Commission Directive 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2004/99/EC

of 1 October 2004

amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid 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) In accordance with Article 6(2) of Directive 91/414/EEC Greece received on 22 October 1999 an application from Nisso Chemical Europe GmbH for the inclusion of the active substance acetamiprid in Annex I to Directive 91/414/EEC. Commission Decision 2000/390/EC[(2)] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) The United Kingdom received an application under Article 6(2) of Directive 91/414/EEC on 11 September 1998 from Bayer plc. (now Bayer CropScience AG) concerning thiacloprid. Commission Decision 2000/181/EC[(3)] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 19 March 2001 (acetamiprid) and 22 November 2000 (thiacloprid).

(4) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 29 June 2004 in the format of the Commission review reports for acetamiprid and thiacloprid.

(5) The review of acetamiprid and thiacloprid did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

(6) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include acetamiprid and thiacloprid in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.

(7) After the inclusion of acetamiprid and thiacloprid in Annex I to Directive 91/414/EEC, Member States should be allowed a reasonable period to implement the provisions of that Directive as regards plant protection products containing those substances and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

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

(9) 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

1 Member States shall adopt and publish by 30 June 2005 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 July 2005.

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

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1 Member States shall review the authorisation for each plant protection product containing acetamiprid or thiacloprid to ensure that the conditions relating to these active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 30 June 2005 at the latest.

2 For each authorised plant protection product containing acetamiprid or thiacloprid 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 December 2004 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. 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 acetamiprid or thiacloprid as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2006 at the latest; or

b in the case of a product containing acetamiprid or thiacloprid as one of several active substances, where necessary, amend or withdraw the authorisation by 30 June 2006 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 January 2005.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 1 October 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC the following rows are added at the end of the table:

No	Common name, identification numbers	IUPAC Name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions
'92	Acetamiprid CAS No 160430-64-8 CIPAC No Not yet allocated	(E)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine	≥ 990 g/kg	1 January 2005	31 December 2014	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Acetamiprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2004 shall be taken into account. In this overall assessment Member States — should pay particular

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

						— attention to worker exposure, should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
93	Thiacloprid CAS No 111988-49-9 CIPAC No 631	(Z)-N-{3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-yliden}cyanamide	≥ 975 g/kg	1 January 2005	31 December 2014	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Thiacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health

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

						on 29 June 2004 shall be taken into account. In this overall assessment Member States — should pay particular attention to the protection of non-target arthropods, — should pay particular attention to the protection of aquatic organisms, — should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil

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						and/ or climatic conditions. Risk mitigation measures should be applied where appropriate.

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

(**1**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/71/EC (OJ L 127, 29.4.2004, p. 104).

(**2**) OJ L 145, 20.6.2000, p. 36.

(**3**) OJ L 57, 2.3.2000, p. 35.