Commission Directive 2010/55/EU of 20 August 2010 amending Annex I to Council Directive 91/414/EEC to renew the inclusion of azoxystrobin as active substance (Text with EEA relevance) (repealed)

COMMISSION DIRECTIVE 2010/55/EU

of 20 August 2010

amending Annex I to Council Directive 91/414/EEC to renew the inclusion of azoxystrobin as active substance

(Text with EEA relevance) (repealed)

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) The inclusion of azoxystrobin in Annex I to Directive 91/414/EEC expires on 31 December 2011. A notification was submitted in accordance with Article 4 of Commission Regulation (EC) No 737/2007 of 27 June 2007 on laying down the procedure of the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances[(2)] for the renewal of the inclusion of azoxystrobin as active substance in Annex I to Directive 91/414/EEC within the time period provided for in that Article.

(2) That notification was found to be admissible by Commission Decision 2008/656/EC of 28 July 2008 on the admissibility of the notifications concerning the renewal of the inclusion in Annex I to Council Directive 91/414/EEC of the active substances azimsulfuron, azoxystrobin, fluroxypyr, imazalil, kresoxim-methyl, prohexadion-calcium and spiroxamin, and establishing the list of the notifiers concerned[(3)].

(3) Within the time period provided for in Article 6 of Regulation (EC) No 737/2007, the notifier submitted the data required in accordance with Article 6 of Regulation (EC) No 737/2007 together with an explanation as regards the relevance of each new study submitted.

(4) The rapporteur Member State prepared an assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter: 'the Authority') and the Commission on 10 June 2009. In addition to the assessment of the substance, that report includes a list of the studies the rapporteur Member State relied on for its assessment.

(5) The Authority communicated the assessment report to the notifier and to all Member States, and forwarded the comments received to the Commission. The Authority also made the assessment report available to the public.

(6) At the request of the Commission, the assessment report was peer reviewed by the Member States and the Authority, the Authority presented its conclusion on the peer review of the risk assessment of azoxystrobin[(4)] to the Commission on 6 April 2010. The assessment report and the conclusion from 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 9 July 2010 in the format of the Commission review report for azoxystrobin.

(7) It has appeared from the various examinations made that plant protection products containing azoxystrobin may be expected to continue to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to renew the inclusion of azoxystrobin in Annex I to Directive 91/414/EEC, in order to ensure that plant protection products containing this active substance may continue to be authorised where they comply with that Directive.

(8) Moreover, the review has established that for the active substance azoxystrobin notified by the main data submitter the manufacturing impurity toluene is of toxicological concern and therefore its presence in the technical material must not exceed the maximum level of 2 grams for kilogram.

(9) From the new data submitted, it appears that azoxystrobin may cause risks for aquatic organisms. Without prejudice to the conclusion that the inclusion of azoxystrobin is to be renewed, it is therefore appropriate to obtain further information on those specific points. Article 6(1) of Directive 91/414/EEC provides that the inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the notifier submit further information to confirm the results of the risk assessment on the basis of most recent scientific knowledge as regards the risk for groundwater contamination with respect to some minor soil transformation products and the risk for aquatic organisms.

(10) A reasonable period should be allowed to elapse before the inclusion of an active substance in Annex I to Directive 91/414/EEC is renewed in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the renewal.

(11) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of renewing the inclusion of an active substance in Annex I thereof, Member States should be allowed a period of six months after renewal to review authorisations of plant protection products containing azoxystrobin to make sure that the requirements laid down in Directive 91/414/EEC, in particular in its Article 13, and the relevant conditions set out in Annex I to that Directive, continue to be satisfied. As appropriate, Member States should renew, where appropriate with modifications, or refuse to renew authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update 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.

(12) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(13) 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 in accordance with the Annex to this Directive.

Article 2

Member States shall adopt and publish by 31 January 2012 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 February 2012.

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 azoxystrobin as an active substance by 31 January 2012.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to azoxystrobin 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 azoxystrobin 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 July 2011 at the latest, Member States shall, where necessary, re-evaluate the products, to take into account developments occurred in the scientific and technical knowledge and 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 azoxystrobin. On the basis of that evaluation, they shall determine whether the product still 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, where necessary, amend or withdraw the authorisation by 31 July 2015.

3 By way of derogation from paragraphs 1 and 2, for each authorised plant protection product containing azoxystrobin as one of several active substances, all of which were listed in Annex I to Directive 91/414/EEC by 31 July 2011 at the latest, and at least one of which was included in Annex I to Directive 91/414/EEC between 1 January 2009 and 31 July 2011, 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 azoxystrobin. 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, where necessary, amend or withdraw the authorisation by 31 July 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.

Article 4

This Directive shall enter into force on 1 August 2011.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 20 August 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, row No 2 is replaced by the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions
‘2	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	methyl (*E*)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate	*≥ 930 g/kg* Toluene maximum content 2 g/kg *Z*-isomer maximum content 25 g/kg	1 August 2011	31 July 2021	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 azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

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

						Chain and Animal Health on 9 July 2010 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified

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

						against this specification of the technical material, — the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms. The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. The Member States concerned

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

						shall request the submission of further studies to finalise the risk assessment on groundwater and aquatic organisms. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2012.’

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

(**1**) OJ L 230, 19.8.1991, p. 1.

(**2**) OJ L 169, 29.6.2007, p. 10.

(**3**) OJ L 214, 9.8.2008, p. 70.

(**4**) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin on request from the European Commission *EFSA Journal 2010; 8(4):1542*.