DIRECTIVES

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)

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

[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).

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 ([1]) 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 ([2]) 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:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 31 January 2010 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 February 2010.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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 aclonifen, imidacloprid and metazachlor as active substances by 31 January 2010.

([1]) OJ 196, 16.8.1967, p. 1.

([2]) OJ L 366, 15.12.1992, p. 10.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to aclonifen, imidacloprid and metazachlor are met, with the exception of those identified in part B of the entry concerning that 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 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing aclonifen, imidacloprid and metazachlor 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 31 July 2009 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 aclonifen, imidacloprid and metazachlor respectively. 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 aclonifen, imidacloprid and metazachlor as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2014 at the latest; or

(b) in the case of a product containing aclonifen, imidacloprid and metazachlor as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 2014 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 August 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 15 December 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'221	Aclonifen CAS No 74070-46-5 CIPAC No 498	2-chloro-6-nitro-3-phenoxyaniline	≥ 970 g/kg The impurity phenol is of toxicological concern and a maximum level of 5 g/kg is established.	1 August 2009	31 July 2019	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing aclonifen for uses other than sunflower, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on aclonifen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in rotational crops and evaluate the dietary exposure of consumers, — the protection of birds, mammals, aquatic organisms and non-target plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall request the submission of further studies on rotational crops residues and relevant information to confirm the risk assessment for birds, mammals, aquatic organisms and non-target plants. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the entry into force of this Directive.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
222	Imidacloprid CAS No 138261-41-3 CIPAC No 582	(E)-1-(6-Chloro-3-pyridinyl-methyl)-N-nitroimidazolidin-2-ylideneamine	≥ 970 g/kg	1 August 2009	31 July 2019	PART A Only uses as insecticide may be authorised. For the protection of non-target organisms, in particular honey bees and birds, for use as seed treatment: — the seed coating shall only be performed in professional seed treatment facilities. These facilities must apply the best available techniques in order to ensure that the release of dust clouds during storage, transport and application can be excluded, — adequate application equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust clouds emission. Member States shall ensure that the label of treated seed includes the indication that the seeds were treated with imidacloprid and sets out the risk mitigation measures provided for in the authorisation. PART B In assessing applications to authorise plant protection products containing imidacloprid for uses other than tomatoes in glasshouses, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imidacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the impact on aquatic organisms, non-target arthropods, earthworms, other soil macroorganisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures, — the protection of honey bees, in particular for spray applications and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. The Member States concerned shall request the submission of: — information to further address the risk assessment for operators and workers, — information to further address the risk to birds and mammals. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the entry into force of this Directive.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
223	Metazachlor CAS No 67129-08-2 CIPAC No 411	2-chloro-N-(pyrazol-1-ylmethyl)acet-2′,6′-xylidide	≥ 940 g/kg The manufacturing impurity toluene is considered to be of toxicological concern and a maximum level of 0,01 % is established.	1 August 2009	31 July 2019	PART A Only uses as herbicide may be authorised; application max. of 1,0 kg/ha only every third year on the same field. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metazachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate. If metazachlor is classified under Directive 67/548/EEC as “limited evidence of a cancerogenic effect”, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer. They shall ensure that the notifiers provide that information to the Commission within six months from the notification of such a classification decision.’

(1) Further details on identity and specification of active substance are provided in the review report.