<sup>8</sup>;

<sup>1</sup> O.J. No. L230/1 19/8/1991 4 O.J. No. L113/5 24/4/2001

<sup>2</sup> O.J. No. L309/14 9/12/2000 5 O.J. No. L175/21 28/6/2001

<sup>3</sup> O.J. No. L69/17 10/3/2001

<sup>6</sup> O.J. No. L175/21 28/6/2001

#### 4. In these Regulations -

- (1) The following Statutory Instruments, as indicated below are hereby revoked -
  - (a) European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 1999, (S.I. No. 182 of 1999);
  - (b) European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations, 1999, (S.I. No. 198 of 1999);
  - (c) European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 3) Regulations, 1999, (S.I. No. 356 of 1999);
  - (d) European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 2000, (S.I. No. 366 of 2000);
  - (e) European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 2001, (S.I. No. 33 of 2001) and
  - (f) European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 3) Regulations, 2001, (S.I. No. 359 of 2001).

## **First Schedule**

### Annex I

## Active Substances Authorised for Use in Plant Protection Products

General provisions applying to all substances listed in this Annex:

For the implementation of the uniform principles of Annex VI in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on the date indicated under "specific provisions" for that substance shall be taken into account.

All review reports (except for confidential information within the meaning of Article 14 of the Directive) shall be kept available for consultation by any interested parties or shall be available to them on specific request.

No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
1	Imazalil CAS No. 73790-28- 0, 35554-44-0 CIPAC No. 335	<ul> <li>(±)-1-(β-allyloxy-2,4- dichlorophenylethyl) imidazole or</li> <li>(±)-allyl 1-(2,4-dichlorophenyl)- 2- imidazol-1-ylethyl ether</li> </ul>	975 g/kg	1.1.1999	31.12.2008	<ul> <li>Only uses as fungicide may be authorised.</li> <li>For the following uses the following particular conditions apply: <ul> <li>post harvest fruit, vegetable and potato treatments may only be authorised when an appropriate decontamination system is available or a risk assessment has demonstrated that the discharge of the treatment solution does not have an unacceptable risk to the environment and in particular to aquatic organisms,</li> <li>post harvest treatment of potatoes may only be authorised when a risk assessment has demonstrated that the discharge of that the discharge of the processing waste from treated potatoes does not have an unacceptable risk to aquatic organisms,</li> <li>outdoor foliar uses may only be authorised when a risk assessment has demonstrated that the use has no unacceptable effects on human and animal health</li> </ul> </li> </ul>

						and the environment. Review report was finalised 11.7.1997.
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
2	Azoxystrobin CAS NO. 131860- 33-8 CIPAC No. 571	Methyl (E)-2-{2[6-(2- cyanophenoxy) pyrimidin-4- yl]oxy phenyl}-3-metho- Xyacrylate	930 g/kg (Z isomer max. 25 g/kg)	1.7.1998	1.7.2008	Only uses as fungicide may be authorised. According to uniform principles, particular attention should be given to the impact on aquatic organisms. Authorisation conditions should include appropriate risk mitigation measures. Review report was finalised 22.4.1998.
3	Kresoxim-methyl CAS No. 143390-89- 0 CIPAC No. 568	Methyl (E)-2-methoxyi-mino-2- [2-(o-tolyloxyme-thyl) phenyl] acetate	910 g/kg	1.2.1999	31.1.2009	Only uses as fungicide may be authorised. According to uniform principles, particular attention should be given to the protection of groundwater under vulnerable conditions. Review report was finalised 16.10.1998.
4	Spiroxamine CAS No.1181134- 30-8 CIPAC No. 572	(8-tert-Butyl-1,4-dioxaspiro [4.5] decan-2-ylmethyl)-ethyl- propylamine	940 g/kg (diastereome- rs A and B combined)	1.9.1999	1.9.2009	<ul> <li>Only uses as a fungicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid <ul> <li>to operator safety and the conditions of authorisation must include appropriate protective measures</li> <li>to the impact on aquatic organisms and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Review report was finalised 12.5.1999.</li> </ul>
5	Azimsulfuron CAS No. 120162-55- 2 CIPAC No. 584	1-(4,6-dimethoxypyrimidin-2- yl)-3-[1-methyl-4-(2-methyl- 2H-tetrazol-5-yl)-pyrazol-5- ylsulfonyl]-urea.	980 g/kg	1.10.1999	1.10.2009	Only uses as a herbicide may be authorised. Aerial application may not be authorised. According to uniform principles, particular attention must be paid - to the impact on aquatic organisms and terrestrial

						non-target plants and where appropriate, risk mitigation measures must be included in the conditions of authorisation (e.g. in rice cultivation minimum holding periods for water prior to discharge). Review report was finalised 2.7.1999.
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
6	Fluroxypyr CAS No. 69377-81-7 CIPAC No. 431	4-amino-3,5-dichloro-6-fluoro- 2-pyridyloxyacetic acid	950 g/kg	1.12.2000	31/11/2010	<ul> <li>Only uses as a herbicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid <ul> <li>to the protection of groundwater</li> <li>to the impact on aquatic organisms and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Account should be taken of additional information requested in point 7 of the review report. The Commission should be informed if the requested additional trials and information as outlined in point 7 of the review report were not submitted by 1.12.2000.</li> <li>Review report was finalised 30.11.1999.</li> </ul>
7	Metsulfuron-methyl CAS No. 74223-64-6 EEC No. 441	Methyl-2-(4-methoxy-6-methyl- 1,3,5,-triazin-2- ylcarbamoylsulfamoyl)benzoate.	960 g/kg	1.7.2001	30.6.2011	<ul> <li>Only uses as a herbicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid <ul> <li>to the protection of groundwater</li> <li>to the impact on aquatic organisms and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Review report was finalised 16.6.2000.</li> </ul>
8	Prohexadione-	Calcium 3,5-dioxo-4-	890 g/kg	1.10.2000	1.10.2010	Only uses as plant growth regulator may be authorised.

	calcium CAS No. 127277-53- 6 CIPAC No. 567	propionylcyclo hexanecarboxylate				Review report was finalised 16.6.2000
9	Triasulfuron CAS No. 82097-50-5 CIPAC No. 480	1-[2-(2-chloroethoxy) phenylsulfonyl]-3-(4-methoxy- 6-methyl-1,3,5-triazin-2-yl)urea	940 g/kg	1.8.2001	31.7.2011	<ul> <li>Only uses as a herbicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid <ul> <li>to the protection of groundwater</li> <li>to the impact on aquatic organisms and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Review report was finalised 13.7.2000.</li> </ul>
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
10	Esfenvalerate CAS NO. 66230-04- 4 CIPAC No. 481	(S)-α-Cyano-3-phenoxybenzyl- (S)-2-(4-chlorophenyl)-3- methylbutyrate	830 g/kg	1.8.2001	31.7.2011	<ul> <li>Only uses as an insecticide may be authorised.</li> <li>According to uniform principles, particular attention must be paid <ul> <li>to the potential impact on aquatic organisms and non-target arthropods and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Review report was finalised 13.7.2000.</li> </ul>
11	Bentazone CAS No. 25057-89-0 CIPAC No. 366	3-isopropyl-(1H)-2,1,3- benzothiadiazin-4-(3H)-one-2,2- dioxide	960 g/kg	1.8.2001	31.7.2011	Only uses as herbicide may be authorised. According to uniform principles, particular attention should be given to the protection of groundwater. Review report was finalised 13.7.2000.
12	Lambda-cyhalothrin CAS No. 91465-08-6 CIPAC No. 463	A 1:1 mixture of : (s)-α-cyano- 3-phenoxybenzyl (Z)-(1R,3R)- 3-(2-chloro-3,3,3- trifluoropropenyl)-2,2- dimethylcyclopropane-	810 g/kg	1.1.2002	31.12.2011	Only uses as an insecticide may be authorised. According to uniform principles, particular attention must be paid to - operator safety - potential impact on aquatic organisms and non-

		carboxylate, and (R)-α-cyano- 3-phenoxybenzyl (Z)-(1S,3S)-3- (2-chloro-3,3,3- trifluoropropenyl)-2,2- dimethylcyclopropane- carboxylate				<ul> <li>target arthropods including bees and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures</li> <li>residues in food and especially the acute effects thereof.</li> <li>Review report was finalised 19.10.2000.</li> </ul>
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
13	(fenhexamid) CAS No. 126833-17- 8 CIPAC No. 603	N-(2,3-dichloro-4- hydroxyphenyl)-1-methyl- cyclohexanecarboxamide	= 950 g/kg	1.6.2001	31.5.2011	Only uses as a fungicide may be authorised. According to uniform principles, particular attention must be paid to the potential impact on aquatic organisms and where appropriate, risk mitigation measures should be included in the conditions of authorisation. Review report was finalised 19.10.2000.
14	Amitrole CAS No 61-82-5 CIPAC No. 90	H-[1,2,4]-triazole-3-ylamine	900 g/kg	1.1.2002	31.12.2011	<ul> <li>Only uses as a herbicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid to the protection of <ul> <li>operators</li> <li>groundwater in vulnerable areas, in particular with respect to non-crop uses</li> <li>beneficial arthropods</li> <li>birds and wild mammals. Use of amitrole during breeding season may only be authorised when an appropriate risk assessment has demonstrated that there is no unacceptable impact and when the conditions of authorisation include, where appropriate, risk mitigation measures.</li> </ul> </li> <li>Review report was finalised 12.12.2000.</li> </ul>
15	Diquat CAS No. 2764-72-9 (ion), 85-00-7	9,10-Dihydro-8a,10a-diazonia- phenanthrene ion (dibromide)	950 g/kg	1.1.2002	31.12.2011	Only uses as a terrestrial herbicide and desiccant may be authorised. Uses in aquatic weed control shall not be authorised.

	(dibromide) CIPAC No. 55					<ul> <li>According to uniform principles, particular attention must be paid <ul> <li>to the potential impact on aquatic organisms and where appropriate, risk mitigation measures must be included in the conditions of authorisation</li> <li>to operator safety as related to non-professional use and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Review report was finalised 12.12.2000.</li> </ul>
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
16	Pyridate CAS No. 55512-33.9 CIPAC No. 447	6-Chloro-3-phenylpyridazin-4- yl S-octyl thiocarbonate	900 g/kg	1.1.2002	31.12.2011	<ul> <li>Only uses as a herbicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid to the <ul> <li>protection of groundwater</li> <li>impact on aquatic organisms and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> </ul> </li> <li>Review report was finalised 12.12.2000.</li> </ul>
17	Thiabendazole CAS No. 148-79-8 CIPAC No. 323	2-Thiazol-4-yl-1H- benzimidazole	985 g/kg	1.1.2002	31.12.2011	Only uses as a fungicide may be authorised. Foliar spray applications shall not be authorised. According to uniform principles, particular attention must be paid to the protection of aquatic and sediment-dwelling organisms and where appropriate, risk mitigation measures should be included in the conditions of authorisation. Suitable risk mitigation measures (e.g. depuration with diatom earth or activated carbon) have to be implemented to protect surface waters from unacceptable levels of contamination via wastewater. Review report was finalised 12.12.2000.
18	Paecilomyces	Not applicable	The absence	1.7.2001	30.06.2011	Only uses as an insecticide may be authorised.

	fumosoroseus Apopka strain 97, PFR 97 or CG 170, ATCC20874		of secondary metabolities should be checked in each fermentation broth by HPLC			Each fermenation broth should be checked by HPLC to ensure that no secondary metabolities are present. Review report was finalised 27.4.2001.
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
19	DPX KE 459 (flupyrsulfuron- methyl) CAS No. 1447 40- 54-5 CIPAC No. 577	2-(4,6-dimethoxypyrimidin-2- ylcarba-moylsulfamoyl)-6- trifluromethylnicotinate monosodium salt	903 g/kg	1.7.2001	30.6.2011	Only uses as a herbicide may be authorised. According to uniform principles, particular attention must be paid to the protection of groundwater. Review report was finalised 27.4.2001.
20	Acibenzolar-s-methyl CAS No. 135158-54- 2 CIPAC No. 597	Benzo[1,2,3]thiadiazole-7- carbothioic acid S-methyl ester	970 g/kg	1.11.2001	31.10.2011	Only uses as a plant activator may be authorised. Review report was finalised 29.6.2001.
21	Cyclanilide CAS No. 113136-77- 9 CIPAC No. 586	Not available	960 g/kg	1.11.2001	31.10.2011	Only uses as a plant growth regulator may be authorised. The maximum content of the impurity 2,4-dichloroaniline (2,4-DCA) in the active substance as manufactured should be 1 g/kg. Review report was finalised 29.6.2001.
22	Ferric phosphate CAS No. 10045-86-0 CIPAC No. 629	Ferric phosphate	990 g/kg	1.11.2001	31.10.2011	Only uses as a molluscicide may be authorised. Review report was finalised 29.6.2001.
23	Pymetrozine	(E)-6-methyl-4-[(pyridin-3-	950 g/kg	1.11.2001	31.10.2011	Only uses as an insecticide may be authorised.

	CAS No. 123312-89- 0 CIPAC No. 593	ylmetylene)amino]-4,5-dihydro- 2H-[1,2,4]-triazin-3 one				According to uniform principles, particular attention must be paid to the protection of aquatic organisms. Review report was finalised 29.6.2001.
24	Pyraflufen-ethyl CAS No. 129630-19- 9 CIPAC No. 605	Ethyl-2-chloro-5-(4-chloro-5- difluoromethoxy-1-mhypyrazol- 3-yl)-4-fluorophenoxyacetate	956 g/kg	1.11.2001	31.10.2011	Only uses as a herbicide may be authorised. According to uniform principles, particular attention must be paid to the protection of algae and aquatic plants and where appropriate, risk mitigation measures should be applied. Review report was finalised 29.6.2001.
No.	Common Name, Identification Nos.	IUPAC Name	Purity <sup>(1)</sup>	Entry into Force	Expiration of Inclusion	Specific Provisions
25	Glyphosate CAS No. 1071-83-6 CIPAC No. 284	N-(phosphonomethyl)-glycin	950 g/kg	1.7.2002	30.6.2012	Only uses as a herbicide may be authorised. According to uniform principles, particular attention must be paid to the protection of groundwater in vulnerable areas, in particular with respect to non-crop uses. Review report was finalised 29.6.2001.
26	Thifensulfuron- methyl CAS No. 79277-27-3 CIPAC No. 452	Methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoyl- sulfamoyl) thiophene-2- carboxy-late	960 g/kg	1.7.2002	30.6.2012	<ul> <li>Only uses as a herbicide may be authorised.</li> <li>According to uniform principles, particular attention must be paid to the - protection of groundwater</li> <li>impact on aquatic plants and where appropriate, risk mitigation measures must be included in the conditions of authorisation.</li> <li>Review report was finalised 29.6.2001.</li> </ul>

(1) Further details identity specification of active substances provided in their review on and are reports. Given under my Official Seal, this 18th day of December, 2001.

L.S.

Joe Walsh Minister for Agriculture, Food and Rural Development.

# Explanatory Note

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

These Regulations give effect to Commission Directive 2000/80/EC of 4 December 2000, Commission Directive 2001/21/EC of 5 March 2001, Commission Directive 2001/28/EC of 20 April 2001, Commission Directive 2001/47/EC of 25 June 2001, Commission Directive 2001/49/EC of 28 June 2001, Commission Directive 2001/87/EC of 12 October 2001 and Commission Directive 2001/99/EC of 21 November 2001. These Regulations, which amend Council Directive 91/414/EEC concerning the placing of plant protection products on the market, consolidate Annex I of that Directive and provide for the inclusion of the active substances: lambda-cyhalothrin, amitrole, diquat, pyridate, thiabendazole, KBR 2738 (fenhexamid), Paecilomyces fumosoroseus (Apopka strain 97, PFR 97 or CG 170, ATCC20874), DPX KE 459 (flupyrsulfuron-methyl), acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine, pyraflufen-ethyl, glyphosate and thifensulfuron-methyl respectively, in Annex I to Council Directive 91/414/EEC.

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