

## DIRECTIVES

## COMMISSION DIRECTIVE 2008/40/EC

of 28 March 2008

## amending Council Directive 91/414/EEC to include amidosulfuron and nicosulfuron 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 <sup>(1)</sup>, and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000 <sup>(2)</sup> and (EC) No 1490/2002 <sup>(3)</sup> lay down the detailed rules for the implementation of the third 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 includes amidosulfuron and nicosulfuron.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifiers. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10(1) of Regulation (EC) No 1490/2002. For amidosulfuron and nicosulfuron the rapporteur Member States were Austria and the United Kingdom and all relevant information was submitted on 31 May 2005 and 7 December 2005 respectively.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 22 January 2007 for amidosulfuron

and nicosulfuron, in the format of the EFSA Scientific Reports <sup>(4)</sup>. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 22 January 2008 in the format of the Commission review reports for amidosulfuron and nicosulfuron.

(4) It has appeared from the various examinations made that plant protection products containing amidosulfuron and nicosulfuron 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 reports. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

(5) 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.

(6) 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 six months after inclusion to review existing authorisations of plant protection products containing amidosulfuron and nicosulfuron 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 way of 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.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/76/EC (OJ L 337, 21.12.2007, p. 100).

<sup>(2)</sup> OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).

<sup>(3)</sup> OJ L 224, 21.8.2002, p. 23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19).

<sup>(4)</sup> EFSA Scientific Report (2007) 116, 1-86, Conclusion regarding the peer review of the pesticide risk assessment of the active substance amidosulfuron (finalised 14 November 2007). EFSA Scientific Report (2007) 120, 1-91, Conclusion regarding the peer review of the pesticide risk assessment of the active substance nicosulfuron (finalised 29 November 2007).

- (7) 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 <sup>(1)</sup> 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.
- (8) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (9) 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 30 April 2009 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 May 2009.

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 amidosulfuron and nicosulfuron as active substances by 30 April 2009.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to amidosulfuron and nicosulfuron 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 amidosulfuron and nicosulfuron 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 October 2008 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 amidosulfuron and nicosulfuron respectively. 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 amidosulfuron and nicosulfuron as the only active substance, where necessary, amend or withdraw the authorisation by 31 October 2012 at the latest; or
- (b) in the case of a product containing amidosulfuron and nicosulfuron as one of several active substances, where necessary, amend or withdraw the authorisation by 31 October 2012 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 November 2008.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 28 March 2008.

*For the Commission*  
Androulla VASSILIOU  
*Member of the Commission*

<sup>(1)</sup> OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).

## ANNEX

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

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
175	Amidosulfuron CAS No 120923-37-7 CIPAC No 515	3-(4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonylaminosulfonyl)urea or 1-(4,6-dimethoxypyrimidin-2-yl)-3-mesy(methyl) sulfamoylurea	≥ 970 g/kg	1 January 2009	31 December 2018	<p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing amidosulfuron for uses other than meadows and pasture, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on amidosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of groundwater due to a potential for groundwater contamination by some of the degradation products when it is applied in regions with vulnerable soil and/or climatic conditions,</li> <li>— the protection of aquatic plants.</li> </ul> <p>In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate.</p>

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
176	Nicosulfuron CAS No 111991-09-4 CIPAC No 709	2-[(4,6-dimethoxypyrimidin-2-yl(carbamoyl)sulfamoyl]-N,N-dimethylnicotinamide or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridyl)sulfonyl)urea	≥ 930 g/kg	1 January 2009	31 December 2018	<p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the potential exposure of the aquatic environment to metabolite DUDN when nicosulfuron is applied in regions with vulnerable soil conditions,</li> <li>— the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,</li> <li>— the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone,</li> <li>— the protection of groundwater and surface water under vulnerable soil and climatic conditions.</li> </ul>

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