

DIRECTIVES

COMMISSION DIRECTIVE 2007/6/EC

of 14 February 2007

amending Council Directive 91/414/EEC to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam 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 United Kingdom received on 4 June 2002 an application from BASF AG, Belgium for the inclusion of the active substance metrafenone in Annex I to Directive 91/414/EEC. Commission Decision 2003/105/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 Germany received on 19 April 2000 an application from AgraQuest for the inclusion of the active substance *Bacillus subtilis* strain QST 713 (hereafter *Bacillus subtilis*) in Annex I to Directive 91/414/EEC. Commission Decision 2001/6/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 19 July 1999 an application from Dow AgroSciences for the inclusion of the active substance spinosad in Annex I to Directive 91/414/EEC. Commission Decision 2000/210/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) In accordance with Article 6(2) of Directive 91/414/EEC Spain received on 17 March 1999 an application from Novartis Crop Protection AG (now Syngenta) for the inclusion of the active substance thiamethoxam in Annex I to Directive 91/414/EEC. Commission Decision 2000/181/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 European Food Safety Authority (EFSA) on 31 October 2003 (metrafenone) and to the Commission on 15 May 2001 (*Bacillus subtilis*), 5 March 2001 (spinosad) and 21 January 2002 (thiamethoxam) respectively.
- (6) For metrafone the assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on 18 January 2005 in the format of the EFSA Scientific Report for metrafenone ⁽⁶⁾. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. For *Bacillus subtilis*, spinosad and thiamethoxam 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 14 July 2006 in the format of the Commission review reports for metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/136/EC (OJ L 349, 12.12.2006, p. 42).

⁽²⁾ OJ L 43, 18.2.2003, p. 45.

⁽³⁾ OJ L 2, 5.1.2001, p. 25.

⁽⁴⁾ OJ L 64, 11.3.2000, p. 24.

⁽⁵⁾ OJ L 57, 2.3.2000, p. 35.

⁽⁶⁾ EFSA Scientific Report (2006)58, 1-72, Conclusion regarding the peer review of the pesticide risk assessment of the active substance metrafenone (finalised: 13 January 2006).

- (7) 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 metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam 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.
- (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 metrafenone, *Bacillus subtilis*, spinosad or thiamethoxam 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 July 2007 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 August 2007.

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 metrafenone, *Bacillus subtilis*, spinosad or thiamethoxam as active substance by 31 July 2007. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to metrafenone, *Bacillus subtilis*, spinosad or thiamethoxam, respectively, 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).

2. By way of derogation from paragraph 1, for each authorised plant protection product containing metrafenone or *Bacillus subtilis* or spinosad or thiamethoxam 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 January 2007 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 metrafenone, *Bacillus subtilis*, spinosad or thiamethoxam. 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 metrafenone or *Bacillus subtilis* or spinosad or thiamethoxam as the only active substance, where necessary, amend or withdraw the authorisation by 31 July 2008 at the latest; or

(b) in the case of a product containing metrafenone or *Bacillus subtilis* or spinosad or thiamethoxam as one of several active substances, where necessary, amend or withdraw the authorisation by 31 July 2008 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 February 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 14 February 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following rows 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 (1)	Entry into force	Expiration of inclusion	Specific provisions
139	Metrafenone CAS No: 220899-03-6 CIPAC No: 752	3'-bromo-2,3,4,6'-tetramethoxy-2', 6-dimethylbenzophenone	≥ 940 g/kg	1 February 2007	31 January 2017	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 metrafenone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
140	<i>Bacillus subtilis</i> (Cohn 1872) Strain QST 713, identical with strain AQ 713 Culture collection No: NRRL B -21661 CIPAC No: not allocated	Not applicable		1 February 2007	31 January 2017	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 <i>Bacillus subtilis</i> , and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
141	<p>Spinosad</p> <p>CAS No: 131929-60-7 (Spinosyn A)</p> <p>131929-63-0 (Spinosyn D)</p> <p>CIPAC No: 636</p>	<p>Spinosyn A: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-D-erythro-pyrano-syloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexa-decahydro-14-methyl-1H-8-oxacy-clododeca[b]jas-indacene-7,15-dione</p> <p>Spinosyn D: (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-D-erythro-pyrano-syloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexa-decahydro-4,14-dimethyl-1H-8-oxacyclododeca[b]jas-indacene-7,15-dione</p> <p>Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D</p>	≥ 850 g/kg	1 February 2007	31 January 2017	<p>PART A</p> <p>Only uses as 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 spinosad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> <p>In this overall assessment Member States</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of aquatic organisms; — must pay particular attention to the risk to earthworms when the substance is used in glasshouses. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
142	Thiamethoxam CAS No: 153719-23-4 CIPAC No: 637	(E,Z)-3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine	≥ 980 g/kg	1 February 2007	31 January 2017	<p>PART A</p> <p>Only uses as 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 thiamethoxam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the potential for groundwater contamination, particularly of the active substance and its metabolites NOA 459602, SYN 501406 and CGA 322704, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — must pay particular attention to the protection of aquatic organisms, — must pay particular attention to the long-term risk to small herbivorous animals if the substance is used for seed treatment. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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