Commission Implementing Regulation (EU) No 1045/2011 of 19 October 2011 concerning the non-approval of the active substance asulam, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Decision 2008/934/EC (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1045/2011

of 19 October 2011

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular Articles 13(2) and 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC[(2)] is to apply, with respect to the procedure and the conditions for approval, to active substances for which completeness has been established in accordance with Article 16 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[(3)]. Asulam is an active substance for which completeness has been established in accordance with that Regulation.

(2) Commission Regulations (EC) No 451/2000[(4)] and (EC) No 1490/2002[(5)] lay down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish lists of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. These lists included asulam.

(3) In accordance with Article 3(2) of Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage

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of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC[(6)] the notifier withdrew its support for the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from entry into force of Regulation (EC) No 1095/2007. 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[(7)] was adopted on the non-inclusion of asulam.

(4) 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 Regulation (EC) No 33/2008.

(5) The application was submitted to the United Kingdom, 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.

(6) The United Kingdom 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 6 November 2009. 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 the risk assessment of asulam to the Commission on 23 September 2010[(8)]. 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 14 July 2011 in the format of the Commission review report for asulam.

(7) During the evaluation of this active substance, concerns were identified. Those concerns were, in particular, the following. It was not possible to perform a reliable consumer exposure assessment as data were missing concerning the presence and toxicity of the metabolite sulfanilamide, as well as concerning the presence of other potentially significant metabolites that were not analysed in the available residue trials and processing studies. Furthermore, no data was available on the toxicological relevance of the impurities in the technical specification of the active substance. In addition, a high risk to birds was identified.

(8) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with Article 21(1) of Regulation (EC) No 33/2008, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.

(9) However, despite the arguments put forward by the applicant, the concerns referred to in recital 7 could not be eliminated. Consequently, it has not been demonstrated that it

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may be expected that, under the proposed conditions of use, plant protection products containing asulam satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(10) Asulam should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

(11) For plant protection products containing asulam, where Member States grant any period of grace in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire on 31 December 2012 at the latest as laid down in the second paragraph of Article 3 of Decision 2008/934/EC.

(12) This Regulation does not prejudice the submission of a further application for asulam pursuant to Article 7 of Regulation (EC) No 1107/2009.

(13) In the interest of clarity, the entry for asulam in the Annex to Decision 2008/934/EC should be deleted.

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

(15) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Non-approval of active substance

The active substance asulam is not approved.

Article 2

Transitional measures

Member States shall ensure that authorisations for plant protection products containing asulam are withdrawn by 31 December 2011.

Article 3

Period of grace

Any period of grace granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on 31 December 2012 at the latest.