DIRECTIVES

COMMISSION DIRECTIVE 2011/14/EU

of 24 February 2011

amending Council Directive 91/414/EEC to include profoxydim as active substance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Spain received on 2 April 1998 an application from BASF SE for the inclusion of the active substance profoxydim in Annex I to Directive 91/414/EEC. Commission Decision 1999/43/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) For that active substance, the effects on human and animal 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 designated rapporteur Member State submitted a draft assessment report on 28 March 2001.

(3) For profoxydim the draft assessment report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 23 November 2010 in the format of the Commission review report for profoxydim.

(4) It has appeared from the various examinations made that plant protection products containing profoxydim 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 profoxydim in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

(5) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of 6 months after inclusion to review existing provisional authorisations of plant protection products containing profoxydim to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should transform existing provisional authorisations into full authorisations, amend them or withdraw them in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(6) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(7) 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 January 2012 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 February 2012.

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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 14, 19.1.1999, p. 30.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing profoxydim as active substance by 31 January 2012. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to profoxydim are met, with the exception of those identified in Part B of the entry concerning the active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13(2) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing profoxydim 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 July 2011 at the latest, 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 to that Directive and taking into account Part B of the entry in Annex I to that Directive concerning profoxydim. 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.

Following that determination Member States shall:

(a) in the case of a product containing profoxydim as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2013 at the latest; or

(b) in the case of a product containing profoxydim as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 2013 or by the date fixed for such an amendment or withdrawal in the respective directive or directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 August 2011.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 24 February 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, the following entry is added at the end of the table:

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'330	Profoxydim CAS No 139001-49-3 CIPAC No 621	2 – [(1 *E*/*Z*) – [(2 *R S*) – 2 – (4 – chlorophenoxy) propoxyimino] butyl] – 3 – hydroxy – 5 – [(3 *R S*; 3 *S R*) – tetrahydro – 2 H – thiopyran – 3 – yl] cyclohex – 2 – enone	≥ 940 g/kg	1 August 2011	31 July 2021	PART A Only uses as herbicide in rice may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on profoxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment, Member States must pay particular attention to: — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the long term risk to non-target organisms. Conditions of authorisation shall include risk mitigation measures where appropriate.'

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