

## COMMISSION DIRECTIVE 2003/119/EC

of 5 December 2003

## amending Council Directive 91/414/EEC to include mesosulfuron, propoxycarbazone and zoxamide 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 2003/84/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 authorities of France received on 15 December 2000 an application from Aventis CropScience France (now Bayer CropScience) for the inclusion of the active substance mesosulfuron (in the form of mesosulfuron methyl) in Annex I to Directive 91/414/EEC. Commission Decision 2001/287/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 of Annexes II and III to Directive 91/414/EEC.
- (2) Germany received an application under Article 6(2) of Directive 91/414/EEC on 25 January 2000, an application from Bayer AG (now Bayer CropScience) concerning propoxycarbazone (in the form of propoxycarbazone sodium; former name: MKH 65 61). This application was declared complete by Commission Decision 2000/463/EC <sup>(4)</sup>.
- (3) The United Kingdom received an application under Article 6(2) of Directive 91/414/EEC on 2 June 1999 from Rohm and Haas France SA (now: Dow AgroSciences) concerning zoxamide (former name: RH-7281). This application was declared complete by Commission Decision 2000/540/EC <sup>(5)</sup>.
- (4) For those 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 draft assessment reports concerning the substances to the Commission on 12 December 2001 (mesosulfuron), 26 March 2001 (propoxycarbazone) and 10 August 2001 (zoxamide).

- (5) 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 October 2003 in the format of the Commission review report for mesosulfuron, propoxycarbazone and zoxamide.
- (6) The review of mesosulfuron, propoxycarbazone and zoxamide did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.
- (7) 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 report. It is therefore appropriate to include mesosulfuron, propoxycarbazone and zoxamide in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.
- (8) 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 mesosulfuron, propoxycarbazone and zoxamide 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.
- (9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (10) 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.

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

<sup>(2)</sup> OJ L 247, 30.9.2003, p. 20.

<sup>(3)</sup> OJ L 99, 10.4.2001, p. 9.

<sup>(4)</sup> OJ L 183, 22.7.2000, p. 21.

<sup>(5)</sup> OJ L 230, 12.9.2000, p. 14.

*Article 2*

1. Member States shall adopt and publish by 30 September 2004 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 October 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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

1. Member States shall review the authorisation for each plant protection product containing mesosulfuron, propoxycarbazono or zoxamide 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 authorisations in accordance with Directive 91/414/EEC by 30 September 2004 at the latest.

2. For each authorised plant protection product containing mesosulfuron, propoxycarbazono or zoxamide as the only active substance, Member States shall 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 Direc-

tive 91/414/EEC. Where necessary and by 31 August 2005 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

3. For each plant protection product containing mesosulfuron, propoxycarbazono or zoxamide together with one or more active substances which are all listed in Annex I to Directive 91/414/EEC, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to that Directive, 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, they shall amend or withdraw the authorisation for each such plant protection product, by the deadline defined for such an amendment or withdrawal in the respective Directives which amended Annex I so as to add the relevant substances to it. Where the respective Directives set different deadlines, the deadline shall be the latest of the dates defined.

*Article 4*

This Directive shall enter into force on 1 April 2004.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 5 December 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 (1)   | Entry into force | Expiration of inclusion | Specific provisions   |
|----|--|---|--|------------------|-------------------------|---|
| 76 | Mesosulfuron<br>CAS No 400852-66-6<br>CIPAC No 441     | 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]- $\alpha$ -(methanesulfonamido)-p-toluic acid         | 930 g/kg   | 1 April 2004     | 31 March 2014           | <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 mesosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 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 protection of aquatic plants;</li> <li>— should pay particular attention to the potential of mesosulfuron and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions.</li> </ul> <p>Risk mitigation measures should be applied where appropriate.</p>  |
| 77 | Propoxycarbazone<br>CAS No 145026-81-9<br>CIPAC No 655 | 2-(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carboxamidossulfonylbenzoicacid-methylester | 974 g/kg<br>(expressed as propoxycarbazone-sodium) | 1 April 2004     | 31 March 2014           | <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 propoxycarbazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 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 of propoxycarbazone and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions;</li> <li>— should pay particular attention to the protection of aquatic ecosystems, especially of aquatic plants.</li> </ul> <p>Risk mitigation measures should be applied where appropriate.</p> <p>The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.</p> |
| 78 | Zoxamide<br>CAS No 156052-68-5<br>CIPAC No 640         | (RS)-3,5-Dichloro-N-(3-chloro-1-ethyl-1-methylacetyl)-p-toluamide   | 950 g/kg   | 1 April 2004     | 31 March 2014           | <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 zoxamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account.</p>   |

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