

## COMMISSION DIRECTIVE 2003/31/EC

of 11 April 2003

## amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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 2003/23/EC <sup>(2)</sup>, and in particular Article 6(1) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market <sup>(3)</sup>, as last amended by Regulation (EC) No 2266/2000 <sup>(4)</sup>, establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin.
- (2) For these active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 <sup>(5)</sup>, as last amended by Regulation (EC) No 2230/95 <sup>(6)</sup>, the following rapporteur Member States were designated and submitted the relevant assessment reports and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92: 2,4-DB: rapporteur Member State Greece, all relevant information was submitted on 30 April 1996; beta-cyfluthrin: rapporteur Member State Germany, all relevant information was submitted on 4 November 1996; cyfluthrin: rapporteur Member State Germany, all relevant information was submitted on 4 November 1996; iprodione: rapporteur Member State France, all relevant information was submitted on 18 July 1996; linuron: rapporteur Member State United Kingdom, all relevant information was submitted on 31 October 1996; maleic hydrazide: rapporteur Member State Denmark, all relevant information was submitted on 5 September 1997; pendimethalin: rapporteur Member State Spain, all relevant information was submitted on 20 May 1998.

- (3) These assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.
- (4) In accordance with Article 6(4) of Directive 91/414/EEC and in view of a possible unfavourable decision for 2,4-DB and for pendimethalin the Commission organised tripartite meetings with the main data submitter and the rapporteur Member State on 7 May 1998 and on 4 June 1999. For both substances the main data submitter provided further data in order to meet the initial concerns.
- (5) The reviews of all active substances were finalised on 3 December 2002 in the format of the Commission review report for 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin.
- (6) The reviews of 2,4-DB, linuron, maleic hydrazide and pendimethalin did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.
- (7) The report on beta-cyfluthrin and on cyfluthrin and further information concerning both substances were also submitted to the Scientific Committee on Plants for separate consultations. The Committee was asked to comment on the appropriate dietary risk assessment to be used and to confirm that the available ecotoxicological data supports uses only in glasshouses and for seed treatment. In its opinions <sup>(7)</sup> <sup>(8)</sup>, the Committee suggested that in addition to a long-term dietary intake risk assessment, as routinely carried out for plant protection products, beta-cyfluthrin and cyfluthrin should also undergo a short-term acute dietary risk assessment to evaluate their potential neurotoxicity properties. The Committee confirmed that uses as seed dressing and in greenhouses (except where beneficial arthropods are used) can be considered safe for non-target terrestrial and aquatic organisms, due to the specific circumstances of these applications and the immobility of beta-cyfluthrin and cyfluthrin in soil. The Committee furthermore supports the conclusions reached during the evaluation by the Member States that field spray applications of beta-cyfluthrin and cyfluthrin have not shown to be sufficiently safe under the criteria required by Annex VI to Directive 91/414/EEC. Following the opinion of the Scientific Committee on Plants the short term dietary risk assessment was subsequently provided and discussed

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 81, 28.3.2003, p. 39.

<sup>(3)</sup> OJ L 366, 15.12.1992, p. 10.

<sup>(4)</sup> OJ L 259, 13.10.2000, p. 27.

<sup>(5)</sup> OJ L 107, 28.4.1994, p. 8.

<sup>(6)</sup> OJ L 225, 22.9.1995, p. 1.

<sup>(7)</sup> Opinion of the Scientific Committee on Plants regarding the inclusion of beta-cyfluthrin in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. (Opinion expressed by the Scientific Committee on Plants, 28 January 2000).

<sup>(8)</sup> Opinion of the scientific Committee on Plants regarding the inclusion of cyfluthrin in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. (Opinion expressed by the Scientific Committee on Plants, 28 January 2000).

with the Member States. It was concluded that the short-term intake of residues is not likely to exceed acceptable limits.

- (8) The report on iprodione and further information were also submitted to the Scientific Committee on Plants for separate consultation. The Scientific Committee was asked to comment on the predicted environmental concentrations in soil and groundwater, and on the acceptable operator exposure level proposed by the rapporteur. In its opinion <sup>(1)</sup>, the Committee agreed that sufficient information was available to reliably estimate the leaching behaviour of the substance for soils with pH above 6. However, the assessment of leaching in soils with pH below 6 deserves further attention, since, for soils with pH below 6, leaching at concentration levels exceeding 0,1 µg/l may occur in some realistic vulnerable situations. The Committee saw no need to use an additional safety factor for the derivation of the acceptable operator exposure level. The observations of the Scientific Committee were taken into account in this Directive and the review report.

- (9) It has appeared from the various examinations made that plant protection products containing 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide or pendimethalin 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 report. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisation of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

- (10) 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 report, except for confidential information, should be kept available or made available by the Member States for consultation by any interested parties.

- (11) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

- (12) After inclusion, Member States should be allowed a reasonable period within which to implement the provisions of Directive 91/414/EEC as regards plant protection products containing 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide or pendimethalin, and in particular, to review existing authorisations to ensure that the conditions regarding those active substances set out in Annex I to Directive 91/414/EEC are satisfied. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (13) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (14) 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 adopt and publish by 30 June 2004 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 July 2004.

When Member States adopt this provision, 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.

#### *Article 3*

1. Member States shall review the authorisation for each plant protection product containing 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide or pendimethalin to ensure that the conditions relating to this active substance set out in Annex I to Directive 91/414/EEC are complied with. Where necessary and by 30 June 2004 at the latest, they shall amend or withdraw the authorisation.

<sup>(1)</sup> Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of iprodione in the context of Council Directive 91/414/EEC. SCP/IPRODIO/002-final adopted 31 January 2002.

2. Member States shall, for each authorised plant protection product containing 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide or pendimethalin 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 31 December 2003 at the latest, 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 to that Directive. 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 December 2007 at the latest, they shall amend or withdraw the authorisation.

*Article 4*

This Directive shall enter into force on 1 January 2004.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2003.

*For the Commission*

David BYRNE

*Member of the Commission*

## ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EC

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
47	2,4-DB CAS No 94-82-6 CIPAC No 83	4-(2,4-dichlorophenoxy) butyric acid	940 g/kg	1 January 2004	31 December 2013	<p>Only use as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on 2,4-DB, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States:</p> <p>must pay particular attention to the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied, where appropriate.</p>
48	Beta-cyfluthrin CAS No 68359-37-5 (unstated stereochemistry) CIPAC No 482	(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylic acid (SR)- $\alpha$ -cyano-(4-fluoro-3-phenoxy-phenyl)methyl ester	965 g/kg	1 January 2004	31 December 2013	<p>Only use as insecticide may be authorised</p> <p>Uses other than ornamental in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by Annex VI. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses and the dietary risks of foliar treatment in edible crops.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on beta-cyfluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment:</p> <p>Member States must pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures.</p>

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
49	Cyfluthrin CAS No 68359-37-5 (unstated stereochemistry)  CIPAC No 385	(RS)- $\alpha$ -cyano-4-fluoro-3-phenoxybenzyl-(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	920 g/kg	1 January 2004	31 December 2013	<p>Only use as insecticide may be authorised</p> <p>Uses other than ornamental in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by Annex VI. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses and the dietary risks of foliar treatment in edible crops.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyfluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment:</p> <p>Member States must pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures.</p>
50	Iprodione CAS No 36734-19-7  CIPAC No 278	3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxo-imidazolidine-1-carboximide	960 g/kg	1 January 2004	31 December 2013	<p>Only use as fungicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iprodione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 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 ground water contamination when the active substance is applied at high use rates (in particular use in turf) on acidic soils (pH below 6) under vulnerable climatic conditions,</li> <li>— must carefully consider the risk to aquatic invertebrates if the active substance is applied directly adjacent to surface waters. Risk mitigation measures should be applied, where appropriate.</li> </ul>

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
51	Linuron CAS No 330-55-2 CIPAC No 76	3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea	900 g/kg	1 January 2004	31 December 2013	<p>Only use as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on linuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 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 wild mammals, non-target arthropods and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate,</li> <li>— must pay particular attention to the protection of operators.</li> </ul>
52	Maleic hydrazide CAS No 123-33-1 CIPAC No 310	6-hydroxy-2H-pyridazin-3-one	940 g/kg The active substance shall comply with Council Directive 79/117/EEC (2), as amended by Council Directive 90/533/EEC (3).	1 January 2004	31 December 2013	<p>Only use as growth regulator may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on maleic hydrazide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 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 non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate,</li> <li>— must pay particular attention to the potential for groundwater contamination, 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>

No	Common name, identification numbers	IUPAC name	Purity <sup>(1)</sup>	Entry into force	Expiration of inclusion	Specific provisions
53	Pendimethalin CAS No 40487-42-1 CIPAC No 357	N-(1-ethylpropyl)-2,6-dinitro-3,4-xylylene	900 g/kg	1 January 2004	31 December 2013	<p>Only use as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pendimethalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health 3 December 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 and non-target terrestrial plants. Conditions of authorisation must include risk mitigation measures, where appropriate,</li> <li>— must pay particular attention to the possibility of short-range transport of the active substance in air.</li> </ul>

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

<sup>(2)</sup> OJ L 33, 8.2.1979, p. 36.

<sup>(3)</sup> OJ L 296, 27.10.1990 p. 63.