DIRECTIVES

COUNCIL DIRECTIVE 2009/82/EC

of 13 July 2009

amending Directive 91/414/EEC to include tetraconazole as an active substance

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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 tetraconazole.

(2) For tetraconazole 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 notifier. 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 tetraconazole the rapporteur Member State was Italy and all relevant information was submitted on 15 July 2005.

(3) The assessment report has been peer reviewed by the Member States and the EFSA, and presented to the Commission on 31 July 2008 in the format of the EFSA Scientific Report for tetraconazole. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 February 2009 in the format of the Commission review report for tetraconazole.

(4) It has appeared from the various examinations made that plant protection products containing tetraconazole 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 have been examined and detailed in the Commission review report. It is therefore appropriate to include tetraconazole in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance 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 as regards tetraconazole, to require that the notifier submits further information on a refined consumer risk assessment, on the specification regarding ecotoxicology, on the fate and behaviour of potential metabolites in all relevant compartments, on the refined risk assessment of such metabolites to birds, mammals aquatic organisms and non-target arthropods and on the potential for endocrine disrupting effects to birds, mammals and fish.

(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 containing tetraconazole 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 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.

[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.

(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 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] 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 Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman.

(11) In accordance with point 34 of the Interinstitutional agreement on better law-making [2], Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public,

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 June 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply these provisions from 1 July 2010.

When they are adopted by Member States, these measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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 tetraconazole as an active substance by 30 June 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to tetraconazole 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 tetraconazole 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 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 tetraconazole. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in points (b), (c), (d) and (e) of Article 4(1) of Directive 91/414/EEC.

Following that determination Member States shall:

(a) in the case of a product containing tetraconazole as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2014; or

(b) in the case of a product containing tetraconazole as one of several active substances, where necessary, amend or withdraw the authorisation by 30 June 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 January 2010.

[1] OJ L 366, 15.12.1992, p. 10.
[2] OJ C 321, 31.12.2003, p. 1.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 13 July 2009.

For the Council
The President
E. ERLANDSSON

ANNEX

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
	'Tetraconazole CAS No 112281-77-3 CIPAC No 726	*(RS)-2-(2,4-dichlorophenyl)-3-(1H-1.2,4-triazol-1-yl)-propyl-1.1,2,2-tetrafluoroethyl ether*	≥ 950 g/kg (racemic mixture) Impurity toluene: not more than 13 g/kg	1 January 2010	31 December 2019	PART A Only uses as fungicide in field crops with an application of max. 0,100 kg/ha every third year on the same field may be authorised. Uses in apples and grapes must not be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tetraconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, The Member States concerned shall request: — the submission of further information on a refined consumer risk assessment, — further information on the specification regarding eco-toxicology, — further information on the fate and behaviour of potential metabolites in all relevant compartments, — the refined risk assessment of such metabolites to birds, mammals aquatic organisms and non-target arthropods, — further information on the potential for endocrine disrupting effects to birds, mammals and fish, They shall ensure that the notifier provides such information to the Commission by 31 December 2011.'

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