

COMMISSION DIRECTIVE 2004/30/EC
of 10 March 2004
amending Council Directive 91/414/EEC to include benzoic acid, flazasulfuron and pyraclostrobin
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⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Directive 91/414/EEC Germany received on 25 May 1998 an application from Menno Chemie Vertriebs-Ges. for the inclusion of the active substance benzoic acid in Annex I to Directive 91/414/EEC. Commission Decision 98/676/EC ⁽²⁾ 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) Spain received an application under Article 6(2) of Directive 91/414/EEC on 16 December 1996 from ISK Biosciences Europe SA concerning flazasulfuron. This application was declared complete by Commission Decision 97/865/EC ⁽³⁾.
- (3) Germany received an application under Article 6(2) of Directive 91/414/EEC on 28 February 2000 from BASF AG concerning pyraclostrobin (former name: BAS 500F). This application was declared complete by Commission Decision 2000/540/EC ⁽⁴⁾.
- (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 designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 22 November 2000 (benzoic acid), 1 August 1999 (flazasulfuron) and 23 November 2001 (pyraclostrobin).
- (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 benzoic acid, flazasulfuron and pyraclostrobin.
- (6) The review of benzoic acid, flazasulfuron and pyraclostrobin 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 benzoic acid, flazasulfuron and pyraclostrobin in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may 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 benzoic acid, flazasulfuron or pyraclostrobin 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.

Article 2

1. Member States shall adopt and publish by 30 November 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.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2003/119/EC (OJ L 325, 12.12.2003, p. 41).

⁽²⁾ OJ L 317, 26.11.1998, p. 47.

⁽³⁾ OJ L 351, 23.12.1997, p. 67.

⁽⁴⁾ OJ L 230, 12.9.2000, p. 14.

They shall apply those provisions from 1 December 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 benzoic acid, flazasulfuron or pyraclostrobin 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 November 2004 at the latest.

2. For each authorised plant protection product containing benzoic acid, flazasulfuron or pyraclostrobin 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 Directive 91/414/EEC. Where necessary and by 30 November 2005 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

3. For each plant protection product containing benzoic acid, flazasulfuron or pyraclostrobin 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 June 2004.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 10 March 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC 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
'80	Benzoic acid CAS No 65-85-0 CIPAC No 622	benzoic acid	990 g/kg	1 June 2004	31 May 2014	Only uses as disinfectant may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on benzoic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account.
81	Flazasulfuron CAS No 104040-78-0 CIPAC No 595	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridyl-sulphonyl)urea	940 g/kg	1 June 2004	31 May 2014	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flazasulfuron, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. 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, — should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
82	Pyraclostrobin CAS No 175013-18-0 CIPAC No 657	methyl N-(2-[[1-(4-chloro-phenyl)-1H-pyrazol-3-yl]oxy-methyl]phenyl) N-methoxy carbamate	975 g/kg The manufacturing impurity dimethylsulfate (DMS) is considered to be of toxicological concern and must not exceed a concentration of 0,0001 % in the technical product	1 June 2004	31 May 2014	<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 pyraclostrobin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States</p> <ul style="list-style-type: none"> — should pay particular attention to the protection of aquatic organisms, especially fish, — should pay particular attention to the protection of terrestrial arthropods and earthworms. <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>

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