COMMISSION DIRECTIVE 2009/154/EC

of 30 November 2009

amending Council Directive 91/414/EEC to include cyflufenamid as active substance

(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 the United Kingdom received on 17 March 2003 an application from Nisso Chemical Europe GmbH for the inclusion of the active substance cyflufenamid in Annex I to Directive 91/414/EEC. Commission Decision 2003/636/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) For that active substance, 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 applicant. The designated rapporteur Member State submitted a draft assessment report on 30 January 2006.

(3) The assessment report was peer reviewed by the Member States and the EFSA and presented to the Commission in the format of the EFSA Scientific Report for cyflufenamid on 8 April 2009 [3]. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 2 October 2009 in the format of the Commission review report for cyflufenamid.

(4) It has appeared from the various examinations made that plant protection products containing cyflufenamid 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 cyflufenamid in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

(5) 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 provisional authorisations of plant protection products containing cyflufenamid 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 transform existing provisional authorisations into full authorisations, amend them or withdraw them in accordance with the provisions of Directive 91/414/EEC. By 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.

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

(7) 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 30 September 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 October 2010.

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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 221, 4.9.2003, p. 42.
[3] Conclusion on pesticide peer review regarding the risk assessment of the active substance cyflufenamid. EFSA Scientific Report (2009) 258, pp. 1-99.

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 cyflufenamid as active substance by 30 September 2010. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to cyflufenamid are met, with the exception of those identified in part B of the entry concerning the 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(2) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing cyflufenamid 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 March 2010 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 cyflufenamid. 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 cyflufenamid as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2011 at the latest; or

(b) in the case of a product containing cyflufenamid as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 2011 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 April 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 30 November 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC, the following entry is added at the end of the table:

No	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'302	Cyflufenamid CAS No: 180409-60-3 CIPAC No: 759	(Z)-N-[α-(cyclopropylmethoxyimino) – 2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide	> 980 g/kg	1 April 2010	31 March 2020	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 cyflufenamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 October 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate.'

[1] Further details on identity and specification of active substances are provided in the review report.