

COMMISSION DIRECTIVE 2010/28/EU
of 23 April 2010
amending Council Directive 91/414/EEC to include metalaxyl as active substance
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

therefore necessary to assess metalaxyl once more taking into account the additional information submitted.

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

(4) An additional assessment report has been submitted by the rapporteur Member State Portugal, which has been peer reviewed by the Member States and the Commission and finalised within the Standing Committee on the Food Chain and Animal Health on 12 March 2010 in the format of the Commission review report for metalaxyl.

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,

(5) The review of metalaxyl did not reveal any open questions to be addressed by the European Food Safety Authority which has taken over the role of the Scientific Committee on Plants.

Whereas:

(1) Metalaxyl is one of the substances listed in Annex I to 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 ⁽²⁾.

(6) It has appeared from the various examinations made that plant protection products containing metalaxyl 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 were examined and detailed in the Commission review report. It is therefore appropriate to include metalaxyl in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing metalaxyl can be granted in accordance with the provisions of that Directive.

(2) As a consequence of the judgment of the Court of Justice of 18 July 2007 in Case C-326/05 P *Industrias Químicas del Vallés v Commission* ⁽³⁾, which annulled Commission Decision 2003/308/EC ⁽⁴⁾ concerning the non-inclusion of metalaxyl in Annex I to Council Directive 91/414/EEC, the Commission adopted Regulation (EC) No 1313/2007 of 8 November 2007 amending Regulations (EC) No 2076/2002 as regards the extension of the time period referred to in Article 8(2) of Council Directive 91/414/EEC with respect to metalaxyl and (EC) No 2024/2006 as regards the deletion of the derogation concerning metalaxyl ⁽⁵⁾ and Regulation (EC) No 416/2008 of 8 May 2008 amending Regulation (EEC) No 3600/92 as regards the assessment of the active substance metalaxyl in the framework of Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽⁶⁾.

(7) 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.

(3) Article 266 TFEU requires the institution whose act has been declared void to take the necessary measures to comply with the judgment of the Court of Justice. It is

(8) 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 6 months after inclusion to review existing authorisations of plant protection products containing metalaxyl 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 366, 15.12.1992, p. 10.

⁽³⁾ [2007] ECR I-6557.

⁽⁴⁾ OJ L 113, 7.5.2003, p. 8.

⁽⁵⁾ OJ L 291, 9.11.2007, p. 11.

⁽⁶⁾ OJ L 125, 9.5.2008, p. 25.

- (9) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.
- (10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (11) 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 31 December 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 January 2011.

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

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing metalaxyl as an active substance by 31 December 2010.

By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to metalaxyl 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.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing metalaxyl 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 30 June 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 metalaxyl. 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 metalaxyl as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2014 at the latest; or
- (b) in the case of a product containing metalaxyl 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 July 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 23 April 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, the following row 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
'309	Metalaxyl CAS No 57837-19-1 CIPAC No 365	Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-DL-alaninate	950 g/kg The impurity 2,6-dimethylaniline was considered of toxicological concern and a maximum level of 1 g/kg is established.	1 July 2010	30 June 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 metalaxyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate.'

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