

COMMISSION IMPLEMENTING DIRECTIVE 2011/44/EU

of 13 April 2011

amending Council Directive 91/414/EEC to include azadirachtin as active substance and amending Commission Decision 2008/941/EC

(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 Article 6(1) thereof,

Whereas:

- (1) Commission Regulations (EC) No 1112/2002 ⁽²⁾ and (EC) No 2229/2004 ⁽³⁾ lay down the detailed rules for the implementation of the fourth 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 included azadirachtin.
- (2) In accordance with Article 24e of Regulation (EC) No 2229/2004 the applicant withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/941/EC of 8 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances ⁽⁴⁾ was adopted on the non-inclusion of azadirachtin.
- (3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the application of the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽⁵⁾.
- (4) The application was submitted to Germany, which had been designated rapporteur Member State by Regulation (EC) No 2229/2004. The time period for the accelerated procedure was respected. The specification of the active

substance and the supported uses are the same as were the subject of Decision 2008/941/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

- (5) Germany evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 10 December 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on azadirachtin to the Commission on 28 October 2010 ⁽⁶⁾. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 March 2011 in the format of the Commission review report for azadirachtin.
- (6) It has appeared from the various examinations made that plant protection products containing azadirachtin 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 azadirachtin 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.
- (7) 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 to require that the applicant submit further information to confirm the relationship between azadirachtin A and the rest of the active components in the neem seeds extract with respect to amount, biological activity and persistence, in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material, residue definition and groundwater risk assessment.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 168, 27.6.2002, p. 14.

⁽³⁾ OJ L 379, 24.12.2004, p. 13.

⁽⁴⁾ OJ L 335, 13.12.2008, p. 91.

⁽⁵⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁶⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance azadirachtin. EFSA Journal 2011;9(3):2008[76pp.].doi:10.2903/j.efsa.2011.2088. Available online: www.efsa.europa.eu

- (8) 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.
- (9) 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 azadirachtin 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.
- (10) 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.
- (11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (12) Decision 2008/941/EC provides for the non-inclusion of azadirachtin and the withdrawal of authorisation of plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning azadirachtin in the Annex to that Decision.
- (13) It is therefore appropriate to amend Decision 2008/941/EC accordingly.
- (14) 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

The line concerning azadirachtin in the Annex to Decision 2008/941/EC is deleted.

Article 3

Member States shall adopt and publish by 30 November 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 December 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 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing azadirachtin as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to azadirachtin 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 azadirachtin 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 April 2011 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 azadirachtin. 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.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

Following that determination Member States shall:

Article 5

This Directive shall enter into force on 1 June 2011.

- (a) in the case of a product containing azadirachtin as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or

Article 6

This Directive is addressed to the Member States.

- (b) in the case of a product containing azadirachtin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 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.

Done at Brussels, 13 April 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

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

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
'350	Azadirachtin CAS No: 11141-17-6 as azadirachtin A CIPAC No: 627 as azadirachtin A	Azadirachtin A: dimethyl (2aR,3S,4S,4aR,5S,7aS,8S, 10R,10aS,10bR)-10- acetoxy-3,5-dihydroxy-4- [(1aR,2S,3aS,6aS,7S,7aS)- 6a-hydroxy-7a-methyl- 3a,6a,7,7a-tetrahydro-2,7- methanofuro[2,3-b]- oxireno[e]oxepin-1a(2H)- yl]-4-methyl-8-[[[(2E)-2- methylbut-2-enoyl]- oxy]octahydro-1H- naphtho[1,8a-c:4,5-b'c']- difuran-5,10a(8H)-dicar- boxylate.	Expressed as azadi- rachtin A: ≥ 111 g/kg Sum of the aflatoxins B ₁ , B ₂ , G ₁ and G ₂ must not exceed 300 µg/kg of the azadirachtin A content.	1 June 2011	31 May 2021	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on azadirachtin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels, — the protection of non-target arthropods and aquatic organisms. Risk mitigation measures shall be applied where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: — the relationship between azadirachtin A and the rest of the active components in the neem seeds extract with respect to amount, biological activity and persistence, in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material, residue definition and groundwater risk assessment. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 December 2013.'

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