

COMMISSION DIRECTIVE 2005/3/EC

of 19 January 2005

amending Council Directive 91/414/EEC to include imazosulfuron, laminarin, methoxyfenozide and s-metolachlor as active substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) In accordance with Article 6(2) of Directive 91/414/EEC Germany received on 27 June 1996 an application from Spiess-Urania Chemicals GmbH for the inclusion of the active substance imazosulfuron in Annex I to Directive 91/414/EEC. Commission Decision 97/865/EC ⁽²⁾ confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (2) Belgium received an application under Article 6(2) of Directive 91/414/EEC on 29 March 2001 from Goëmar SA for the inclusion of the active substance laminarin in Annex I to Directive 91/414/EEC. Commission Decision 2001/861/EC ⁽³⁾ confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) The United Kingdom received an application under Article 6(2) of Directive 91/414/EEC on 21 February 2000 from Rohm and Haas France SA (now Dow AgroSciences) for the inclusion of the active substance methoxyfenozide in Annex I to Directive 91/414/EEC. Commission Decision 2001/385/EC ⁽⁴⁾ confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (4) Belgium received an application under Article 6(2) of Directive 91/414/EEC on 1 August 1997 from Novartis

NV (now Syngenta) for the inclusion of the active substance s-metolachlor in Annex I to Directive 91/414/EEC. Commission Decision 98/512/EC ⁽⁵⁾ confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

- (5) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 17 June 1998 (imazosulfuron), on 2 June 2003 (laminarin), on 2 August 2002 (methoxyfenozide) and 3 May 1999 (s-metolachlor).
- (6) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 8 October 2004 in the format of the Commission review reports for imazosulfuron, laminarin, methoxyfenozide and s-metolachlor.
- (7) For imazosulfuron, the dossier and the information from the review were also submitted to the Scientific Committee on Plants. The report of this Committee was formally adopted on 25 April 2001 ⁽⁶⁾.
- (8) The Committee was asked to comment on the relevance of the metabolite IPSN due to its presence in soil and water. In its opinion the Committee concluded that there is no significant health risk arising from IPSN in the groundwater, and that the risk to soil micro-organisms, aquatic invertebrates, fish and the acute risk to earthworms are sufficiently addressed. The Committee also concluded that on the basis of worst-case exposure estimates further information is required to assess some other risks from IPSN. The Committee finally concluded that the risk to the environment and the toxicological risk to human health from the parent substance and/or metabolites other than IPSN, in some studies formed at levels comparable to IPSN, have not been fully assessed and therefore should be addressed during the further evaluation.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/99/EC (OJ L 309, 6.10.2004, p. 6).

⁽²⁾ OJ L 351, 23.12.1997, p. 67.

⁽³⁾ OJ L 321, 6.12.2001, p. 34.

⁽⁴⁾ OJ L 137, 19.5.2001, p. 30.

⁽⁵⁾ OJ L 228, 15.8.1998, p. 35.

⁽⁶⁾ Opinion of the Scientific Committee on Plants regarding the inclusion of imazosulfuron in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market — SCP/IMAZO/002-Final, published 21 May 2001.

- (9) The recommendations of the Scientific Committee were taken into account during the further review, in this Directive and in the Review Report.
- (10) With respect to IPSN, additional data on the risk based on worst-case exposure estimates and identified by the Scientific Committee have been delivered by the notifier and assessed. The evaluation within the Standing Committee concluded that in the light of the additional data submitted by the notifier, and under the proposed conditions of use, there would be no harmful effect on humans from IPSN.
- (11) With respect to imazosulfuron and other metabolites than IPSN, no other metabolites than IPSN occur in levels that are considered as 'relevant' in the sense of the provisions of Directive 91/414/EEC. Therefore the evaluation within the Standing Committee concluded that the risk can be assessed with the data available.
- (12) Following this assessment, the evaluation within the Standing Committee furthermore concluded that under the proposed conditions of use, in particular the maximum dose rate of 0,05 kg active substance/ha, and when appropriate risk mitigation measures are applied, there would be no harmful effect on humans and no unacceptable risk to the environment from imazosulfuron and its metabolites.
- (13) The review of laminarin, methoxyfenozide and s-metolachlor did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or of the European Food Safety Authority.
- (14) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) 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 imazosulfuron, laminarin, methoxyfenozide and s-metolachlor in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.
- (15) After inclusion of imazosulfuron, laminarin, methoxyfenozide and s-metolachlor in Annex I to Directive 91/414/EEC, Member States should be allowed a reasonable period to implement the provisions of

Directive 91/414/EEC as regards plant protection products containing those substances and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

- (16) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (17) 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

1. Member States shall adopt and publish by 30 September 2005 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 October 2005.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1. Member States shall review the authorisation for each plant protection product containing imazosulfuron, laminarin, methoxyfenozide or s-metolachlor to ensure that the conditions relating to this active substance set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 30 September 2005 at the latest.

2. For each authorised plant protection product containing imazosulfuron, laminarin, methoxyfenozide or s-metolachlor 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 March 2005 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. 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 imazosulfuron, laminarin, methoxyfenozide or s-metolachlor as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2006 at the latest; or
- (b) in the case of a product containing imazosulfuron, laminarin, methoxyfenozide or s-metolachlor as one of several active substances, where necessary, amend or

withdraw the authorisation by 30 September 2006 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 April 2005.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 19 January 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC the following rows are added at the end of the table:

No	Common name, identification numbers	IUPAC Name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
95	Imazosulfuron CAS No: 122548-33-8 CIPAC No: 590	1-(2-chloroimidazo[1,2- <i>a</i>]pyridin-3-ylsulphonyl)-3-(4,6-dimethoxypyrimidin-2-yl)urea	≥ 980 g/kg	1 April 2005	31 March 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic and terrestrial non-target plants. Risk mitigation measures should be applied where appropriate.
96	Laminarin CAS No: 9008-22-4 CIPAC No: 671	(1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)	≥ 860 g/kg on dry matter	1 April 2005	31 March 2015	Only uses as elicitor of the crop's self-defence mechanisms may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on laminarin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account.
97	Methoxyfenozide CAS No: 161050-58-4 CIPAC No: 656	N- <i>tert</i> -Butyl-N'-(3-methoxy- <i>o</i> -toluoyl)-3,5-xylohydrazide	≥ 970 g/kg	1 April 2005	31 March 2015	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on methoxyfenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of terrestrial and aquatic non-target arthropods. Risk mitigation measures should be applied where appropriate.

No	Common name, identification numbers	IUPAC Name	Purity(*)	Entry into force	Expiration of inclusion	Specific provisions
98	S-metolachlor CAS No: 87392-12-9 (S-isomer) 178961-20-1 (R-isomer) CIPAC No: 607	Mixture of: (aRS, 1 S)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methylethyl)acetamide (80-100%) and: (aRS, 1 R)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methylethyl)acetamide (20-0%)	≥ 960 g/kg	1 April 2005	31 March 2015	<p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on s-metolachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account.</p> <p>In this overall assessment Member States</p> <ul style="list-style-type: none"> — should pay particular attention to the potential for groundwater contamination, particularly of the active substance and its metabolites CGA 51202 and CGA 354743, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — should pay particular attention to the protection of aquatic plants. <p>Risk mitigation measures should be applied where appropriate.</p>

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