

## COMMISSION DIRECTIVE 2002/64/EC

of 15 July 2002

**amending Council Directive 91/414/EEC to include cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M and picolinafen as active substances**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

concerning picolinafen. Commission Decision 1999/555/EC <sup>(7)</sup> confirmed that the dossier was 'complete'.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection products on the market <sup>(1)</sup>, as last amended by Commission Directive 2002/48/EC <sup>(2)</sup>, and in particular Article 6(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Directive 91/414/EEC, the United Kingdom received on 28 April 1997 an application from BASF for the inclusion of the active substance cinidon-ethyl in Annex I to Directive 91/414/EEC. Commission Decision 98/398/EC <sup>(3)</sup> confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements laid down in Annexes II and III to Directive 91/414/EEC.
- (2) Italy received an application under Article 6(2) of Directive 91/414/EEC on 30 April 1997 from Dow Agro-Sciences, concerning cyhalofop butyl. Commission Decision 98/242/EC <sup>(4)</sup> confirmed that the dossier was 'complete'.
- (3) France received an application under Article 6(2) of Directive 91/414/EEC on 20 October 1996 from DuPont de Nemours concerning famoxadone. Commission Decision 97/591/EC <sup>(5)</sup> confirmed that the dossier was 'complete'.
- (4) Belgium received an application under Article 6(2) of Directive 91/414/EEC on 2 February 1998 from Dow Agro Sciences concerning florasulam. Commission Decision 98/676/EC <sup>(6)</sup> confirmed that the dossier was 'complete'.
- (5) Belgium received an application under Article 6(2) of Directive 91/414/EEC on 9 February 1996 from Novartis Crop Protection AG (now Syngenta) concerning metalaxyl-m. Decision 97/591/EC confirmed that the dossier was 'complete'.
- (6) Germany received an application under Article 6(2) of Directive 91/414/EEC on 10 May 1999 from BASF-AG

- (7) For these active substances, the effects on human health and the environment have been assessed, in accordance with Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The nominated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 2 November 1998 (cinidon-ethyl), 30 November 1998 (cyhalofop butyl), 5 August 1998 (famoxadone), 19 November 1999 (florasulam), 27 July 1999 (metalaxyl-m) and 21 December 2000 (picolinafen).
- (8) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The reviews were finalised on 19 April 2002 in the format of the Commission review reports for cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M and picolinafen.
- (9) The reviews of cinidon-ethyl, metalaxyl-M and picolinafen did not reveal any open questions which would have required a consultation of the Scientific Committee on Plants.
- (10) As regards cyhalofop butyl, the Scientific Committee on Plants was asked to comment on potential effects on aquatic organisms and non-target arthropods and on operator exposure. In its opinion <sup>(8)</sup> the Committee noted that aerial application of the active substance may pose an unacceptable risk to aquatic organisms within flooded paddy fields and in adjacent drainage canals, if they are of low depth. Terrestrial applications to flooded paddies may pose an unacceptable risk to aquatic organisms within the paddy fields. The Committee considered the use unlikely to be harmful to bees but highlighted remaining uncertainty with regard to other non-target arthropods, which should be addressed by an extended test. This information was subsequently provided and evaluated. The Committee was further of the opinion that the operator exposure to cyhalofop-butyl has been adequately addressed.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.<sup>(2)</sup> OJ L 148, 6.6.2002, p. 19.<sup>(3)</sup> OJ L 176, 20.6.1998, p. 34.<sup>(4)</sup> OJ L 96, 28.3.1998, p. 45.<sup>(5)</sup> OJ L 239, 30.8.1997, p. 48.<sup>(6)</sup> OJ L 317, 26.11.1998, p. 47.<sup>(7)</sup> OJ L 210, 10.8.1999, p. 22.<sup>(8)</sup> Opinion of the scientific Committee on Plants on the evaluation of cyhalofop-butyl (DE-537) in the context of Council Directive 91/414/EEC concerning the placing of plant-protection products on the market (SCP/CYHALO/002 final, adopted 7 March 2001).

- (11) As regards famoxadone, the Committee was asked to comment on the effects to *Daphnia* and earthworms, in particular in relation to degradation products of the active substance and on the relevance to humans of the eye effect observed in the 12-month dog study and possible implications for risk assessment for operators. In its opinion <sup>(1)</sup> the Committee commented that the risk to *Daphnia* of famoxadone and its metabolites has been sufficiently addressed. The Committee further noted that the metabolites IN-KZ007 and IN-JS940 are unlikely to present an acute risk to earthworms but was unable to evaluate the likely chronic risks of the parent substance or metabolites to earthworms when more than six applications per season are assumed. The Committee, finally, was of the opinion that the eye effect of famoxadone in dogs is to be considered relevant for humans pending a more complete understanding of the mechanism of action. The observations of the Scientific Committee were taken into consideration in formulating this Directive and the relevant review report.
- (12) As regards florasulam, the Committee was asked to comment on the relevance of two degradation products of the active substance (ASTCA and DFP-ASTCA), and on the approach proposed to establish an acute reference dose. In its opinion <sup>(2)</sup> the Committee concluded that modelling results do not indicate potential groundwater contamination above a threshold of toxicological concern for the parent substance or its breakdown products. Neither the active substance nor the main metabolite appears to pose an unacceptable risk to non-target aquatic organisms. Data reportedly showing no toxicity to soil and aquatic organisms of the degradation products ASTCA and DFP-ASTCA were not available to the Committee, and would need to be assessed. This information was subsequently submitted by the notifier and evaluated by the rapporteur Member State. The Committee was further of the opinion that the allocation of an acute reference dose is not warranted.
- (13) It has appeared from the various examinations made that plant-protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review reports. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant-protection products containing the active substances concerned can be granted in accordance with the provisions of that Directive.
- (14) The Commission review report is required for the proper implementation by the Member States, of several

sections of the uniform principles laid down in Directive 91/414/EEC. It is, therefore, appropriate to provide that the finalised review reports, except for confidential information, should be kept available or made available by the Member States for consultation by any interested parties.

- (15) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant-protection products containing cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M or picolinafen and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.
- (16) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (17) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

#### Article 2

Member States shall keep available the review reports for cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M and picolinafen, except for confidential information within the meaning of Article 14 of Directive 91/414/EEC, for consultation by any interested parties or shall make it available to them on specific request.

#### Article 3

Member States shall adopt and publish by 31 March 2003 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 April 2003.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

<sup>(1)</sup> Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of famoxadone in the context of Directive 91/414/EEC concerning the placing of plant-protection products on the market (SCP/FAMOX/002 final, adopted 5 September 2001).

<sup>(2)</sup> Opinion of the Scientific Committee on Plants regarding the inclusion of florasulam in Annex I to Directive 91/414/EEC concerning the placing of plant-protection products on the market (SCP/FLORES/002 final, adopted 29 October 2001).

*Article 4*

1. Member States shall review the authorisation for each plant-protection product containing cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M or picolinafen to ensure that the conditions relating to these active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw the authorisation in accordance with Directive 91/414/EEC before 31 March 2003.

2. Member States shall, for each authorised plant-protection product containing cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M or picolinafen as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 1 October 2002, re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article

4(1)(b), (c), (d) and (e) of Directive 91/414/EEC. Where necessary and by 31 March 2004 at the latest, they shall amend or withdraw the authorisation for each such plant-protection product.

*Article 5*

This Directive shall enter into force on 1 October 2002.

*Article 6*

This Directive is addressed to the Member States.

Done at Brussels, 15 July 2002.

*For the Commission*

David BYRNE

*Member of the Commission*

## ANNEX

In Annex I the following rows are added at the end of the table:

| No  | Common name, identification numbers                   | IUPAC name   | Purity (%) | Entry into force | Expiration of inclusion | Specific provisions  |
|-----|---|--|------------|------------------|-------------------------|--|
| '33 | Cinidon-ethyl<br>CAS No 142891-20-1<br>CIPAC No 598   | (Z)-ethyl 2-chloro-3-[2-chloro-5-(cyclohex-1-ene-1,2-dicarboximido)phenyl]acrylate | 940 g/kg   | 1 October 2002   | 30 September 2012       | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cinidon-ethyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> <li>— should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil (e.g. soils with neutral or high pH values) and/or climatic conditions,</li> <li>— should pay particular attention to the protection of aquatic organisms.</li> </ul> <p>Conditions of authorisation must include risk-mitigation measures, where appropriate.</p>  |
| 34  | Cyhalofop butyl<br>CAS No 122008-85-9<br>CIPAC No 596 | Butyl-(R)-2-[4(4-cyano-2-fluorophenoxy)phenoxy]propionate                          | 950 g/kg   | 1 October 2002   | 30 September 2012       | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyhalofop butyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> <li>— Member States must carefully consider the potential impact of aerial applications to non-target organisms and in particular to aquatic species. Conditions of authorisation must include restrictions or risk mitigation measures, where appropriate,</li> <li>— Member States must carefully consider the potential impact of terrestrial applications on aquatic organisms within paddy fields. Conditions of authorisation must include risk-mitigation measures, where appropriate.</li> </ul> |

| No | Common name, identification numbers              | IUPAC name   | Purity (%) | Entry into force | Expiration of inclusion | Specific provisions  |
|----|--|--|------------|------------------|-------------------------|--|
| 35 | Famoxadone<br>CAS No 131807-57-3<br>CIPAC No 594 | 3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione                   | 960 g/kg   | 1 October 2002   | 30 September 2012       | <p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on famoxadone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> <li>— Member States must pay particular attention to potential chronic risks of the parent substance or metabolites to earthworms,</li> <li>— Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk-mitigation measures,</li> <li>— Member States should pay particular attention to the protection of operators.</li> </ul> |
| 36 | Florasulam<br>CAS No 145701-23-1<br>CIPAC No 616 | 2', 6', 8-Trifluoro-5-methoxy-[1,2,4]-triazolo [1,5-c] pyrimidine-2-sulphonanilide | 970 g/kg   | 1 October 2002   | 30 September 2012       | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> <li>— should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk-mitigation measures, where appropriate.</li> </ul>   |

| No | Common name, identification numbers               | IUPAC name  | Purity ( <sup>1</sup> ) | Entry into force | Expiration of inclusion | Specific provisions  |
|----|---|---|-------------------------|------------------|-------------------------|--|
| 37 | Metalaxyl-M<br>CAS No 70630-17-0<br>CIPAC No 580  | Methyl(R)-2-[[{(2,6-dimethylphenyl)methoxyacetyl} amino} propionate         | 910 g/kg                | 1 October 2002   | 30 September 2012       | <p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Metalaxyl-M, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> <li>— particular attention should be given to the potential for groundwater contamination by the active substance or its degradation products CGA 62826, and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk-mitigation measures should be applied, where appropriate.</li> </ul> |
| 38 | Picolinafen<br>CAS No 137641-05-5<br>CIPAC No 639 | 4'-Fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide | 970 g/kg                | 1 October 2002   | 30 September 2012       | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on picolinafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> <li>— must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk-mitigation measures, where appropriate.</li> </ul>   |

(<sup>1</sup>) Further details on identity and specification of active substances are provided in the review report.'