Commission Directive 2011/6/EU of 20 January 2011 amending Council Directive 91/414/EEC to include buprofezin as active substance (Text with EEA relevance)

COMMISSION DIRECTIVE 2011/6/EU

of 20 January 2011

amending Council Directive 91/414/EEC to include buprofezin 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) Commission Regulations (EC) No 451/2000[(2)] and (EC) No 1490/2002[(3)] lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included buprofezin. By Commission Decision 2008/771/EC[(4)] it was decided not to include buprofezin in Annex I to Directive 91/414/EEC.

(2) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I[(5)].

(3) The application was submitted to the United Kingdom, which had been designated rapporteur Member State by Regulation (EC) No 33/2008. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as those that were the subject of Decision 2008/771/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(4) The United Kingdom evaluated the new information and data submitted by the applicant and prepared an additional report in August 2009. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 21 August 2009.

(5) The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at

the request of the Commission, the additional report was peer reviewed by the Member States and the Authority. The Authority then presented its conclusion on buprofezin to the Commission on 21 May 2010[6]. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 23 November 2010 in the format of the Commission review report for buprofezin.

(6) The additional report by the rapporteur Member State and the new conclusion by the Authority concentrate on the concerns that lead to the non-inclusion. Those concerns were, in particular, the impossibility to perform a reliable consumer exposure assessment because of lack of data to determine an appropriate residue definition.

(7) The new information submitted by the applicant enabled a consumer exposure assessment. The information currently available indicates that the risk to consumers is acceptable.

(8) Consequently, the additional data and information provided by the applicant permit to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.

(9) It has appeared from the various examinations made that plant protection products containing buprofezin may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) 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 buprofezin in Annex I, 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.

(10) Without prejudice to that conclusion, it is appropriate to obtain confirmatory information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that the inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the applicant submit further information to confirm the processing and conversion factors in the consumer risk assessment.

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

(12) 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 bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or 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

This Directive shall enter into force on 1 February 2011.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 January 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common Name, Identification Numbers	IUPAC Name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions
‘325	Buprofezin CAS No: *953030-84-7* CIPAC No: 681	(Z)-2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one	≥ 985 g/kg	1 February 2011	31 January 2021	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on buprofezin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on

a Further details on identity and specification of active substance are provided in the review report.

						the Food Chain and Animal Health on 23 November 2010, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the operators' and workers' safety and ensure that conditions of use impose adequate personal protective equipment where appropriate; (b) the dietary exposure of consumers to the buprofezin (aniline) metabolites in

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						processed food; (c) the application of an appropriate waiting period for rotational crops in greenhouses; (d) the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the processing and conversion factors for consumer risk assessment.

a Further details on identity and specification of active substance are provided in the review report.

						The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 January 2013.’

a Further details on identity and specification of active substance are provided in the review report.

(**1**) OJ L 230, 19.8.1991, p. 1.

(**2**) OJ L 55, 29.2.2000, p. 25.

(**3**) OJ L 224, 21.8.2002, p. 23.

(**4**) OJ L 263, 2.10.2008, p. 18.

(**5**) OJ L 15, 18.1.2008, p. 5.

(**6**) European Food Safety Authority: Conclusion on the peer review of the pesticide risk assessment of the active substance buprofezin EFSA Journal 2010; 8(6):1624. [77 pp.]. doi:10.2903/j.efsa.2010.1624. Available online: www.efsa.europa.eu