Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2008/107/EC

of 25 November 2008

amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim 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 abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim.

(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 abamectin the rapporteur Member State was the Netherlands and all relevant information was submitted on 27 October 2005. For epoxiconazole, fenpropimorph and fenpyroximate the rapporteur Member State was Germany and all relevant information was submitted on 28 April 2005, 17 March 2005 and 25 October 2005 respectively. For tralkoxydim the rapporteur Member State was the United Kingdom and all relevant information was submitted on 6 September 2005.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 29 May 2008 for abamectin, on 26 March 2008 for epoxiconazole and tralkoxydim, on 14 April 2008 for fenpropimorph, on 5 May 2008 for fenpyroximate 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 11 July

2008 in the format of the Commission review reports for abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim.

(4) It has appeared from the various examinations made that plant protection products containing abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim 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/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that abamectin should be subjected to further studies on the specification and further information is required to confirm the risk to birds and mammals, to aquatic organisms, and to groundwater with respect to the metabolite U8. Epoxiconazole should be subjected to further testing of its potential endocrine disrupting properties and to a monitoring programme to assess the long-range atmospheric transport and related environmental risks; further information is required as regards the residues of its metabolites in primary crops, rotational crops and products of animal origin as well as information to address the long-term risk to herbivorous birds and mammals. Fenpropimorph should be subjected to further testing to confirm the mobility in soil of metabolite BF-421-7. Fenpyroximate should be subjected to further testing for confirmation of the risk to aquatic organisms from metabolites containing the benzyl moiety and the risk of biomagnification in aquatic food chains. Tralkoxydim should be subjected to further testing for confirmation of the long-term risk to herbivorous mammals. All the above mentioned studies and information should be presented by the notifiers within the deadlines set in Annex I of this Directive.

(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 abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim 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[(5)] 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 October 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 November 2009.

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 abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances by 31 October 2009.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim 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 abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim 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 April 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 abamectin,

epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim 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 abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2013 at the latest; or

b in the case of a product containing abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2013 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 May 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 25 November 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[a]	Entry into force	Expiration of inclusion	Specific provisions
‘216	Abamectin CAS No 71751-41-2 avermectin B_{1a} CAS No 65195-55-3 Avermectin B_{1b} CAS No 65195-56-4 abamectin CIPAC No 495	Avermectin B_{1a} (10E,14E,16E,22Z)-(1R,4S,5′S,6S,6′R,8R,12S,13S,20R,21R,24S)-6′-[(S)-sec-butyl]-21,24-dihydroxy-5′,11.13,22-tetramethyl-2-oxo-3.7,19-trioxatetracyclo[15.6.1.1^{4,8}0^{20,24}]pentacosa-10.14,16,22-tetraene-6-spiro-2′-(5′,6′-dihydro-2′H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside Avermectin B_{1b} (10E,14E,16E,22Z)-(1R,4S,5′S,6S,6′R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6′-isopropyl-5′,11.13,22-tetramethyl-2-oxo-3.7,19-trioxatetracyclo[15.6.1.1^{4,8}0^{20,24}]pentacosa-10.14,16,22-tetraene-6-spiro-2′-(5′,6′-dihydro-2′H-pyran)-12-yl 2,6-	≥ 850 g/kg	1 May 2009	30 April 2019	PART A Only uses as insecticide, acaricide. PART B In assessing applications to authorise plant protection products containing abamectin for uses other than citrus, lettuce and tomatoes, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary

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

		dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside				data and information are provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on (abamectin), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety

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

						and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the residues in food of plant origin and evaluate the dietary exposure of consumers, — the protection of bees, non-target arthropods, birds, mammals and aquatic organisms. In relation to these identified risks risk mitigation measures, such as buffer

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						zones, waiting periods, should be applied where appropriate. The Member States concerned shall request the submission of: — further studies on the specification, — information to further address the risk assessment for birds and mammals, — information to address the risk to aquatic organisms with respect to the major soil metabolites, — information to address the risk

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

						to groundwater with respect to the metabolite U8. They shall ensure that the notifiers provide such studies to the Commission within two years from the entry into force of this Directive.
217	Epoxiconazole CAS No 135319-73-2 (formerly 106325-08-0) CIPAC No 609	(2RS, 3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1H-1.2,4-triazole	≥ 920 g/kg	1 May 2009	30 April 2019	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on epoxiconazole, and in particular

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

						Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 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

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

						where appropriate, — the dietary exposure of consumers to the epoxiconazole (triazole) metabolites, — the potential for long-range transport via air, — the risk to aquatic organisms, birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further studies addressing the

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						potential endocrine disrupting properties of epoxiconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines. The Member States concerned shall ensure that the notifier presents to the Commission not later than 30 June 2009 a monitoring programme to assess the long-range atmospheric transport of epoxiconazole and related environmental risks. The results of this monitoring shall be submitted as a

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

						monitoring report to the Commission by 31 December 2011 at the latest. The concerned Member States shall ensure that the notifier submits within two years from the entry into force of this Directive, at the latest, information on residues of epoxiconazole metabolites in primary crops, rotational crops and products of animal origin and information to further address the long-term risk to herbivorous birds and mammals.
218	Fenpropimorph CAS No 67564-91-4 CIPAC No 427	(RS)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine	≥ 930 g/kg	1 May 2009	30 April 2019	PART A Only uses as fungicide may be authorised.

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

						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenpropimorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account. In this overall assessment Member

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

						States must pay particular attention to: — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, such as restrictions of the daily work rate, — the protection of the groundwater, when the active substance is applied in regions with

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

						— vulnerable soil and/or climatic conditions, — the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones, reduction of run-off and drift reduction nozzles. The Member States concerned shall request the submission of further studies to confirm the mobility in soil of the metabolite BF-421-7. They shall ensure that the notifiers at whose request

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

						fenpropimorph has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
219	Fenpyroximate CAS No 134098-61-6 CIPAC No 695	tert-butyl (E)-alpha-(1,3-dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-p-toluate	> 960 g/kg	1 May 2009	30 April 2019	PART A Only uses as acaricide may be authorised. The following uses must not be authorised: — applications in high crops with a high risk of spray drift, for example tractor mounted air-blast sprayer and hand-held applications.

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

						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenpyroximate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account. In this overall assessment Member

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

						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 and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. The Member States concerned shall request the

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

						submission of information to further address: — the risk to aquatic organisms from metabolites containing the benzyl moiety, — the risk of biomagnification in aquatic food chains. They shall ensure that the notifiers at whose request fenpyroximate has been included in this Annex provide such information to the Commission within two years from the entry into force of this Directive.
220	Tralkoxydim CAS No 87820-88-0 CIPAC No 544	(RS)-2-[(EZ)-1-(ethoxyimino)propyl]-3-hydroxy-5-mesitylcyclohex-2-en-1-one	≥ 960 g/kg	1 May 2009	30 April 2019	PART A Only uses as herbicide may be authorised.

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

						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tralkoxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account. In this overall assessment Member

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

						States must pay particular attention to: — the protection of the groundwater, in particular from the soil metabolite R173642 when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of herbivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of:

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

						— information to further address the long-term risk to herbivorous mammals arising from the use of tralkoxydim. They shall ensure that the notifiers at whose request tralkoxydim has been included in this Annex provide such information to the Commission within two years from the entry into force of this Directive.’

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

(**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) 148. Conclusion regarding the peer review of the pesticide risk assessment of the active substance abamectin (finalised 29 May 2008).
EFSA Scientific Report (2008) 138. Conclusion regarding the peer review of the pesticide risk assessment of the active substance epoxiconazole (finalised 26 March 2008).
EFSA Scientific Report (2008) 144. Conclusion regarding the peer review of the pesticide risk assessment of the active substance fenpropimorph (finalised 14 April 2008).
EFSA Scientific Report (2008) 143, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fenpyroximate (finalised 5 May 2008).
EFSA Scientific Report (2008), Conclusion regarding the peer review of the pesticide risk assessment of the active substance tralkoxydim (finalised 26 March 2008).

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