

**COMMISSION DIRECTIVE 2003/23/EC
of 25 March 2003**

amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid 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 ⁽¹⁾, as last amended by Commission Directive 2002/81/EC ⁽²⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Directive 91/414/EEC France received on 2 December 1997 an application from Cyanamid NV/SA (now BASF AG) for the inclusion of the active substance imazamox in Annex I to Directive 91/414/EEC. Commission Decision 1998/676/EC ⁽³⁾ confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (2) Italy received a similar application on 29 May 1998 from Novartis Protezione Piante SpA (now Syngenta) concerning oxasulfuron. This application was declared complete by Commission Decision 1999/237/EC ⁽⁴⁾.
- (3) Italy received a similar application on 3 July 1996 from Hoechst Schering AgrEvo GmbH (now Bayer Crop Science) concerning ethoxysulfuron. This application was declared complete by Commission Decision 97/591/EC ⁽⁵⁾.
- (4) Germany received a similar application on 30 March 2000 from Aventis Crop Science (now Bayer Crop Science) concerning foramsulfuron. This application was declared complete by Commission Decision 2000/540/EC ⁽⁶⁾.
- (5) Italy received a similar application on 16 June 1997 from Rhone-Poulenc Agro SA (now Bayer Crop Science) concerning oxadiargyl. This application was declared complete by Commission Decision 98/398/EC ⁽⁷⁾.
- (6) France received a similar application on 16 December 1999 from Ishira Sangyo Kaisha Ltd concerning cyazofamid. This application was declared complete by Commission Decision 2000/412/EC ⁽⁸⁾.
- (7) For these active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The nominated rapporteur Member States, submitted a draft assessment report concerning the substance to the Commission on 9 September 1999 (imazamox), 10 May 2000 (oxasulfuron), 20 May 1998 (ethoxysulfuron), 1 June 2001 (foramsulfuron), 20 July 1999 (oxadiargyl) and 27 August 2001 (cyazofamid).
- (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 review was finalised on 3 December 2002 in the format of the Commission review reports for imazamox, oxadiargyl, oxasulfuron, ethoxysulfuron, foramsulfuron and cyazofamid.
- (9) The reviews of imazamox, oxasulfuron foramsulfuron, oxadiargyl and cyazofamid did not reveal any open questions or concern, which would have required a consultation of the Scientific Committee on Plants.
- (10) The documents and information on ethoxysulfuron were also submitted to the Scientific Committee for Plants for separate consultation. In a first consultation the Scientific Committee was invited to comment on the occurrence of uterine tumours in rats. In its opinion ⁽⁹⁾ the Committee considered the increase in uterine tumour incidence in rats of no relevance to human risk as it occurred only at a high dose causing marked general toxicity. No additional mechanistic studies were deemed necessary. An additional consultation was made on the potential risk to aquatic organisms. In its second opinion ⁽¹⁰⁾ the Committee concluded that assessment of the risk of ethoxysulfuron to aquatic organisms was lacking in several respects, in particular with respect to sediment-dwelling organisms. Also assessment of the risk to aquatic plants and algae from the metabolite Hoe 136086 of ethoxysulfuron was considered incomplete.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 276, 12.10.2002, p. 28.

⁽³⁾ OJ L 317, 26.11.1998, p. 47.

⁽⁴⁾ OJ L 87, 31.3.1999, p. 15.

⁽⁵⁾ OJ L 239, 30.8.1997, p. 48.

⁽⁶⁾ OJ L 230, 12.9.2000, p. 14.

⁽⁷⁾ OJ L 176, 20.6.1998, p. 34.

⁽⁸⁾ OJ L 155, 28.6.2000, p. 62.

⁽⁹⁾ Opinion of the Scientific Committee on Plants regarding the evaluation of ethoxysulfuron in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market SCP/ETHOXY/002-Final — adopted 22 September 2000.

⁽¹⁰⁾ Opinion on the evaluation of ethoxysulfuron (AE F095404) in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market — SCP/ETHOXY-Bis/002 adopted 7 June 2001.

Additional studies and information were subsequently provided by the applicant and the risk assessment for the active substance and its degradation products was revised by the rapporteur Member State.

- (11) 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 this active substance can be granted in accordance with the provisions of that Directive.
- (12) The Commission review reports are 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 within the meaning of Article 14 of Directive 91/414/EEC, should be kept available or made available by the Member States for consultation by any interested parties.
- (13) 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 imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl or cyazofamid 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.
- (14) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (15) 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 31 December 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 January 2004.

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.

Article 3

1. Member States shall review the authorisation for each plant protection product containing imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl, or cyazofamid 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, they shall amend or withdraw the authorisation in accordance with Directive 91/414/EEC before 31 December 2003.

2. Member States shall, for each authorised plant protection product containing imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl, or cyazofamid 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 30 June 2003, 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 December 2004 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

Article 4

This Directive shall enter into force on 1 July 2003.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 25 March 2003.

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 |
|----|--|---|------------|------------------|-------------------------|---|
| 41 | Imazamox CAS No 114311-32-9 CIPAC No 619 | (±)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolyl-5-(methoxymethyl) nicotinic acid | 950 g/kg | 1 July 2003 | 30 June 2013 | <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 imazamox, 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.</p> <p>In this overall assessment Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.</p> |
| 42 | Oxasulfuron CAS No 144651-06-9 CIPAC No 626 | Oxetan-3-yl 2[(4,6-dimethylpyrimidin-2-yl) carbamoyl-sulfamoyl] benzoate | 960 g/kg | 1 July 2003 | 30 June 2013 | <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 oxasulfuron, 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.</p> <p>— Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions.</p> <p>Risk mitigation measures should be applied, where appropriate.</p> |
| 43 | Ethoxysulfuron CAS No 126801-58-9 CIPAC No 591 | 3-(4,6-dimethoxypyrimidin-2-yl)-1-(2-ethoxyphenoxy-sulfonyl)urea | 950 g/kg | 1 July 2003 | 30 June 2013 | <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 ethoxysulfuron, 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.</p> <p>Member States should pay particular attention to the protection of non-target aquatic plants and algae in drainage canals. Risk mitigation measures should be applied where appropriate.</p> |

| No | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Entry into force | Expiration of inclusion | Specific provisions |
|----|---|---|-----------------------|------------------|-------------------------|--|
| 44 | Foramsulfuron CAS No 173159-57-4 CIPAC No 659 | 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea | 940 g/kg | 1 July 2003 | 30 June 2013 | <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 foramsulfuron, 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.</p> <p>In this overall assessment Member States should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied, where appropriate.</p> |
| 45 | Oxadiargyl CAS No 39807-15-3 CIPAC No 604 | 5-tert-butyl-3-(2,4-dichloro-5-propargyloxyphenyl)-1,3,4-oxadiazol-2-(3H)-one | 980 g/kg | 1 July 2003 | 30 June 2013 | <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 oxadiargyl, 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.</p> <p>In this overall assessment Member States should pay particular attention to the protection of algae and aquatic plants. Risk mitigation measures should be applied where appropriate.</p> |
| 46 | Cyazofamid CAS No 120116-88-3 CIPAC No 653 | 4-chloro-2cyano-N,N-dimethyl-5-P-tolyimidazole -1-sulfonamide | 935 g/kg | 1 July 2003 | 30 June 2013 | <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 cyazofamid, 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> <ul style="list-style-type: none"> — Member States must pay particular attention to the protection of aquatic organisms; — Member States must pay particular attention to the degradation kinetics of the metabolite CTCA in soil, especially for Northern European regions. <p>Risk mitigation measures or use restrictions should be applied where appropriate.</p> |

⁽¹⁾ Further details on identity and specification of active substances are provided in the review report.