Commission Directive 2008/70/EC of 11 July 2008 amending Council Directive 91/414/EEC to include tritosulfuron as an active substance (Text with EEA relevance)

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

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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 8 June 2001 an application from BASF AG for the inclusion of the active substance tritosulfuron in Annex I to Directive 91/414/EEC. Commission Decision 2002/268/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 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 designated rapporteur Member State submitted a draft assessment report on 5 September 2002.

(3) For tritosulfuron the draft assessment reports were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 20 May 2008 in the format of the Commission review report for tritosulfuron.

(4) The documents and information on tritosulfuron were also submitted to the European Food Safety Authority (EFSA) for separate consultation. The EFSA was invited to prepare a scientific opinion on the toxicological relevance of the soil and groundwater metabolite TBSA of tritosulfuron in the context of the human risk assessment. The EFSA was asked whether, on the basis of the data available, the metabolite TBSA shows a genotoxic potential or an indication of impaired fertility and what are the implications for toxicological reference values for humans.

(5) In its opinion of 11 December 2007[(3)], the EFSA concluded that TBSA did not show any clastogenic or other genotoxic potential and has no direct effect on fertility and that therefore there is no requirement for any adjustment of the default safety factor for potential effect on fertility. That opinion was taken into account.

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(6) It has appeared from the various examinations made that plant protection products containing the active substance 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 tritosulfuron in Annex I to that Directive, 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.

(7) 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 six months after inclusion to review existing provisional authorisations of plant protection products containing tritosulfuron 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.

(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

1 Member States shall adopt and publish by 31 May 2009 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 June 2009.

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 in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing tritosulfuron as active substance by 31 May 2009. By that date, they shall in particular verify that the

conditions in Annex I to that Directive relating to tritosulfuron, 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 tritosulfuron 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 30 November 2008 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 tritosulfuron. 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 tritosulfuron as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2010 at the latest; or

b in the case of a product containing tritosulfuron as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2010 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 December 2008.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 July 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission