Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances (Text with EEA relevance)

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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) 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 includes aclonifen, imidacloprid and metazachlor.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifiers. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10(1) of Regulation (EC) No 1490/2002. For aclonifen and imidacloprid the rapporteur Member State was Germany and all relevant information was submitted on 11 September 2006 and on 13 June 2006 respectively. For metazachlor the rapporteur Member State was United Kingdom and all relevant information was submitted on 30 September 2005.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 31 July 2008 for aclonifen, on 29 May 2008 for imidacloprid and on 14 April 2008 for metazachlor in the format of the EFSA Scientific Reports[(4)]. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 September 2008 in the format of the Commission review reports for aclonifen, imidacloprid and metazachlor.

(4) It has appeared from the various examinations made that plant protection products containing aclonifen, imidacloprid and metazachlor 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 reports. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that aclonifen should be subjected to further testing for evaluation of residues in rotational crops and for the confirmation of the risk assessment for birds, mammals, aquatic organisms and non-target plants and that imidacloprid should be subjected to further testing for confirmation of the risk assessment for operators and workers and the risk to birds and mammals and such studies should be presented by the notifier. Furthermore for metazachlor it is appropriate to obtain additional information on certain specific points. Article 5(5) of Directive 91/414/EEC provides that an inclusion may be reviewed at any time if there are indications that the criteria referred to in paragraphs 1 and 2 are no longer satisfied. The notifier has submitted information which at this stage is considered to be sufficient to address the relevance of certain metabolites. However, a decision on the classification of metazachlor under Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(5)] is not yet finalised. Such decision might lead to the need for further information on these metabolites. The information submitted by the notifier to address the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer is, at this stage, considered as sufficient. However, if a decision is adopted under Directive 67/548/EEC by which metazachlor is classified as 'limited evidence of a cancerogenic effect', further information will be needed on the relevance of those metabolites with respect to cancer. Article 6(1) of Directive 91/414/EEC provides that the inclusion of a substance in Annex I to that Directive may be subject to conditions. The inclusion of metazachlor should therefore be subject to a condition concerning the submission of further information in case that substance is classified under Directive 67/548/EEC.

(6) 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.

(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 authorisations of plant protection products containing aclonifen, imidacloprid and metazachlor 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 way of 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) 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[(6)] 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.

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

(10) 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**) EFSA Scientific Report (2008) 149, Conclusion regarding the peer review of the pesticide risk assessment of the active substance aclonifen (finalised 31 July 2008).
EFSA Scientific Report (2008) 148, Conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid (finalised 29 May 2008).
EFSA Scientific Report (2008) 145, Conclusion regarding the peer review of the pesticide risk assessment of the active substance metazachlor (finalised 14 April 2008).

(**5**) OJ 196, 16.8.1967, p. 1.

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