

DIRECTIVES

COMMISSION DIRECTIVE 2010/25/EU

of 18 March 2010

amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spirodiclofen as active substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

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) In accordance with Article 6(2) of Directive 91/414/EEC Italy received on 29 November 2002 an application from Dow AgroScience for the inclusion of the active substance penoxsulam in Annex I to Directive 91/414/EEC. Commission Decision 2004/131/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) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received on 9 January 2004 an application from DuPont Ltd for the inclusion of the active substance proquinazid in Annex I to Directive 91/414/EEC. Commission Decision 2004/686/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) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 23 August 2001 an application from Bayer CropScience for the inclusion of the active substance spirodiclofen in Annex I to Directive 91/414/EEC. Commission Decision 2002/593/EC ⁽⁴⁾ confirmed that the dossier was 'complete' in the sense

(4) 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 a draft assessment report on 10 February 2005 (penoxsulam), 14 March 2006 (proquinazid) and 21 April 2004 (spirodiclofen).

(5) The assessment reports were peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission in the format of the EFSA Scientific Reports on 31 August 2009 for penoxsulam ⁽⁵⁾, on 13 October 2009 ⁽⁶⁾ for proquinazid and on 27 July 2009 ⁽⁷⁾ for spirodiclofen. These reports and the draft assessment reports were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 22 January 2010 in the format of the Commission review reports for penoxsulam, proquinazid and spirodiclofen.

(6) 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 penoxsulam, proquinazid and spirodiclofen in Annex I to that Directive, 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.

⁽⁵⁾ EFSA Scientific Report (2009) 343, 1-90, Conclusion regarding the peer review of the pesticide risk assessment of the active substance penoxsulam (finalised: 31 August 2009).

⁽⁶⁾ EFSA Scientific Report (2009) 7(10):1350, 1-135, Conclusion regarding the peer review of the pesticide risk assessment of the active substance proquinazid (finalised: 13 October 2009).

⁽⁷⁾ EFSA Scientific Report (2009) 339, 1-86, Conclusion regarding the peer review of the pesticide risk assessment of the active substance spirodiclofen (finalised: 27 July 2009).

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 37, 10.2.2004, p. 34.

⁽³⁾ OJ L 313, 12.10.2004, p. 21.

⁽⁴⁾ OJ L 192, 11.7.2002, p. 60.

- (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 the inclusion of a substance in Annex I may be subject to conditions. It is appropriate, as regards penoxsulam, to require that the notifier submits further information on the off-field risk to higher aquatic plants.
- (8) 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 provisional authorisations of plant protection products containing penoxsulam, proquinazid or spirodiclofen 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 transform existing provisional authorisations into full authorisations, amend them or withdraw them 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.
- (9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (10) 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 31 January 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 February 2011.

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 in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing penoxsulam, proquinazid or spirodiclofen as active substance by 31 January 2011. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to penoxsulam, proquinazid and spirodiclofen, are met, with the exception of those identified in part B of the entry concerning the 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(2) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing penoxsulam, proquinazid or spirodiclofen 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 2010 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 penoxsulam, proquinazid or spirodiclofen. 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 penoxsulam, proquinazid or spirodiclofen as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2012 at the latest; or
- (b) in the case of a product containing penoxsulam, proquinazid or spirodiclofen as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 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 August 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 18 March 2010.

For the Commission

The President

José Manuel BARROSO

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 (¹)	Entry into force	Expiration of inclusion	Specific provisions
'306	Penoxsulam CAS No 219714-96-2 CIPAC No 758	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide	> 980 g/kg The impurity Bis-CHYMP 2-chloro-4-[2-(2-chloro-5-methoxy-4-pyrimidinyl)hydrazino]-5-methoxypyrimidine must not exceed 0,1 g/kg in the technical material	1 August 2010	31 July 2020	<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 penoxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 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"> — the protection of aquatic organisms, — the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops, — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information to address the off-field risk to higher aquatic plants. They shall ensure that the notifier provides such information to the Commission by 31 July 2012.</p> <p>The Rapporteur Member State shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.</p>
307	Proquinazid CAS No 189278-12-4 CIPAC No 764	6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one	> 950 g/kg	1 August 2010	31 July 2020	<p>PART A</p> <p>Only uses as fungicide 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 proquinazid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention:</p> <ul style="list-style-type: none"> — to the long-term risk to earthworm-eating birds for uses in grapevine, — to the risk to aquatic organisms,

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
						<p>— the dietary exposure of consumers to proquinazid residues in products of animal origin and in succeeding rotational crops,</p> <p>— to the operator safety.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Rapporteur Member State shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.</p>
308	Spirodiclofen CAS No 148477-71-8 CIPAC No 737	3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	<p>> 965 g/kg</p> <p>The following impurities must not exceed a certain amount in the technical material:</p> <p>3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one (BA)-2740 enol): ≤ 6 g/kg</p> <p>N,N-dimethylacetamide: ≤ 4 g/kg</p>	1 August 2010	31 July 2020	<p>PART A</p> <p>Only uses as acaricide or insecticide 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 spirodiclofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention:</p> <p>— to the long-term risk to aquatic organisms,</p> <p>— to the operator safety,</p> <p>— to the risk to bee brood.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p>

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