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Legislation

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Contents

[1] Text with EEA relevance

(Continued overleaf)

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

EN

[1] Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 314/2008

of 4 April 2008

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [1], and in particular Article 138(1) thereof,

Whereas:

(1) Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto.

(2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 5 April 2008.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 April 2008.

For the Commission

Jean-Luc DEMARTY

Director-General for Agriculture and Rural Development

[1] OJ L 350, 31.12.2007, p. 1.

ANNEX

to Commission Regulation of 4 April 2008 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	JO	63,1
	MA	41,5
	TN	125,1
	TR	92,9
	ZZ	80,7
0707 00 05	EG	178,8
	MA	131,7
	TR	127,6
	ZZ	146,0
0709 90 70	MA	56,1
	TR	109,4
	ZZ	82,8
0805 10 20	EG	47,9
	IL	55,6
	MA	55,4
	TN	53,8
	TR	61,4
	ZZ	54,8
0805 50 10	AR	53,2
	IL	117,7
	TR	133,6
	ZA	147,5
	ZZ	113,0
0808 10 80	AR	90,2
	BR	85,6
	CA	97,5
	CL	90,1
	CN	85,4
	MK	54,3
	US	112,4
	UY	58,0
	ZA	73,0
	ZZ	82,9
0808 20 50	AR	71,8
	CL	89,7
	CN	52,7
	ZA	97,3
	ZZ	77,9

(1) Country nomenclature as fixed by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 315/2008

of 4 April 2008

amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the lists of rapid tests

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ([1]), and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out a list of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals.

(3) On 30 August 2007, a laboratory informed the Commission that it will cease marketing the approved rapid test for the monitoring of the bovine spongiform encephalopathy (BSE). It is therefore appropriate to delete that test (Institut Pourquier Speed'it BSE) from the list of rapid tests for the monitoring of BSE in bovine animals in Chapter C of Annex X to Regulation (EC) No 999/2001.

(4) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In Chapter C of Annex X to Regulation (EC) No 999/2001, point 4 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 April 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

([1]) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 21/2008 (OJ L 9, 12.1.2008, p. 3).

ANNEX

In Annex X, Chapter C, to Regulation (EC) No 999/2001, point 4 is replaced by the following:

'4. ***Rapid tests***

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

— immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrPRes (Prionics-Check Western test),

— chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test & Enfer TSE Kit version 2.0, automated sample preparation),

— microplate-based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),

— sandwich immunoassay for PrPRes carried out following denaturation and concentration steps (Bio-Rad Te-SeE test),

— microplate-based immunoassay (ELISA) which detects Proteinase K-resistant PrPRes with monoclonal antibodies (Prionics-Check LIA test),

— conformation-dependent immunoassay, BSE antigen test kit (Beckman Coulter InPro CDI kit),

— chemiluminescent ELISA for qualitative determination of PrP^{Sc} (CediTect BSE test),

— immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA),

— lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Prionics Check PrioSTRIP),

— two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP^{Sc} (Roboscreen Beta Prion BSE EIA Test Kit),

— sandwich ELISA for the detection of Proteinase K-resistant PrP^{Sc} (Roche Applied Science PrionScreen),

— antigen-capture ELISA using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Fujirebio FRELISA BSE post-mortem rapid BSE Test).

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), the following methods shall be used as rapid tests for the monitoring of TSE in ovine and caprine animals:

— conformation-dependent immunoassay, BSE antigen test kit (Beckman Coulter InPro CDI kit),

— sandwich immunoassay for PrPRes carried out following denaturation and concentration steps (Bio-Rad Te-SeE test),

— sandwich immunoassay for PrPRes carried out following denaturation and concentration steps (Bio-Rad Te-SeE Sheep/Goat test),

— chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer TSE Kit version 2.0),

— microplate-based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),

— immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

— microplate-based chemiluminiscent immunoassay for the detection of PrP^{Sc} in ovine tissues (POURQUIER'S-LIA Scrapie),

— immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrPRes (Prionics-Check Western Small Ruminant test),

— microplate-based chemiluminescent immunoassay for the detection of Proteinase K-resistant PrP^{Sc} (Prionics Check LIA Small Ruminants).

In all tests, sample tissue on which the test must be applied must comply with the manufacturer's instructions for use.

Producers of rapid tests must have a quality assurance system in place that has been approved by the Community Reference Laboratory (CRL) and ensures that the test performance does not change. Producers must provide the CRL with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the CRL and provided that the CRL finds that the change does not alter the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.'

COMMISSION REGULATION (EC) No 316/2008

of 4 April 2008

amending the representative prices and additional duties for the import of certain products in the sugar sector fixed by Regulation (EC) No 1109/2007 for the 2007/08 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 318/2006 of 20 February 2006 on the common organisation of the markets in the sugar sector [1],

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector [2], and in particular of the Article 36,

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2007/08 marketing year are fixed by Commission Regulation (EC) No 1109/2007 [3]. These prices and duties have been last amended by Commission Regulation (EC) No 211/2008 [4].

(2) The data currently available to the Commission indicate that the said amounts should be changed in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties on imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EC) No 1109/2007 for the 2007/08 marketing year are hereby amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 5 April 2008.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 April 2008.

For the Commission

Jean-Luc DEMARTY

Director-General for Agriculture and Rural Development

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[1] OJ L 58, 28.2.2006, p. 1. Regulation as last amended by Regulation (EC) No 1260/2007 (OJ L 283, 27.10.2007, p. 1). Regulation (EC) No 318/2006 will be replaced by Regulation (EC) No 1234/2007 (OJ L 299, 16.11.2007, p. 1) as from 1 October 2008.

[2] OJ L 178, 1.7.2006, p. 24. Regulation as last amended by Regulation (EC) No 1568/2007 (OJ L 340, 22.12.2007, p. 62).

[3] OJ L 253, 28.9.2007, p. 5.

[4] OJ L 65, 8.3.2008, p. 3.

ANNEX

Amended representative prices and additional duties applicable to imports of white sugar, raw sugar and products covered by CN code 1702 90 95 applicable from 5 April 2008

(EUR)

CN code	Representative price per 100 kg of the product concerned	Additional duty per 100 kg of the product concerned
1701 11 10 (1)	21,18	5,71
1701 11 90 (1)	21,18	11,12
1701 12 10 (1)	21,18	5,52
1701 12 90 (1)	21,18	10,60
1701 91 00 (2)	21,90	15,08
1701 99 10 (2)	21,90	9,76
1701 99 90 (2)	21,90	9,76
1702 90 95 (3)	0,22	0,42

(1) Fixed for the standard quality defined in Annex I.III to Council Regulation (EC) No 318/2006 (OJ L 58, 28.2.2006, p. 1).
(2) Fixed for the standard quality defined in Annex I.II to Regulation (EC) No 318/2006.
(3) Fixed per 1 % sucrose content.

DIRECTIVES

COMMISSION DIRECTIVE 2008/43/EC

of 4 April 2008

setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses [1], and in particular the second sentence of the second paragraph of Article 14 thereof,

Whereas:

(1) Directive 93/15/EEC lays down rules for ensuring the safe and secure circulation of explosives on the community market.

(2) As provided for in that Directive, it is necessary to ensure that undertakings in the explosives sector possess a system for keeping track of explosives in order to be able to identify those holding the explosives at any time.

(3) Unique identification of explosives is essential if accurate and complete records of explosives are to be kept at all stages of the supply chain. This should allow the identification and the traceability of an explosive from its production site and its first placing on the market until its final user and its use with a view to preventing misuse and theft and to assisting law enforcement authorities in the tracing of the origin of lost or stolen explosives.

(4) The measures provided for in this Directive are in accordance with the opinion of the Management Committee established pursuant to Article 13(1) of Directive 93/15/EEC,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Subject matter

This Directive sets up a harmonised system for the unique identification and traceability of explosives for civil uses.

Article 2

Scope

This Directive shall not apply to the following:

(a) explosives transported and delivered unpackaged or in pump trucks for their direct unloading into the blast-hole;

(b) explosives manufactured at the blasting sites, and that are loaded immediately after being produced (*in situ* production);

(c) ammunitions.

CHAPTER 2

PRODUCT IDENTIFICATION

Article 3

Unique identification

1. Member States shall ensure that undertakings in the explosives sector which manufacture or import explosives or assemble detonators shall mark explosives and each smallest packaging unit with a unique identification.

Where an explosive is subject to further manufacturing processes, manufacturers shall not be required to mark the explosive with a new unique identification unless the original unique identification is no longer marked in compliance with Article 4.

[1] OJ L 121, 15.5.1993, p. 20. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

2. Paragraph 1 shall not apply where the explosive is manufactured for export and is marked with an identification in accordance with the requirements of the importing country, which allows traceability of the explosive.

3. The unique identification shall comprise the components described in the Annex.

4. Each manufacturing site shall be attributed a three-digit code by the national authority of the Member States where it is established.

5. Where the manufacturing site is located outside the Community, the manufacturer being established in the Community shall contact a national authority of the Member State of import in order for the manufacturing site to be attributed a code.

Where the manufacturing site is located outside the Community and the manufacturer is not established in the Community, the importer of the explosives concerned shall contact a national authority of the Member State of import in order for the manufacturing site to be attributed a code.

6. Member States shall ensure that distributors which repackage explosives make sure that the unique identification is affixed to the explosive and the smallest packaging unit.

Article 4

Marking and affixation

The unique identification shall be marked on or firmly affixed to the article concerned in a durable way and so as to ensure that it is clearly legible.

Article 5

Cartridged explosives and explosives in sacks

For cartridged explosives and explosives in sacks, the unique identification shall consist of an adhesive label or direct printing on each cartridge or sack. An associated label shall be placed on each case of cartridges.

In addition, undertakings may use a passive inert electronic tag attached to each cartridge or sack and similarly, an associated electronic tag for each case of cartridges.

Article 6

Two-component explosives

For packaged two-component explosives, the unique identification shall consist of an adhesive label or direct printing on each smallest packaging unit containing the two components.

Article 7

Plain detonators and fuses

For plain detonators or fuses, the unique identification shall consist of an adhesive label or direct printing or stamping on the detonator shell. An associated label shall be placed on each case of detonators or fuses.

In addition, undertakings may use a passive inert electronic tag attached to each detonator or fuse, and an associated tag for each case of detonators or fuses.

Article 8

Electric, non-electric and electronic detonators

For electric, non-electric and electronic detonators, the unique identification shall consist either of an adhesive label on the wires or tube, or an adhesive label or direct printing or stamping on the detonator shell. An associated label shall be placed on each case of detonators.

In addition, undertakings may use a passive inert electronic tag attached to each detonator, and an associated tag for each case of detonators.

Article 9

Primers and boosters

For primers and boosters, the unique identification shall consist of an adhesive label or direct printing on the primer or booster. An associated label shall be placed on each case of primers or boosters.

In addition, undertakings may use a passive inert electronic tag attached to each primer or booster, and an associated tag for each case of primers or boosters.

Article 10

Detonating cords and safety fuses

For detonating cords and safety fuses, the unique identification shall consist of an adhesive label or direct printing on the bobbin. The unique identification will be marked every 5 meters on either the external envelope of the cord or fuse or the plastic extruded inner layer immediately under the exterior fibre of the cord or fuse. An associated label shall be placed on each case of detonating cord or fuse.

In addition, undertakings may use a passive inert electronic tag inserted within the cord, and an associated tag for each case of cord or fuse.

Article 11

Cans and drums containing explosives

For cans and drums containing explosives, the unique identification shall consist of an adhesive label or direct printing on the can or drum containing the explosives.

In addition, undertakings may use a passive inert electronic tag attached to each can and drum.

Article 12

Copies of the original label

Undertakings may attach adhesive detachable copies of the original label to the explosives for use by their clients. Those copies shall be visibly marked as copies of the original to prevent misuse.

CHAPTER 3

DATA COLLECTION AND RECORD-KEEPING

Article 13

Data collection

1. Member States shall ensure that undertakings in the explosives sector put in place a system for collecting data in relation to explosives including their unique identification throughout the supply chain and life cycle.

2. The data collection system shall allow the undertakings to keep track of the explosives in such a way that those holding the explosives can be identified at any time.

3. Member States shall ensure that the data collected including the unique identifications is kept and maintained for a period of 10 years after the delivery or whenever known after the end of the life cycle of the explosive even if undertakings have ceased trading.

Article 14

Obligations of undertakings

Member States shall ensure that the undertakings in the explosives sector fulfil the following:

(a) keeping a record of all identifications of explosives, together with all pertinent information including the type of explosive, the company or person to the custody of whom it was given;

(b) recording the location of each explosive while the explosive is in their possession or custody until it is either transferred to another undertaking or used;

(c) at regular interval testing their data collection system in order to ensure its effectiveness and the quality of the data recorded;

(d) keeping and maintaining the data collected including the unique identifications for the period specified in paragraph 3 of Article 13;

(e) protecting the data collected against accidental or malicious damage or destruction;

(f) providing the competent authorities, upon their request, with the information concerning the origin and location of each explosive during its life cycle and throughout the supply chain;

(g) providing the responsible Member State authorities with the name and contact details of a person able to provide the information described in point (f) outside normal business hours.

For the purpose of point (d), the undertaking shall, in the case of explosives manufactured or imported before the date specified in the second subparagraph of Article 15(1), maintain records in accordance with existing national provisions.

CHAPTER 4

FINAL PROVISIONS

Article 15

Transposition

1. Member States shall adopt and publish, by 5 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 5 April 2012.

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.

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 16

Entry into force

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Article 17

This Directive is addressed to the Member States.

Done at Brussels, 4 April 2008.

For the Commission

Günter VERHEUGEN

Vice-President

ANNEX

The unique identification shall comprise:

1. a human readable part of the identification containing the following:

   (a) the name of the manufacturer;

   (b) an alphanumerical code containing:

      (i) two letters identifying the Member State (place of production or import onto the Community market, e.g. AT = Austria);

      (ii) three digits identifying the name of the manufacturing site (attributed by the national authorities);

      (iii) the unique product code and logistical information designed by the manufacturer;

2. an electronic readable identification in barcode and/or matrix code format that relates directly to the alphanumerical identification code.

   Example:

3. For articles too small to affix the unique product code and logistical information designed by the manufacturer, the information under 1(b)(i), 1(b)(ii) and 2 shall be considered sufficient.

COMMISSION DIRECTIVE 2008/44/EC

of 4 April 2008

amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole 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 Belgium received on 19 April 2002 an application from Kumiai Chemicals Industry Co. Ltd for the inclusion of the active substance benthiavalicarb in Annex I to Directive 91/414/EEC. Commission Decision 2003/35/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 26 April 2001 an application from BASF AG for the inclusion of the active substance boscalid in Annex I to Directive 91/414/EEC. Commission Decision 2002/268/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 26 March 1997 an application from Luxan B.V. for the inclusion of the active substance carvone in Annex I to Directive 91/414/EEC. Commission Decision 1999/610/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 United Kingdom received on 25 March 2002 an application from Bayer AG for the inclusion of the active substance fluoxastrobin in Annex I to Directive 91/414/EEC. Decision 2003/35/EC 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) In accordance with Article 6(2) of Directive 91/414/EEC Belgium received on 15 September 2002 an application from Prophyta for the inclusion of the active substance *Paecilomyces lilacinus* strain 251 (hereafter *Paecilomyces lilacinus*) in Annex I to Directive 91/414/EEC. Commission Decision 2003/305/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.

(6) In accordance with Article 6(2) of Directive 91/414/EEC United Kingdom received on 25 March 2002 an application from Bayer CropScience for the inclusion of the active substance prothioconazole in Annex I to Directive 91/414/EEC. Decision 2003/35/EC 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.

(7) 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 report on 13 April 2004 (benthiavalicarb), 22 November 2002 (boscalid), 16 October 2000 (carvone), 2 September 2003 (fluoxastrobin), 3 November 2004 (*Paecilomyces lilacinus*) and 18 October 2004 (prothioconazole).

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2008/41/EC (OJ L 89, 1.4.2008, p. 12).
[2] OJ L 11, 16.1.2003, p. 52.
[3] OJ L 92, 9.4.2002, p. 34.
[4] OJ L 242, 14.9.1999, p. 29.
[5] OJ L 112, 6.5.2003, p. 10.

(8) 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 15 June 2007 for fluoxastrobin [1] and *Paecilomyces lilacinus* [2] and on 12 July for benthiavalicarb [3] and prothioconazole [4]. These reports and the draft assessment reports for boscalid and carvone were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and the review was finalised on 22 January 2008 in the format of the Commission review reports for benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole.

(9) 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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole 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.

(10) Without prejudice to the above conclusion, for fluoxastrobin and prothioconazole it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that fluoxastrobin should be subjected to further testing for confirmation of the risk assessment for surface water and for non-rat metabolites and that prothioconazole should be subjected to further testing for confirmation of the risk assessment as regards the triazole metabolite derivatives and the risk to granivorous birds and mammals and that such studies should be presented by the notifiers.

(11) 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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole 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.

(12) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(13) 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 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 February 2009.

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.

[1] *EFSA Scientific Report* (2007) 102, 1-84, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluoxastrobin (finalised: 13 June 2007).

[2] *EFSA Scientific Report* (2007) 103, 1-35, Conclusion regarding the peer review of the pesticide risk assessment of the active substance *Paecilomyces lilacinus* strain 251 (finalised: 13 June 2007).

[3] *EFSA Scientific Report* (2007) 107, 1-81, Conclusion regarding the peer review of the pesticide risk assessment of the active substance benthiavalicarb (finalised: 12 July 2007).

[4] *EFSA Scientific Report* (2007) 106, 1-98, Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole (finalised: 12 July 2007).

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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole as active substance by 31 January 2009. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole, 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) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole 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 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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole. 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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2010 at the latest; or

(b) in the case of a product containing benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 2010 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 2008.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 4 April 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

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 (*)	Entry into force	Expiration of inclusion	Specific provisions
'169	Benthiavalicarb CAS No 413615-35-7 CIPAC No 744	[(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl) ethyl]carbamoyl}-2-methylpropyl] carbamic acid	≥ 910 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: 6,6′-difluoro-2,2′-dibenzothiazole: < 3,5 mg/kg bis(2-amino-5-fluorophenyl) disulfide: < 14 mg/kg	1 August 2008	31 July 2018	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 benthiavalicarb, 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. In this overall assessment Member States must pay particular attention to: — the operator safety, — the protection of non-target arthropods. Conditions of use shall include adequate risk mitigation measures, where appropriate. In assessing applications to authorise plant protection products containing benthiavalicarb for uses other than in glasshouses, 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. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
170	Boscalid CAS No 188425-85-6 CIPAC No 673	2-Chloro-*N*-(4′-chlorobiphenyl-2-yl)nicotinamide	≥ 960 g/kg	1 August 2008	31 July 2018	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 boscalid, 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. In this overall assessment Member States must pay particular attention — to the operator safety, — to the long term risk to birds and soil organisms, — to the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include adequate risk mitigation measures, where appropriate.
171	Carvone CAS No 99-49-0 (d/l mixture) CIPAC No 602	5-isopropenyl-2-methylcyclohex-2-en-1-one	≥ 930 g/kg with a d/l ratio of at least 100:1	1 August 2008	31 July 2018	Part A Only uses as plant growth regulator may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carvone, 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. In this overall assessment Member States must pay particular attention to the operator safety. Conditions of use shall include risk mitigation measures, where appropriate.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
172	Fluoxastrobin CAS No 361377-29-9 CIPAC No 746	(*E*)-{2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime	≥ 940 g/kg	1 August 2008	31 July 2018	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 fluoxastrobin, 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. In this overall assessment Member States must pay particular attention to: — the operator safety, in particular when handling the undiluted concentrate. Conditions of use shall include adequate protective measures, such as wearing a face shield, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate, — the risk of accumulation in the soil surface, if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — data to allow a comprehensive aquatic risk assessment to be made taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures, — data on toxicity of non-rat metabolites if straw from treated areas is to be used as feedstuff. They shall ensure that the notifier at whose request fluoxastrobin has been included in this Annex provide such studies to the Commission within two years from the entry into force of the Directive of inclusion.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
173	*Paecilomyces lilacinus* (Thom) Samson 1974 strain 251 (AGAL: No 89/030550) CIPAC No 753	Not applicable		1 August 2008	31 July 2018	Part A Only uses as nematicide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on *Paecilomyces lilacinus*, 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. In this overall assessment Member States must pay particular attention to: — the operator safety (although there was no need to set an AOEL, as a general rule, microorganisms should be considered as potential sensitisers), — the protection of leaf dwelling non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.
174	Prothioconazole CAS No 178928-70-6 CIPAC No 745	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione	≥ 970 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: — Toluene: < 5 g/kg — Prothioconazole-desthio (2-(1-chlorocyclopropyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0,5 g/kg (LOD)	1 August 2008	31 July 2018	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 prothioconazole, 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. In this overall assessment Member States must pay particular attention to: — the operator safety in spray applications. Conditions of use shall include adequate protective measures, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
						Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin, — a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds, — information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment. They shall ensure that the notifier at whose request prothioconazole has been included in this Annex provide such studies to the Commission within two years from the entry into force of the Directive of inclusion.'

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

COMMISSION DIRECTIVE 2008/45/EC

of 4 April 2008

amending Council Directive 91/414/EEC as regards an extension of the use of the active substance metconazole

(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 the second indent of the second subparagraph of Article 6(1) thereof,

Whereas:

(1) By Commission Directive 2006/74/EC [2] metconazole was included as active substance in Annex I to Directive 91/414/EEC.

(2) When applying for the inclusion of metconazole its notifier BASF Aktiengesellschaft submitted data on uses to control fungi which supported the overall conclusion that it may be expected that plant protection products containing metconazole will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. Therefore, metconazole was included in Annex I to that Directive with the specific provisions that Member States may only authorise uses as fungicide.

(3) In addition to the control of fungi in certain agricultural uses, the notifier now has applied for an amendment to those specific provisions as regards the use as a plant growth regulator. In order to support such an extension of the use, the notifier submitted additional information.

(4) Belgium evaluated the information and data submitted by the notifier. It informed the Commission in October 2007 that it concluded that the requested extension of use does not cause any risks in addition to those already taken into account in the specific provisions for metconazole in Annex I to Directive 91/414/EEC and in the Commission review report for that substance. This is particularly the case since the extension covers applications at rates that are lower than those necessary for a use as fungicide while the other application parameters as set out in the specific provisions of Annex I to Directive 91/414/EEC remain unchanged.

(5) Therefore it is justified to modify the specific provisions for metconazole.

(6) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(7) 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 5 August 2008 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 6 August 2008.

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.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2008/41/EC (OJ L 89, 1.4.2008, p. 12).
[2] OJ L 235, 30.8.2006, p. 17.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 4 April 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC, row 136 is replaced by the following:

'136	Metconazole CAS No 125116-23-6 (unstated stereo-chemistry) CIPAC No 706	(1RS,5RS:1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol	≥ 940 g/kg (sum of *cis*-and *trans*-isomers)	1 June 2007	31 May 2017	Part A Only uses as fungicide and plant growth regulator may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account. In this overall assessment: — Member States must pay particular attention to the protection of aquatic organisms, birds and mammals. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate.'