Commission Implementing Directive 2011/40/EU of 11 April 2011 amending Council Directive 91/414/EEC to include sintofen as active substance and amending Commission Decision 2008/934/EC (Text with EEA relevance)

COMMISSION IMPLEMENTING DIRECTIVE 2011/40/EU

of 11 April 2011

amending Council Directive 91/414/EEC to include sintofen as active substance and amending Commission Decision 2008/934/EC

(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 sintofen.

(2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances[(4)] was adopted on the non-inclusion of sintofen.

(3) 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)].

(4) The application was submitted to France, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also

complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) France evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 14 January 2010. 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 Authority presented its conclusion on sintofen to the Commission on 26 November 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 11 March 2011 in the format of the Commission review report for sintofen.

(6) It has appeared from the various examinations made that plant protection products containing sintofen 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 have been examined and detailed in the Commission review report. It is therefore appropriate to include sintofen 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.

(7) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the applicant submit further information confirming: the specification of the technical material, the relevance of the impurities present in the technical specifications, the relevance of the test material used in the toxicity and ecotoxicity dossiers and the metabolic profile of sintofen in rotational crops.

(8) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(9) 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 authorisations of plant protection products containing sintofen 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 vary, replace or withdraw, as appropriate, existing authorisations, 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.

(10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation

of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market[7] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I.

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

(12) Decision 2008/934/EC provides for the non-inclusion of sintofen and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning sintofen in the Annex to that Decision.

(13) It is therefore appropriate to amend Decision 2008/934/EC accordingly.

(14) 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:

(**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 333, 11.12.2008, p. 11.

(**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 sintofen. EFSA Journal 2010;8(12): [49 pp.]. doi:10.2903/j.efsa.2010.1931. Available online: www.efsa.europa.eu/efsajournal.htm

(**7**) OJ L 366, 15.12.1992, p. 10.