

DIRECTIVES

COMMISSION DIRECTIVE 2010/82/EU

of 29 November 2010

amending Council Directive 91/414/EEC as regards an extension of the use of the active substance tetraconazole

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 the second indent of the second subparagraph of Article 6(1) thereof,

Whereas:

- (1) By Council Directive 2009/82/EC ⁽²⁾ tetraconazole was included as active substance in Annex I to Directive 91/414/EEC for use as a fungicide.
- (2) However, the inclusion of tetraconazole is limited to uses on field crops with a restricted rate and timing of application. Uses on apples and grapes are entirely excluded. Those restrictions were necessary because at the time of inclusion the information required for the groundwater assessment was insufficient, in particular as regards the risk of contamination by two metabolites which had not been identified by the notifier. As regards uses on apples and grapes, the information necessary for the assessment of the risk to consumers was incomplete.
- (3) The notifier Isagro has requested an amendment to the inclusion of tetraconazole extending its use as a fungicide by removing those restrictions. It has submitted further scientific data in support of its request.
- (4) Italy which had been designated rapporteur Member State by Commission Regulation (EC) No 1490/2002 ⁽³⁾

assessed those data and submitted to the Commission on 10 February 2010 an addendum to the draft assessment report on tetraconazole, which was circulated for comments to the other Member States and to the European Food Safety Authority (EFSA). The draft assessment report together with that addendum was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 28 October 2010 in the format of the Commission review report for tetraconazole.

- (5) The new data submitted by the notifier and the new assessment carried out by the rapporteur Member State indicate that the requested extension of use does not cause any risks in addition to those already taken into account in the specific provisions for tetraconazole in Annex I to Directive 91/414/EEC and in the Commission review report for that substance. In particular as regards the risk of groundwater contamination, the rapporteur Member State considered that the new study submitted by the notifier identifies those metabolites and that there is no unacceptable leaching. Concerning use on apples and grapes, it concluded that, as completed by the new supervised and field trials, the residue data show that there are no risks as regards the acute and chronic intake by consumers.
- (6) In accordance with Article 5(1)(a) and (b) of Directive 91/414/EEC, it is therefore justified to modify the specific provisions for tetraconazole by removing the restrictions on its use as a fungicide.
- (7) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 196, 28.7.2009, p. 10.

⁽³⁾ OJ L 224, 21.8.2002, p. 23.

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Annex I to Directive 91/414/EEC, in the column 'Specific provisions' of the row for 'Tetraconazole', Part A is replaced by the following:

'PART A

Only uses as fungicide may be authorised.'

Article 2

Member States shall adopt and publish by 31 March 2011 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 April 2011.

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.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 November 2010.

For the Commission

The President

José Manuel BARROSO
