Commission Implementing Regulation (EU) No 1078/2011 of 25 October 2011 concerning the non-approval of the active substance propanil, 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1078/2011

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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 Article 13(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)]. Propanil 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 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 propanil.

(3) In accordance with Article 11f of Regulation (EC) No 1490/2002 and Article 12(1)(a) and (2)(b) of that Regulation, Commission Decision 2008/769/EC of 30 September 2008 concerning the non-inclusion of propanil in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance[(6)] was adopted.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 1078/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 Italy, 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 2008/769/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(6) Italy 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 26 February 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 the risk assessment of propanil to the Commission on 23 February 2011[7]. 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 27 September 2011 in the format of the Commission review report for propanil.

(7) Based on the new data submitted by the applicant and included in the additional report an acceptable operator exposure level could be set. However, during the evaluation of this active substance, a number of other concerns have been identified. In particular, it was not possible to perform a reliable consumer exposure assessment as data were missing on the toxicity of metabolite 3,4-DCA which may be higher than the parent compound. Moreover, no maximum residue levels could be proposed for the supported use on rice as the submitted trials have not been conducted according to the critical good agricultural practices. A high risk to birds and mammals has been identified while a high risk for aquatic organisms and non-target arthropods cannot be excluded on the basis of the data made available by the applicant. In addition, a potential for long-range transport through the atmosphere cannot be excluded.

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