

COMMISSION DIRECTIVE 2002/81/EC
of 10 October 2002
amending Council Directive 91/414/EEC to include flumioxazine as active substance
(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 2002/64/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 May 1994 an application from Sumitomo SA for the inclusion of the active substance flumioxazine in Annex I to Directive 91/414/EEC. Commission Decision 97/631/EC ⁽³⁾ of 12 September 1997 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) For this active substance, 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 applicant. The nominated rapporteur Member State, submitted a draft assessment report concerning the substance to the Commission on 20 January 1998.
- (3) The draft assessment report has 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 28 June 2002 in the format of the Commission review report for flumioxazine.
- (4) The dossier and the information from the review were also submitted to the Scientific Committee for Plants. The Committee was asked to comment on the test protocols used in higher tier studies to assess effects of the active substance on aquatic plants and earthworms and on development effects seen in animal studies. In its opinion ⁽⁴⁾ the Committee noted that the available higher tier study in aquatic plants is insufficient for a full assessment of exposure/effect relationships. The studies in earthworms and those on developmental toxicity were considered sufficient and adequate to support the risk assessments. The observations of the Scientific Committee were taken into consideration in formulating this Directive and the relevant review report. A revised risk assessment for aquatic plants was made on the basis of the available standard study.
- (5) It has appeared from the various examinations made that plant protection products containing flumioxazine 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 flumioxazine 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.

- (6) 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.
- (7) 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 flumioxazine 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.
- (8) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (9) 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 report for flumioxazine, 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.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 189, 18.7.2002, p. 27.

⁽³⁾ OJ L 262, 24.9.1997, p. 7.

⁽⁴⁾ Opinion of the Scientific Committee on Plants regarding the inclusion of flumioxazine in Annex I to Council Directive 91/414/EEC concerning the placing of plant-protection products on the market (SCP/FLUMIO/002 — final, 23.5.2001).

Article 3

Member States shall adopt and publish by 30 June 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 July 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.

Article 4

1. Member States shall review the authorisation for each plant-protection product containing flumioxazine 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 30 June 2003.

2. Member States shall, for each authorised plant-protection product containing flumioxazine 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 January

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 30 June 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 January 2003.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 10 October 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I the following row is added at the end of the table:

No	Common name, identification Nos	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
'39	Flumioxazine CAS No 103361-09-7 CICAP No 578	N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboximide	960 g/kg	1 January 2003	31 December 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 flumioxazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 June 2002 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must carefully consider the risk to aquatic plants and algae. Conditions of authorisation must include risk mitigation measures, where appropriate.

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