

DIRECTIVES

COMMISSION DIRECTIVE 2008/113/EC

of 8 December 2008

amending Council Directive 91/414/EEC to include several micro-organisms 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) Commission Regulations (EC) No 1112/2002 ⁽²⁾ and (EC) No 2229/2004 ⁽³⁾ lay down the detailed rules for the implementation of the fourth 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 the active substances listed in the Annex to this Directive.
- (2) By Commission Regulation (EC) No 1095/2007 ⁽⁴⁾ a new Article 24b was inserted into Regulation (EC) No 2229/2004 to allow active substances for which there are clear indications that it may be expected that they do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, to be included in Annex I to Directive 91/414/EEC without detailed scientific advice from the European Food Safety Authority (EFSA) having been sought.
- (3) For the active substances listed in the Annex to this Directive the Commission examined in accordance with Article 24a of Regulation (EC) No 2229/2004 the effects on human, animal health, groundwater and the environment for a range of uses proposed by the notifiers, with the conclusion that those active substances satisfy the requirements of Article 24b of Regulation (EC) No 2229/2004.
- (4) In accordance with Article 25(1) of Regulation (EC) No 2229/2004 the Commission has submitted draft review reports for the active substances listed in the Annex to this Directive to the Standing Committee on the Food Chain and Animal Health, for examination. Those 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 11 July 2008 in the format of the Commission review reports. In accordance with Article 25a of Regulation (EC) No 2229/2004 the Commission is to request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest.
- (5) It has appeared from the various examinations made that plant protection products containing the active substances listed in the Annex to this Directive 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 have been examined and detailed in the Commission review report. It is therefore appropriate to include in Annex I to that Directive the active substances listed in the Annex to this Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.
- (6) 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.
- (7) 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 the active substances listed in the Annex 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

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 168, 27.6.2002, p. 14.

⁽³⁾ OJ L 379, 24.12.2004, p. 13.

⁽⁴⁾ OJ L 246, 21.9.2007, p. 19.

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.

- (8) 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 ⁽¹⁾ 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 that have been adopted until now amending Annex I.
- (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

Member States shall adopt and publish by 31 October 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 November 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 the active substances listed in the Annex as active substances by 31 October 2009.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to the active substances listed in the Annex are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holders of the authorisations have, or have access to, dossiers 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 one of the active substances listed in the Annex 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 30 April 2009 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 the active substances listed in the Annex. 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 one of the active substances listed in the Annex as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2014 at the latest; or
- (b) in the case of a product containing one of the active substances listed in the Annex as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2014 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.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

Article 4

This Directive shall enter into force on 1 May 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 8 December 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

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 (1)	Entry into force	Expiration of inclusion	Specific provisions
199	<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> STRAIN: ABTS-1857 Culture collection: No SD-1372, STRAIN: GC-91 Culture collection: No NCTC 11821	Not applicable	No relevant impurities	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> ABTS-1857 (SANCO/1539/2008) and GC-91 (SANCO/1538/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
200	<i>Bacillus thuringiensis</i> subsp. <i>israeliensis</i> (serotype H-14) STRAIN: AM65-52 Culture collection: No ATCC-1276	Not applicable	No relevant impurities	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>israeliensis</i> (serotype H-14) AM65-52 (SANCO/1540/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
201	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> STRAIN: ABTS 351 Culture collection: No ATCC SD-1275 STRAIN: PB 54 Culture collection: No CECT 7209 STRAIN: SA 11 Culture collection: No NRRL B-30790 STRAIN: SA 12 Culture collection: No NRRL B-30791 STRAIN: EG 2348 Culture collection: No NRRL B-18208	Not applicable	No relevant impurities	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS 351 (SANCO/1541/2008), PB 54 (SANCO/1542/2008), SA 11, SA 12 and EG 2348 (SANCO/1543/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
202	<i>Bacillus thuringiensis</i> subsp. <i>Tenebrionis</i> STRAIN: NB 176 (TM 14 1) Culture collection: No SD-5428	Not applicable	No relevant impurities	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> NB 176 (SANCO/1545/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
203	<i>Beauveria bassiana</i> STRAIN: ATCC 74040 Culture collection: No ATCC 74040 STRAIN: GHA Culture collection: No ATCC 74250	Not applicable	Max level of beauvericin: 5 mg/kg	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Beauveria bassiana</i> ATCC 74040 (SANCO/1546/2008) and GHA (SANCO/1547/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
204	<i>Cydia pomonella Granulovirus</i> (CpGV)	Not applicable	Contaminating micro-organisms (<i>Bacillus cereus</i>) < 1 × 10 ⁶ CFU/g	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Cydia pomonella Granulovirus</i> (CpGV) (SANCO/1548/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
205	<i>Lecanicillium muscarium</i> (formerly <i>Verticillium lecanii</i>) STRAIN: Ve 6 Culture collection: No CABI (=IMI) 268317, CBS 102071, ARSEF 5128	Not applicable	No relevant impurities	1 May 2009	30 April 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Lecanicillium muscarium</i> (formerly <i>Verticillium lecanii</i>) Ve 6 (SANCO/1861/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
206	<i>Metarhizium anisopliae</i> var. <i>anisopliae</i> (formerly <i>Metarhizium anisopliae</i>) STRAIN: BIPESCO 5/f52 Culture collection: No Ma. 43; No 275-86 (acronyms V275 or KVL 275); No KVL 99-112 (Ma 275 or V 275); No DSM 3884; No ATCC 90448; No ARSEF 1095	Not applicable	No relevant impurities	1 May 2009	30 April 2019	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <i>Metarhizium anisopliae</i> var. <i>anisopliae</i> (formerly <i>Metarhizium anisopliae</i>) BIPESCO 5 and F52 (SANCO/1862/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
207	<p><i>Phlebiopsis gigantea</i></p> <p>STRAIN: VRA 1835</p> <p>Culture collection: No ATCC 90304</p> <p>STRAIN: VRA 1984</p> <p>Culture collection: No DSM16201</p> <p>STRAIN: VRA 1985</p> <p>Culture collection: No DSM 16202</p> <p>STRAIN: VRA 1986</p> <p>Culture collection: No DSM 16203</p> <p>STRAIN: FOC PG B20/5</p> <p>Culture collection: No IMI 390096</p> <p>STRAIN: FOC PG SP log 6</p> <p>Culture collection: No IMI 390097</p> <p>STRAIN: FOC PG SP log 5</p> <p>Culture collection: No IMI390098</p> <p>STRAIN: FOC PG BU 3</p> <p>Culture collection: No IMI 390099</p> <p>STRAIN: FOC PG BU 4</p> <p>Culture collection: No IMI 390100</p> <p>STRAIN: FOC PG 410.3</p> <p>Culture collection: No IMI 390101</p> <p>STRAIN: FOC PG97/1062/116/1.1</p> <p>Culture collection: No IMI 390102</p> <p>STRAIN: FOC PG B22/SP1287/3.1</p> <p>Culture collection: No IMI 390103</p> <p>STRAIN: FOC PG SH 1</p> <p>Culture collection: No IMI 390104</p> <p>STRAIN: FOC PG B22/SP1190/3.2</p> <p>Culture collection: No IMI 390105</p>	Not applicable	No relevant impurities	1 May 2009	30 April 2019	<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 <i>Phlebiopsis gigantea</i> (SANCO/1863/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p>

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
208	<i>Pythium oligandrum</i> STRAINS: M1 Culture collection No ATCC 38472	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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>Pythium oligandrum</i> M1 (SANCO/1864/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
209	<i>Streptomyces</i> K61 (formerly <i>S. griseoviridis</i>) STRAIN: K61 Culture collection: No DSM 7206	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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>Streptomyces</i> (formerly <i>Streptomyces griseoviridis</i>) K61 (SANCO/1865/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
210	<i>Trichoderma atroviride</i> (formerly <i>T. harzianum</i>) STRAIN: IMI 206040 Culture collection No IMI 206040, ATCC 20476; STRAIN: T11 Culture collection: No Spanish type culture collection CECT 20498, identical with IMI 352941	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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 reports on <i>Trichoderma atroviride</i> (formerly <i>T. harzianum</i>) IMI 206040 (SANCO/1866/2008) and T-11 (SANCO/1841/2008) respectively, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
211	<i>Trichoderma polysporum</i> STRAIN: <i>Trichoderma polysporum</i> IMI 206039 Culture collection No IMI 206039, ATCC 20475	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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>Trichoderma polysporum</i> IMI 206039 (SANCO/1867/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
212	<i>Trichoderma harzianum</i> Rifai STRAIN: <i>Trichoderma harzianum</i> T-22; Culture collection No ATCC 20847 STRAIN: <i>Trichoderma harzianum</i> ITEM 908; Culture collection No CBS 118749	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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 reports on <i>Trichoderma harzianum</i> T-22 (SANCO/1839/2008) and ITEM 908 (SANCO/1840/2008) respectively and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
213	<i>Trichoderma asperellum</i> (formerly <i>T. harzianum</i>) STRAIN: ICC012 Culture collection No CABI CC IMI 392716 STRAIN: <i>Trichoderma asperellum</i> (formerly <i>T. viride</i> T25) T11 Culture collection No CECT 20178 STRAIN: <i>Trichoderma asperellum</i> (formerly <i>T. viride</i> TV1) TV1 Culture collection No MUCL 43093	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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 reports on <i>Trichoderma asperellum</i> (formerly <i>T. harzianum</i>) ICC012 (SANCO/1842/2008) and <i>Trichoderma asperellum</i> (formerly <i>T. viride</i> T25 and TV1) T11 and TV1 (SANCO/1868/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
214	<i>Trichoderma gamsii</i> (formerly <i>T. viride</i>) STRAINS: ICC080 Culture collection No IMI CC number 392151 CABI	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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>Trichoderma viride</i> (SANCO/1868/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
215	<i>Verticillium albo-atrum</i> (formerly <i>Verticillium dahliae</i>) STRAIN: <i>Verticillium albo-atrum</i> isolate WCS850 Culture collection No CBS 276.92	Not applicable	No relevant impurities	1 May 2009	30 April 2019	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>Verticillium albo-atrum</i> (formerly <i>Verticillium dahliae</i>) WCS850 (SANCO/1870/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

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