

**COMMISSION DIRECTIVE 2010/20/EU****of 9 March 2010****amending Council Directive 91/414/EEC to remove tolylfluanid as active substance and on the withdrawal of authorisations for plant protection products containing that substance****(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 <sup>(1)</sup>, and in particular the third indent of Article 6(1) thereof,

Whereas:

- (1) Tolylfluanid is included in Annex I to Directive 91/414/EEC, which sets out the list of active substances authorised for use in plant protection products.
- (2) By Commission Decision 2007/322/EC of 4 May 2007 laying down protective measures concerning uses of plant protection products containing tolylfluanid leading to the contamination of drinking water <sup>(2)</sup> it was decided that Member States in which ozone is used for the treatment of drinking water are to prohibit any uses of tolylfluanid which may result in a contamination of drinking water with nitrosamines. The reason for that measure was that it had been discovered that by such a treatment a metabolite of that active substance, N,N-dimethylsulfamide, may be converted into nitrosamines which are harmful to human health.
- (3) Under Decision 2007/322/EC Member States further had to ensure that the notifier at whose request tolylfluanid had been included in Annex I to Directive 91/414/EEC submitted studies on the leaching behaviour of that active substance and on the conditions under which the formation of nitrosamines can be excluded.
- (4) On 5 July 2007, the notifier Bayer CropScience submitted the required studies to the rapporteur Member State, including studies and information on the physical, chemical and toxicological fate and behaviour of the metabolite N,N-dimethylsulfamide and on its ecotoxicological properties.
- (5) An addendum to the assessment report, concerning the evaluation of those studies and information, was submitted by the rapporteur Member State to the

Commission on 20 February 2008. This addendum was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health on 22 January 2010.

- (6) In this addendum it was concluded that the concerns as regards the leaching behaviour of tolylfluanid and the formation of nitrosamines could not be eliminated. In addition, it was found that the use of plant protection products containing tolylfluanid may lead to unacceptable concentrations of the metabolite N,N-dimethylsulfamide in groundwater. Consequently, it was concluded that tolylfluanid no longer satisfies the requirements of Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (7) The notifier submitted its comments on the addendum to the assessment report. Those comments were carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and its evaluation have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing tolylfluanid satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.
- (8) Tolylfluanid should therefore be removed from Annex I to Directive 91/414/EEC.
- (9) Measures should be taken to ensure that authorisations granted for plant protection products containing tolylfluanid are withdrawn within a fixed period of time as short as possible and are not renewed and that no new authorisations for such products are granted.
- (10) Given the nature of the risks caused by that active substance, any period of grace granted by a Member State for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing tolylfluanid should be as short as possible and should expire at latest 1 year from the entry into force of this Directive.
- (11) This Directive does not prejudice the submission of an application for tolylfluanid in accordance with Article 6(2) of Directive 91/414/EEC in view of a possible inclusion in Annex I to that Directive.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 119, 9.5.2007, p. 49.

(12) 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*

In Annex I to Directive 91/414/EEC, row 122, concerning tolylfluanid, is deleted.

*Article 2*

Member States shall adopt and publish, by 31 August 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 September 2010.

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*

Member States shall ensure that:

- (a) authorisations for plant protection products containing tolylfluanid are withdrawn by 30 November 2010 at the latest;
- (b) no authorisations for plant protection products containing tolylfluanid are granted or renewed from 1 December 2010.

*Article 4*

Any period of grace granted by Member States in accordance with Article 4(6) of Directive 91/414/EEC shall be as short as possible and shall expire on 31 May 2011 at the latest.

*Article 5*

This Directive shall enter into force on 1 June 2010.

*Article 6*

This Directive is addressed to the Member States.

Done at Brussels, 9 March 2010.

*For the Commission*

*The President*

José Manuel BARROSO