

DIRECTIVES

COMMISSION DIRECTIVE 2011/22/EU

of 3 March 2011

amending Council Directive 91/414/EEC to include bispyribac as active substance

(Text with EEA relevance)

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) In accordance with Article 6(2) of Directive 91/414/EEC Italy received on 26 February 2002 an application from Bayer CropScience for the inclusion of the active substance bispyribac (also called bispyribac sodium, according to the form in which the active substance is contained in the representative formulation on which the dossier is based) in Annex I to Directive 91/414/EEC. Commission Decision 2003/305/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) For that active substance, 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 applicant. The designated rapporteur Member State submitted a draft assessment report on 1 August 2003.
- (3) The draft assessment report was peer reviewed by the Member States and the European Food Safety Authority (EFSA) in the format of the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance bispyribac on 12 July 2010 ⁽³⁾. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and

Animal Health and was finalised on 28 January 2011 in the format of the Commission review report for bispyribac.

- (4) It has appeared from the various examinations made that plant protection products containing bispyribac 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 bispyribac in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.
- (5) Without prejudice to that conclusion, it is appropriate to obtain confirmatory 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. Therefore, it is appropriate to require that the applicant submit further information to confirm the risk assessment on the potential for groundwater contamination by metabolites M03 ⁽⁴⁾, M04 ⁽⁵⁾ and M10 ⁽⁶⁾.
- (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 6 months after inclusion to review existing provisional authorisations of plant protection products containing bispyribac 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.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 112, 6.5.2003, p. 10.

⁽³⁾ EFSA Journal (2010) 8(1):1692, Conclusion on the peer review of the pesticide risk assessment of the active substance bispyribac (unless otherwise stated all data evaluated refer to the variant bispyribac-sodium). doi:10.2903/j.efsa.2010.1692. Available online: www.efsa.europa.eu

⁽⁴⁾ 2-hydroxy-4,6-dimethoxypyrimidine

⁽⁵⁾ 2,4-dihydroxy-6-methoxypyrimidine

⁽⁶⁾ sodium 2-hydroxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl)oxybenzoate

- (7) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (8) 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 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 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.

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 bispyribac as 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 bispyribac 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 bispyribac 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 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 bispyribac. 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 bispyribac as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2013 at the latest; or
- (b) in the case of a product containing bispyribac as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 2013 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, 3 March 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, the following entry is added at the end of the table:

No	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'329	Bispyribac CAS N° 125401-75-4 CIPAC N° 748	2,6-bis(4,6-dimethoxy-pyrimidin-2-yloxy)benzoic acid	≥ 930 g/kg (referred to as bispyribac-sodium)	1 August 2011	31 July 2021	<p>PART A</p> <p>Only uses as herbicide in rice 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 bispyribac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.</p> <p>Conditions of authorisation shall include risk mitigation measures where appropriate.</p> <p>The Member States concerned shall request the submission of further information as regards the possible groundwater contamination by metabolites M03 (2-hydroxy-4,6-dimethoxypyrimidine), M04 (2,4-dihydroxy-6-methoxypyrimidine) and M10 (sodium 2-hydroxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl)oxybenzoate).</p> <p>They shall ensure that the applicant provides such information to the Commission by 31 July 2013.'</p>

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