Commission Directive 2010/57/EU of 26 August 2010 amending Annex I to Council Directive 91/414/EEC to renew the inclusion of imazalil as active substance (Text with EEA relevance) (repealed)

COMMISSION DIRECTIVE 2010/57/EU

of 26 August 2010

amending Annex I to Council Directive 91/414/EEC to renew the inclusion of imazalil 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(Text with EEA relevance) (repealed)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 imazalil 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 imazalil 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 9 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 the Member States and forwarded the comments received to the Commission. The Authority also makes available the assessment report available for 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 imazalil[(4)] to the Commission on 4 March 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 imazalil.

(7) It has appeared from the various examinations made that plant protection products containing imazalil 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 imazalil 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) Based on the review report which supports a lower level of purity compared to the level of inclusion of imazalil in Annex I to Directive 91/414/EEC and taking into account that no toxicologically or ecotoxicologically significant impurities are present, the purity level should be modified.

(9) It is necessary to include specific provisions requiring Member States, when authorising plant protection products containing imazalil, to pay particular attention to certain points or to ensure that appropriate risk mitigation measures are taken. In particular, the Member States should ensure that: the test materials used in the toxicity dossiers will be compared and verified against the specification of the technical material as commercially manufactured; the acute dietary exposure situation will pose no risk to the consumers, when reviewing maximum residue levels.

(10) From the new data submitted, it appears that imazalil and its degradation products in soil and surface water systems may cause risks for soil micro-organisms and aquatic organisms; negligible groundwater exposure needs to be confirmed; further investigation is needed on the nature of residues in processed commodities. Without prejudice to the conclusion that the inclusion of imazalil 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 as regards the route of degradation of imazalil in soil and surface water systems, environmental data to ensure that groundwater exposure is negligible and a hydrolysis study to investigate the nature of residues in processed commodities.

(11) 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.

(12) 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 imazalil 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.

(13) It is therefore appropriate to amend Directive 91/414/EEC 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 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 imazalil 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 imazalil 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 imazalil 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 imazalil. 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 imazalil 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 imazalil. 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, 26 August 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, row No 1 is replaced by the following:

No	Common name, identification numbers	IUPAC name	Purity[a]	Entry into force	Expiration of inclusion	Specific provisions
‘1	imazalil CAS No 35554-44-0 73790-28-0 (replaced) CIPAC No 335	(RS)-1-(β-allyloxy-2,4-dichlorophenethyl)imidazole or allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether	≥ 950 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 imazalil, 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 acute dietary exposure situation of consumers in view of future revisions of maximum residue levels, — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — ensure that appropriate

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

						waste management practices to handle the waste solution remaining after application, such as the cleaning water of the drenching system and the discharge of the processing waste are put in place. Prevention of any accidental spillage of treatment solution. Member States permitting the release of waste water into the sewage system shall

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

						— ensure that a local risk assessment is carried out, risk to aquatic organisms and soil micro-organisms and long-term risk to granivorous birds and mammals. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further information and in particular confirmatory data on:

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

						— route of degradation of imazalil in soil and surface water systems, — environmental data to support the managing measures that Member States have to put in place to ensure that groundwater exposure is negligible, — a hydrolysis study to investigate the nature of residues in processed commodities. They shall ensure that the notifier provides such information to the

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

						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 imazalil' on request from the European Commission, *EFSA Journal* 2010, 8(3):1526.