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⁽¹⁾ Text with EEA relevance

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 796/2011

of 8 August 2011

amending for the 155th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network,⁽¹⁾ and in particular Articles 7(1)(a), 7a(1) and 7a(5) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.

(2) On 29 July 2011 the Sanctions Committee of the United Nations Security Council decided to add two legal persons, groups or entities to its list of persons, groups

and entities to whom the freezing of funds and economic resources should apply. It also decided to amend two entries on the list.

(3) Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly.

(4) In order to ensure that the measures provided for in this Regulation are effective, this Regulation should enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of 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, 8 August 2011.

For the Commission,

On behalf of the President,

Head of the Service for Foreign Policy Instruments

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

(1) The following entries shall be added under the heading 'Legal persons, groups and entities':

- (a) 'Emarat **Kavkaz**. Other information: (a) Mainly active in the Russian Federation, Afghanistan and Pakistan; (b) Led by Doku Khamatovich Umarov. Date of designation referred to in Article 2a(4)(b): 29.7.2011.'
- (b) '**Tehrik-e Taliban Pakistan (TTP)** (*alias* (a) Tehrik-I-Taliban Pakistan, (b) Tehrik-e-Taliban, (c) Pakistani Taliban, (d) Tehreek-e-Taliban). Other information: (a) Tehrik-e Taliban is based in the tribal areas along the Afghanistan/Pakistan border; (b) Formed in 2007, its leader is Hakimullah Mehsud; (c) Wali Ur Rehman is the Emir of TTP for South Waziristan. Date of designation referred to in Article 2a (4) (b): 29.7.2011.'

(2) The entry 'Hakimullah Mehsud (*alias* (a) Hakeemullah Mehsud, (b) Zulfiqar). Date of birth: Approximately 1979. Place of birth: Pakistan. Nationality: Pakistani. Other information: (a) Reportedly born in South Waziristan, Pakistan; (b) Believed to be residing in Pakistan; (c) Leader of Tehrik-i-Taliban Pakistan, an organization based in the tribal areas along the Afghanistan-Pakistan border. Date of designation referred to in Article 2a(4)(b): 21.10.2010.' under the heading 'Natural persons' shall be replaced by the following:

'Hakimullah **Mehsud** (*alias* (a) Hakeemullah Mehsud, (b) Zulfiqar). Date of birth: Approximately 1979. Place of birth: Pakistan. Nationality: Pakistani. Other information: (a) Reportedly born in South Waziristan, Pakistan; (b) Believed to be residing in Pakistan; (c) Leader of Tehrik-e Taliban Pakistan (TTP), an organization based in the tribal areas along the Afghanistan-Pakistan border. Date of designation referred to in Article 2a(4)(b): 21.10.2010.'

(3) The entry 'Wali Ur Rehman. Date of birth: Approximately 1970. Place of birth: Pakistan. Nationality: Pakistani. Other information: (a) Reportedly born in South Waziristan, Pakistan; (b) Believed to be residing in Pakistan; (c) Emir of Tehrik-i-Taliban for Southwest Waziristan Agency, Federally Administered Tribal Areas, Pakistan. Date of designation referred to in Article 2a(4)(b): 21.10.2010.' under the heading 'Natural persons' shall be replaced by the following:

'Wali **Ur Rehman**. Date of birth: Approximately 1970. Place of birth: Pakistan. Nationality: Pakistani. Other information: (a) Reportedly born in South Waziristan, Pakistan; (b) Believed to be residing in Pakistan; (c) Emir of Tehrik-e Taliban Pakistan (TTP) for South Waziristan Agency, Federally Administered Tribal Areas, Pakistan. Date of designation referred to in Article 2a(4)(b): 21.10.2010.'

COMMISSION IMPLEMENTING REGULATION (EU) No 797/2011

of 9 August 2011

approving the active substance spiroxamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

azoxystrobin, fluroxypyr, imazalil, kresoxim-methyl, prohexadion-calcium and spiroxamine, and establishing the list of the notifiers concerned ⁽⁵⁾.

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(b) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply to active substances listed in Annex I to Commission Regulation (EC) No 737/2007 of 27 June 2007 on laying down the procedure of the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances ⁽³⁾, with respect to the procedure and the conditions for approval. Spiroxamine is listed in Annex I to Regulation (EC) No 737/2007.
- (2) The approval of spiroxamine, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances ⁽⁴⁾, expires on 31 December 2011. A notification was submitted in accordance with Article 4 of Regulation (EC) No 737/2007 for the renewal of the inclusion of spiroxamine in Annex I to Directive 91/414/EEC within the time period provided for in that Article.
- (3) That notification was found to be admissible by Commission Decision 2008/656/EC of 28 July 2008 on the admissibility of the notifications concerning the renewal of the inclusion in Annex I to Council Directive 91/414/EEC of the active substances azimsulfuron,

- (4) Within the time period provided for in Article 6 of Regulation (EC) No 737/2007, the notifier submitted the data required in accordance with that Article together with an explanation as regards the relevance of each new study submitted.
- (5) The rapporteur Member State prepared an assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 17 September 2009. In addition to the assessment of the active substance, that report includes a list of the studies the rapporteur Member State relied on for its assessment.
- (6) The Authority communicated the assessment report to the notifier and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the assessment report available to the public.
- (7) At the request of the Commission, the assessment report was peer reviewed by the Member States and the Authority. The Authority presented its conclusion on the peer review of the risk assessment of spiroxamine ⁽⁶⁾ to the Commission on 1 September 2010. The assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 17 June 2011 in the format of the Commission review report for spiroxamine.
- (8) It has appeared from the various examinations made that plant protection products containing spiroxamine may be expected to continue to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve spiroxamine.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 169, 29.6.2007, p. 10.

⁽⁴⁾ OJ L 153, 11.6.2011, p. 1.

⁽⁵⁾ OJ L 214, 9.8.2008, p. 70.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance spiroxamine. *EFSA Journal* 2010; 8(9)1719 [102 pp.], doi:10.2903/j.efsa.2010_1719. Available online: www.efsa.europa.eu

- (9) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions not provided for in the first inclusion in Annex I to Directive 91/414/EEC.
- (10) Without prejudice to the conclusion that spiroxamine should be approved, it is, in particular, appropriate to require further confirmatory information.
- (11) A reasonable period should be allowed to elapse before approval in order to permit Member States and interested parties to prepare themselves to meet the new requirements resulting from the approval.
- (12) Without prejudice to the obligations provided for by Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009 the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing spiroxamine. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (13) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽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 which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.
- (14) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

- (15) 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

Approval of active substance

The active substance spiroxamine, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing spiroxamine as an active substance by 30 June 2012.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in Part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing spiroxamine as either the only active substance or as one of several active substances all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 December 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account Part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing spiroxamine as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or
- (b) in the case of a product containing spiroxamine as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

*Article 3***Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 4***Entry into force and application**

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

It shall apply from 1 January 2012.

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

Done at Brussels, 9 August 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Spiroxamine CAS No 1181134-30-8 CIPAC No 572	8- <i>tert</i> -butyl-1,4- dioxaspiro[4.5] decan-2- ylmethyl(ethyl) (propyl)amine (ISO)	≥ 940 g/kg (diastereomers A and B combined)	1 January 2012	31 December 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiroxamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment; (b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities; (c) the groundwater exposure assessment for metabolite M03 ⁽²⁾; (d) the risk to aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by two years after the adoption of specific guidance and the information set out in points (b), (c) and (d) by 31 December 2013.

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

⁽²⁾ M03: [(8-*tert*-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, the entry relating to spiroxamine is deleted;

(2) in Part B, the following entry is added:

'7	Spiroxamine CAS No 1181134-30-8 CIPAC No 572	8- <i>tert</i> -butyl-1,4-dioxaspiro [4.5]decan-2-ylmethyl(ethyl) (propyl)amine (ISO)	≥ 940 g/kg (diastereomers A and B combined)	1 January 2012	31 December 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiroxamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment; (b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities; (c) the groundwater exposure assessment for metabolite M03 (*);
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						(d) the risk to aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by two years after the adoption of specific guidance and the information set out in points (b), (c) and (d) by 31 December 2013.
(*) M03: [(8-tert-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide.						

COMMISSION IMPLEMENTING REGULATION (EU) No 798/2011

of 9 August 2011

approving the active substance oxyfluorfen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Articles 13(2) and 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 ⁽³⁾, with respect to the procedure and the conditions for approval. Oxyfluorfen is an active substance for which completeness has been established in accordance with that Regulation.
- (2) Commission Regulations (EC) No 451/2000 ⁽⁴⁾ and (EC) No 1490/2002 ⁽⁵⁾ lay down the detailed rules for the implementation of the second and third stages 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 included oxyfluorfen.
- (3) In accordance with Article 3(2) of Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC ⁽⁶⁾ the notifier withdrew its

support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from entry into force of that Regulation. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances ⁽⁷⁾ was adopted on the non-inclusion of oxyfluorfen.

- (4) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Regulation (EC) No 33/2008 laying down detailed rules for the application of Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I.
- (5) The application was submitted to Spain, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.
- (6) Spain evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 13 January 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on oxyfluorfen to the Commission on 23 November 2010 ⁽⁸⁾. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁴⁾ OJ L 55, 29.2.2000, p. 25.

⁽⁵⁾ OJ L 224, 21.8.2002, p. 23.

⁽⁶⁾ OJ L 246, 21.9.2007, p. 19.

⁽⁷⁾ OJ L 333, 11.12.2008, p. 11.

⁽⁸⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance oxyfluorfen. EFSA Journal 2010;8(11):1906. [78 pp.]. doi:10.2903/j.efsa.2010.1906. Available online: www.efsa.europa.eu

within the Standing Committee on the Food Chain and Animal Health and finalised on 17 June 2011 in the format of the Commission review report for oxyfluorfen.

- (7) It has appeared from the various examinations made that plant protection products containing oxyfluorfen 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 as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve oxyfluorfen in accordance with Regulation (EC) No 1107/2009.
- (8) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.
- (9) Without prejudice to the conclusion that oxyfluorfen should be approved, it is, in particular, appropriate to require further confirmatory information.
- (10) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.
- (11) Without prejudice to the obligations defined by Regulation (EC) No 1107/2009 as a consequence of the approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of 6 months after approval to review authorisations of plant protection products containing oxyfluorfen. Member States should, as appropriate, vary, replace or withdraw existing authorisations. By way of derogation from the above deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (12) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽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 which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances. In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽²⁾ should be amended accordingly.

- (13) Decision 2008/934/EC provides for the non-inclusion of oxyfluorfen and the withdrawal of authorisations for plants protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning oxyfluorfen in the Annex to that Decision. It is therefore appropriate to amend Decision 2008/934/EC accordingly.
- (14) 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

Approval of active substance

The active substance oxyfluorfen, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing oxyfluorfen as an active substance by 30 June 2012.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in Part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

⁽²⁾ OJ L 153, 11.6.2011, p. 1.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing oxyfluorfen as either the only active substance or as one of several active substances all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011, by 31 December 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account Part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009. Following that determination Member States shall:

- (a) in the case of a product containing oxyfluorfen as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or
- (b) in the case of a product containing oxyfluorfen as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.

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

Done at Brussels, 9 August 2011.

Article 3

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 4

Amendments to Decision 2008/934/EC

The line concerning oxyfluorfen in the Annex to Decision 2008/934/EC is deleted.

Article 5

Entry into force and date of application

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

It shall apply from 1 January 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Oxyfluorfen CAS No 42874-03-3 CIPAC No 538	2-chloro- α,α,α -trifluoro- <i>p</i> -tolyl 3-ethoxy-4-nitro-phenyl ether	≥ 970 g/kg Impurities: N,N-dimethylnitrosamine: not more than 50 μ g/kg	1 January 2012	31 December 2021	PART A Only uses as herbicide for banded applications close to ground from autumn to early spring may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxyfluorfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. In this overall assessment Member States shall: (a) pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; (b) pay particular attention to the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured including information on the relevance of the impurities; (2) the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies; (3) the potential risk to aquatic organisms for the active substance and for the metabolites RH-45469 ⁽²⁾, MW 306 ⁽³⁾, MW 347 ⁽⁴⁾, MW 274 ⁽⁵⁾ and for the unidentified metabolite Deg 27; (4) the potential risk from bioaccumulation and biomagnification in the aquatic food chain, including sediment dwellers; (5) exposure data for banded application adequate for use as drift mitigation values. The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) and (2) by 30 June 2012 and the information set out in points (3) to (5) by 31 December 2013.

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

⁽²⁾ 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-[(methoxymethyl)amino]phenol.

⁽³⁾ 3-chloro-4-[3-(ethenyloxy)-4-hydroxyphenoxy]benzoic acid.

⁽⁴⁾ 2-chloro-1-(3-methoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene.

⁽⁵⁾ 4-(3-ethoxy-4-hydroxyphenoxy)benzoic acid.

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'11	Oxyfluorfen CAS No 42874-03-3 CIPAC No 538	2-chloro- α,α,α -trifluoro- <i>p</i> -tolyl 3-ethoxy-4-nitrophenyl ether	≥ 970 g/kg Impurities: N,N-dimethylnitrosamine: not more than 50 $\mu\text{g/kg}$	1 January 2012	31 December 2021	PART A Only uses as herbicide for banded applications close to ground from autumn to early spring may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxyfluorfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. In this overall assessment Member States shall: (a) pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; (b) pay particular attention to the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured including information on the relevance of the impurities; (2) the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies;
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					(3) the potential risk to aquatic organisms for the active substance and for the metabolites RH-45469 (*), MW 306 (**), MW 347 (***), MW 274 (****) and for the unidentified metabolite Deg 27; (4) the potential risk from bioaccumulation and biomagnification in the aquatic food chain, including sediment dwellers; (5) exposure data for banded application adequate for use as drift mitigation values. The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) and (2) by 30 June 2012 and the information set out in points (3) to (5) by 31 December 2013.
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(*) 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-[(methoxymethyl)amino]phenol.
(**) 3-chloro-4-[3-(ethenyloxy)-4-hydroxyphenoxy]benzoic acid.
(***) 2-chloro-1-(3-methoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene.
(****) 4-(3-ethoxy-4-hydroxyphenoxy)benzoic acid.'

COMMISSION IMPLEMENTING REGULATION (EU) No 799/2011**of 9 August 2011****amending Annex I to Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽¹⁾, and in particular Article 15(5) thereof,

Whereas:

- (1) Commission Regulation (EC) No 669/2009 ⁽²⁾ lays down rules concerning the increased level of official controls to be carried out on imports of feed and food of non-animal origin listed in Annex I thereto ('the list'), at the points of entry into the territories referred to in Annex I to Regulation (EC) No 882/2004.
- (2) Article 2 of Regulation (EC) No 669/2009 provides that the list is to be reviewed on a regular basis, and at least quarterly, taking into account at least the sources of information referred to in that Article.
- (3) The occurrence and relevance of food incidents notified through the Rapid Alert System for Food and Feed (RASFF), the findings of missions to third countries carried out by the Food and Veterinary Office, as well as the quarterly reports on consignments of feed and food of non-animal origin submitted by Member States to the Commission in accordance with Article 15 of Regulation (EC) No 669/2009 indicate that the list should be amended.
- (4) In particular, the list should be amended by deleting the entries for commodities for which those information sources indicate an overall satisfactory degree of compliance with the relevant safety requirements provided for in Union legislation and for which an increased level of official control is therefore no longer justified.
- (5) In addition, certain other commodities for which the information sources indicate a degree of non-compliance

with the relevant safety requirements, thereby warranting the introduction of an increased level of official controls, should be included in the list.

- (6) The entries in the list for certain imports from Azerbaijan, China, Egypt, India and Pakistan should therefore be amended accordingly.
- (7) As regards the entry for imports of fresh peppers from Thailand, a clarification is necessary in the interest of clarity of Union legislation concerning the CN codes affected.
- (8) The amendment to the list concerning the deletion of the references to commodities should apply as soon as possible, as the original safety concerns have been satisfied. Accordingly, those amendments should apply from the date of entry into force of this Regulation.
- (9) Taking into account the number of amendments that need to be made to Annex I to Regulation (EC) No 669/2009, it is appropriate to replace it by the text in the Annex to this Regulation.
- (10) Regulation (EC) No 669/2009 should therefore be amended accordingly.
- (11) 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

Annex I to Regulation (EC) No 669/2009 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*.

It shall apply from 1 October 2011.

However, the deletion of the entry for Pakistan for basmati rice shall apply from the date of entry into force of this Regulation.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1.

⁽²⁾ OJ L 194, 25.7.2009, p. 11.

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

Done at Brussels, 9 August 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

‘ANNEX I

A. Feed and food of non-animal origin subject to an increased level of official controls at the designated point of entry

Feed and food (intended use)	CN code ⁽¹⁾	Country of origin	Hazard	Frequency of physical and identity checks (%)
— Groundnuts (peanuts), in shell	— 1202 10 90	Argentina (AR)	Aflatoxins	10
— Groundnuts (peanuts), shelled	— 1202 20 00			
— Peanut butter	— 2008 11 10			
— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98			
<i>(Feed and food)</i>				
Hazelnuts (in shell or shelled)	0802 21 00; 0802 22 00	Azerbaijan (AZ)	Aflatoxins	10
<i>(Feed and food)</i>				
— Groundnuts (peanuts), in shell	— 1202 10 90	Brazil (BR)	Aflatoxins	10
— Groundnuts (peanuts), shelled	— 1202 20 00			
— Peanut butter	— 2008 11 10			
— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98			
<i>(Feed and food)</i>				
Dried Noodles	ex 1902	China (CN)	Aluminium	10
<i>(Food)</i>				
Fresh pomelos	ex 0805 40 00	China (CN)	Pesticide residues analysed with multi-residue methods based on GC-MS and LC-MS or with single-residue methods ⁽¹¹⁾	20
<i>(Food)</i>				
Tea leaves (black and green)	0902	China (CN)	Pesticide residues analysed with multi-residue methods based on GC-MS and LC-MS or with single-residue methods ⁽¹⁰⁾	10
<i>(Food)</i>				

Feed and food (intended use)	CN code ⁽¹⁾	Country of origin	Hazard	Frequency of physical and identity checks (%)
— Yardlong beans (<i>Vigna unguiculata</i> spp. <i>sesquipedalis</i>) — Bitter melon (<i>Momordica charantia</i>) — Lauki (<i>Lagenaria siceraria</i>) — Peppers (<i>Capsicum</i> spp.) — Aubergines (Food — fresh, chilled or frozen vegetables)	— ex 0708 20 00; ex 0710 22 00 — ex 0709 90 90; ex 0710 80 95 — ex 0709 90 90; ex 0710 80 95 — 0709 60 10; ex 0709 60 99; 0710 80 51; ex 0710 80 59 — 0709 30 00; ex 0710 80 95	Dominican Republic (DO)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽³⁾	50
— Oranges (fresh or dried) — Peaches (excluding nectarines) — Pomegranates — Strawberries — Green beans (Food — fresh fruits and vegetables)	— 0805 10 20; 0805 10 80 — 0809 30 90 — ex 0810 90 95 — 0810 10 00 — ex 0708 20 00	Egypt (EG)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽⁷⁾	10
Peppers (<i>Capsicum</i> spp.) (Food — fresh, chilled or frozen)	0709 60 10; ex 0709 60 99; 0710 80 51; ex 0710 80 59	Egypt (EG)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽¹²⁾	10
— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled — Peanut butter (Feed and Food)	— 1202 10 90 — 1202 20 00 — 2008 11 10	Ghana (GH)	Aflatoxins	50
Curry leaves (<i>Bergera/Murraya koenigii</i>) (Food — fresh herbs)	ex 1211 90 85	India (IN)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single residue methods ⁽⁵⁾	10

Feed and food (intended use)	CN code ⁽¹⁾	Country of origin	Hazard	Frequency of physical and identity checks (%)
— Chilli (<i>Capsicum annuum</i>), whole	— 0904 20 10	India (IN)	Aflatoxins	50
— Chilli (<i>Capsicum annuum</i>), crushed or ground	— ex 0904 20 90			
— Chilli products (curry)	— 0910 91 05			
— Nutmeg (<i>Myristica fragrans</i>)	— 0908 10 00			
— Mace (<i>Myristica fragrans</i>)	— 0908 20 00			
— Ginger (<i>Zingiber officinale</i>)	— 0910 10 00			
— <i>Curcuma longa</i> (turmeric)	— 0910 30 00			
(Food — dried spices)				
— Groundnuts (peanuts), in shell	— 1202 10 90	India (IN)	Aflatoxins	20
— Groundnuts (peanuts), shelled	— 1202 20 00			
— Peanut butter	— 2008 11 10			
— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98			
(Feed and food)				
Feed additives and premixtures	ex 2309	India (IN)	Cadmium and lead	10
(Feed)				
Fresh okra (Food)	ex 0709 90 90	India (IN)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽²⁾	10
Watermelon (<i>egusi</i> , <i>Citrullus lanatus</i>) seeds and derived products (Food)	ex 1207 99 97; ex 1106 30 90; ex 2008 99 99	Nigeria (NG)	Aflatoxins	50
— Chilli (<i>Capsicum annuum</i>), whole	— 0904 20 10	Peru (PE)	Aflatoxins and Ochratoxin A	10
— Chilli (<i>Capsicum annuum</i>), crushed or ground	— ex 0904 20 90			
(Food — dried spice)				
— Fresh chilli peppers (<i>Capsicum</i> spp.) (Food)	0709 60 10, ex 0709 60 99	Thailand (TH)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽⁹⁾	10

Feed and food (intended use)	CN code ⁽¹⁾	Country of origin	Hazard	Frequency of physical and identity checks (%)
— Coriander leaves	— ex 0709 90 90	Thailand (TH)	Salmonella ⁽⁶⁾	10
— Basil (holy, sweet)	— ex 1211 90 85			
— Mint	— ex 1211 90 85			
(Food — fresh herbs)				
— Coriander leaves	— ex 0709 90 90	Thailand (TH)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽⁴⁾	20
— Basil (holy, sweet)	— ex 1211 90 85			
(Food — fresh herbs)				
— Yardlong beans (<i>Vigna unguiculata</i> spp. <i>sesquipedalis</i>)	— ex 0708 20 00; ex 0710 22 00	Thailand (TH)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽⁴⁾	50
— Aubergines	— 0709 30 00; ex 0710 80 95			
— Brassica vegetables	— 0704; ex 0710 80 95			
(Food — fresh, chilled or frozen vegetables)				
— Sweet Peppers (<i>Capsicum annuum</i>)	— 0709 60 10; 0710 80 51	Turkey (TR)	Pesticide residues analysed with multi- residue methods based on GC-MS and LC-MS or with single-residue methods ⁽⁸⁾	10
— Tomatoes	— 0702 00 00; 0710 80 70			
(Food — fresh, chilled or frozen vegetables)				
Dried grapes (vine fruit)	0806 20	Uzbekistan (UZ)	Ochratoxin A	50
(Food)				
— Groundnuts (peanuts), in shell	— 1202 10 90	South Africa (ZA)	Aflatoxins	10
— Groundnuts (peanuts), shelled	— 1202 20 00			
— Peanut butter	— 2008 11 10			
— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98			
(Feed and food)				

Feed and food (intended use)	CN code ⁽¹⁾	Country of origin	Hazard	Frequency of physical and identity checks (%)
— Chilli (<i>Capsicum annuum</i>), crushed or ground	— ex 0904 20 90	All third countries	Sudan dyes	10
— Chilli products (curry)	— 0910 91 05			
— <i>Curcuma longa</i> (turmeric)	— 0910 30 00			
(Food — dried spices)				
— Red palm oil	— ex 1511 10 90			
(Food)				

⁽¹⁾ Where only certain products under any CN code are required to be examined and no specific subdivision under that code exists in the goods nomenclature, the CN code is marked “ex” (for example, ex 1006 30: only Basmati rice for direct human consumption is included).

⁽²⁾ In particular residues of: Acephate, Methamidophos, Triazophos, Endosulfan, Monocrotophos.

⁽³⁾ In particular residues of: Amitraz, Acephate, Aldicarb, Benomyl, Carbendazim, Chlorfenapyr, Chlorpyrifos, CS2 (Dithiocarbamates), Diafenthiuron, Diazinon, Dichlorvos, Dicofof, Dimethoate, Endosulfan, Fenamidone, Imidacloprid, Malathion, Methamidophos, Methiocarb, Methomyl, Monocrotophos, Omethoate, Oxamyl, Profenofos, Propiconazole, Thiabendazol, Thiacloprid.

⁽⁴⁾ In particular residues of: Acephate, Carbaryl, Carbendazim, Carbofuran, Chlorpyrifos, Chlorpyrifos-methyl, Dimethoate, Ethion, Malathion, Metalaxyl, Methamidophos, Methomyl, Monocrotophos, Omethoate, Prophenophos, Prothiophos, Quinalphos, Triadimefon, Triazophos, Dicrotophos, EPN, Triforine.

⁽⁵⁾ In particular residues of: Triazophos, Oxydemeton-methyl, Chlorpyrifos, Acetamiprid, Thiamethoxam, Clothianidin, Methamidophos, Acephate, Propargite, Monocrotophos.

⁽⁶⁾ Reference method EN/ISO 6579 or a method validated against it as referred to in Article 5 of Commission Regulation (EC) No 2073/2005 (OJ L 338, 22.12.2005, p. 1).

⁽⁷⁾ In particular residues of: Carbendazim, Cyfluthrin Cyprodinil, Diazinon, Dimethoate, Ethion, Fenitrothion, Fenpropathrin, Fludioxonil, Hexaflumuron, Lambda-cyhalothrin, Methiocarb, Methomyl, Omethoate, Oxamyl, Phenthoate, Thiophanate-methyl.

⁽⁸⁾ In particular residues of: Methomyl, Oxamyl, Carbendazim, Clofentezine, Diafenthiuron, Dimethoate, Formetanate, Malathion, Procymidone, Tetradifon, Thiophanate-methyl.

⁽⁹⁾ In particular residues of: Carbofuran, Methomyl, Omethoate, Dimethoate, Triazophos, Malathion, Profenofos, Prothiophos, Ethion, Carbendazim, Triforine, Procymidone, Formetanate.

⁽¹⁰⁾ In particular residues of: Buprofezin; Imidacloprid; Fenvalerate and Esfenvalerate (Sum of RS & SR isomers); Profenofos; Trifluralin; Triazophos; Triadimefon and Triadimenol (sum of triadimefon and triadimenol), Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)).

⁽¹¹⁾ In particular residues of: Triazofos, Triadimefon and Triadimenol (sum of triadimefon and triadimenol), Parathion-methyl, Fenthoate.

⁽¹²⁾ In particular residues of: Carbofuran (sum), Chlorpyrifos, Cypermethrin (sum), Cyproconazole, Dicofof (sum), Difenconazole, Dinotefuran, Ethion, Flusilazole, Folpet, Prochloraz, Profenofos, Propiconazole, Thiophanate-methyl and Triforine.

B. Definitions

For the purposes of this Annex, “Sudan dyes” refers to the following chemical substances:

- (i) Sudan I (CAS Number 842-07-9);
- (ii) Sudan II (CAS Number 3118-97-6);
- (iii) Sudan III (CAS Number 85-86-9);
- (iv) Scarlet Red; or Sudan IV (CAS Number 85-83-6).⁹

COMMISSION IMPLEMENTING REGULATION (EU) No 800/2011**of 9 August 2011**

approving the active substance tefluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and amending Commission Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 ⁽³⁾, with respect to the procedure and the conditions for approval. Tefluthrin is an active substance for which completeness has been established in accordance with that Regulation.
- (2) Commission Regulations (EC) No 451/2000 ⁽⁴⁾ and (EC) No 1490/2002 ⁽⁵⁾ lay down the detailed rules for the implementation of the second and third stages 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 included tefluthrin.
- (3) In accordance with Article 3(2) of Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC ⁽⁶⁾ the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months

from entry into force of that Regulation. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances ⁽⁷⁾ was adopted on the non-inclusion of tefluthrin.

- (4) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Regulation (EC) No 33/2008 laying down detailed rules for the application of Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I.
- (5) The application was submitted to Germany, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.
- (6) Germany evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 9 December 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on tefluthrin to the Commission on 20 August 2010 ⁽⁸⁾. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 17 June 2011 in the format of the Commission review report for tefluthrin.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁴⁾ OJ L 55, 29.2.2000, p. 25.

⁽⁵⁾ OJ L 224, 21.8.2002, p. 23.

⁽⁶⁾ OJ L 246, 21.9.2007, p. 19.

⁽⁷⁾ OJ L 333, 11.12.2008, p. 11.

⁽⁸⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance tefluthrin. EFSA Journal 2010; 8(5):1592. [67 pp.]. doi:10.2903/j.efsa.2010.1592. Available online: www.efsa.europa.eu

- (7) It has appeared from the various examinations made that plant protection products containing tefluthrin 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 were examined and detailed in the Commission review report. It is therefore appropriate to approve tefluthrin in accordance with Regulation (EC) No 1107/2009.
- (8) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.
- (9) Without prejudice to the conclusion that tefluthrin should be approved, it is, in particular, appropriate to require further confirmatory information.
- (10) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the approval.
- (11) Without prejudice to the obligations defined by Regulation (EC) No 1107/2009 as a consequence of the approval taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of 6 months after approval to review authorisations of plant protection products containing tefluthrin. Member States should, as appropriate, vary, replace or withdraw existing authorisations in accordance with the provisions of Directive 91/414/EEC. By way of derogation from the above deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC of each plant protection product for each intended use in accordance with the uniform principles.
- (12) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market⁽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 which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.
- (13) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances⁽²⁾ should be amended accordingly.
- (14) Decision 2008/934/EC provides for the non-inclusion of tefluthrin and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning tefluthrin in the Annex to that Decision. It is therefore appropriate to amend Decision 2008/934/EC accordingly.
- (15) 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

Approval of active substance

The active substance tefluthrin, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing tefluthrin as an active substance by 30 June 2012.

By that date they shall in particular verify that the conditions in the Annex I to this Regulation are met, with the exception of those identified in Part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing tefluthrin as either the only active substance or as one of several active substances all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 December 2011 at the latest, Member States shall re-evaluate the product in accordance with

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

⁽²⁾ OJ L 153, 11.6.2011, p. 1

the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account Part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing tefluthrin as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or
- (b) in the case of a product containing tefluthrin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.

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

Done at Brussels, 9 August 2011.

Article 3

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 4

Amendments to Decision 2008/934/EC

The line concerning tefluthrin in the Annex to Decision 2008/934/EC is deleted.

Article 5

Entry into force and date of application

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

It shall apply from 1 January 2012.

For the Commission

The President

José Manuel BARROSO

Conditions of approval as active substance under Regulation (EC) No 1107/2009:

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Tefluthrin CAS No: 79538-32-2 CIPAC No: 451	2,3,5,6-tetrafluoro-4-methylbenzyl (1R, 3R)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Tefluthrin is a 1:1 mixture of Z-(1R, 3R) and Z-(1S, 3S) enantiomers.	≥ 920 g/kg Hexachlorobenzene: not more than 1 mg/kg	1 January 2012	31 December 2021	PART A Only uses as insecticide may be authorised. The seed coating shall only be performed in professional seed treatment facilities. These facilities shall apply the best available techniques in order to exclude the release of dust clouds during storage, transport and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tefluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operators and workers safety and include among the authorised conditions of use the application of adequate personal protective equipment as well as respiratory protective equipment, — the risk to birds and mammals. Risk mitigation measures should be applied to grant a high degree of incorporation in soil and avoidance of spillage, — ensure that the label of treated seed includes the indication that the seeds were treated with tefluthrin and sets out the risk mitigation measures provided for in the authorisation. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured; (2) a validated analytical method for water; (3) the possible environmental impact of the preferential degradation/conversion of the isomers and an estimation of the relative toxicity and risk assessment for the workers. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in point (2) by 31 December 2012, and the information set out in point (3) 2 years after the adoption of a specific guidance document on evaluation of isomers mixture.

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

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011 the following entry is added:

10	Tefluthrin CAS No: 79538-32-2 CIPAC No: 451	2,3,5,6-tetrafluoro-4-methylbenzyl (1RS, 3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Tefluthrin is a 1:1 mixture of Z-(1R, 3R) and Z-(1S, 3S) enantiomers.	≥ 920 g/kg Hexachlorobenzene: not more than 1 mg/kg	1 January 2012	31 December 2021	PART A Only uses as insecticide may be authorised. The seed coating shall only be performed in professional seed treatment facilities. These facilities shall apply the best available techniques in order to exclude the release of dust clouds during storage, transport and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tefluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operators and workers safety and include among the authorised conditions of use the application of adequate personal protective equipment as well as respiratory protective equipment, — the risk to birds and mammals. Risk mitigation measures should be applied to grant a high degree of incorporation in soil and avoidance of spillage, — ensure that the label of treated seed includes the indication that the seeds were treated with tefluthrin and sets out the risk mitigation measures provided for in the authorisation. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured; (2) a validated analytical method for water; (3) the possible environmental impact of the preferential degradation/conversion of the isomers and an estimation of the relative toxicity and risk assessment for the workers. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in point (2) by 31 December 2012, and the information set out in point (3) 2 years after the adoption of a specific guidance document on evaluation of isomers mixture.'
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COMMISSION IMPLEMENTING REGULATION (EU) No 801/2011**of 9 August 2011****amending Regulation (EU) No 206/2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽¹⁾, and in particular the introductory phrase of Article 8, the first subparagraph of Article 8(1), and Article 8(4), thereof,

Whereas:

- (1) Commission Regulation (EU) No 206/2010 ⁽²⁾ lays down the veterinary certification requirements for the introduction into the Union of certain consignments of live animals or fresh meat. It also lays down the lists of third countries, territories or parts thereof from which those consignments may be introduced into the Union.
- (2) Regulation (EU) No 206/2010 provides that consignments of fresh meat intended for human consumption are to be imported into the Union only if they come from the third countries, territories or parts thereof listed in Part 1 of Annex II to that Regulation for which there is a model veterinary certificate corresponding to the consignment concerned listed in that Part.
- (3) Four parts of the territory of Botswana are listed in Part 1 of Annex II to Regulation (EU) No 206/2010 as regions from which imports of fresh de-boned and matured meat from ungulates into the Union are authorised. Those regions consist of a number of veterinary disease control zones.
- (4) On 5 May 2011, Botswana informed the Commission of a suspicion of foot-and-mouth disease based on clinical signs found in eight cattle on a farm. The outbreaks were confirmed, and notified to the Commission, on 11 May 2011 based on the isolation of a SAT2 foot-and-mouth disease virus.
- (5) The outbreaks occurred in the veterinary disease control zone 6, which forms part of one of the four parts of the territory of Botswana from which imports of fresh de-boned and matured meat from ungulates into the Union are authorised.
- (6) Due to the risk of introduction of foot-and-mouth disease through imports into the Union of fresh meat from species susceptible to that disease, and considering the guarantees given by Botswana allowing for regionalisation of the country, the authorisation of Botswana to export fresh de-boned and matured meat from ungulates into the Union from the affected part of its territory should be suspended as from 11 May 2011, the date of confirmation of the outbreaks of foot-and-mouth disease.
- (7) Annex II to Regulation (EU) No 206/2010 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ OJ L 18, 23.1.2003, p. 11.

⁽²⁾ OJ L 73, 20.3.2010, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

In Part 1 of Annex II to Regulation (EU) No 206/2010 the entry for Botswana is replaced by the following:

'BW – Botswana	BW-0	Whole country	EQU, EQW				
	BW-1	The veterinary disease control zones 3c, 4b, 5, 6, 8, 9 and 18	BOV, OVI, RUF, RUW	F	1	11 May 2011	1 December 2007
	BW-2	The veterinary disease control zones 10, 11, 13 and 14	BOV, OVI, RUF, RUW	F	1		7 March 2002
	BW-3	The veterinary disease control zone 12	BOV, OVI, RUF, RUW	F	1	20 October 2008	20 January 2009
	BW-4	The veterinary disease control zone 4a, except the intensive surveillance buffer zone of 10 km along the boundary with the foot-and-mouth disease vaccination zone and wildlife management areas	BOV	F	1		18 February 2011'

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, 9 August 2011.

For the Commission
The President
 José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 802/2011**of 9 August 2011****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

Implementing Regulation (EU) No 543/2011 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 Annex XVI, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 10 August 2011.

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

Done at Brussels, 9 August 2011.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

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
0707 00 05	TR	140,7
	ZZ	140,7
0709 90 70	TR	132,3
	ZZ	132,3
0805 50 10	AR	67,9
	TR	63,0
	UY	72,6
	ZA	72,5
	ZZ	69,0
0806 10 10	EG	165,5
	MA	187,2
	TR	161,9
	ZZ	171,5
0808 10 80	AR	97,7
	BR	64,6
	CL	91,0
	CN	56,0
	NZ	99,8
	US	121,3
	ZA	91,5
	ZZ	88,8
0808 20 50	AR	68,0
	CL	75,1
	CN	49,3
	NZ	108,0
	ZA	102,9
	ZZ	80,7
0809 20 95	TR	333,3
	US	510,8
	ZZ	422,1
0809 30	TR	126,9
	ZZ	126,9
0809 40 05	BA	49,9
	IL	149,1
	XS	57,7
	ZZ	85,6

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 9 August 2011

on the compliance of standard EN 16156:2010 ‘Cigarettes — Assessment of the ignition propensity — Safety requirement’ and of standard EN ISO 12863:2010 ‘Standard test method for assessing the ignition propensity of cigarettes’ with the general safety requirement of Directive 2001/95/EC of the European Parliament and of the Council and publication of the references of standard EN 16156:2010 ‘Cigarettes — Assessment of the ignition propensity — Safety requirement’ and of standard EN ISO 12863:2010 ‘Standard test method for assessing the ignition propensity of cigarettes’ in the *Official Journal of the European Union*

(notified under document C(2011) 5626)

(Text with EEA relevance)

(2011/496/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety⁽¹⁾, and in particular the first subparagraph of Article 4(2) thereof,

After consulting the Standing Committee set up in accordance with Article 5 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services⁽²⁾,

Whereas:

(1) Article 3(1) of Directive 2001/95/EC obliges producers to place only safe products on the market.

(2) Under the second subparagraph of Article 3(2) of Directive 2001/95/EC, a product shall be presumed safe, as far as the risks and risk categories covered by the relevant national standards are concerned, when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the *Official Journal of the European Union*, in accordance with Article 4(2) of the Directive.

(3) Pursuant to Article 4(1) of the Directive, European standards are established by European standardisation bodies under mandates drawn up by the Commission.

(4) Pursuant to Article 4(2), the Commission is to publish the references of such standards.

(5) In June 2008, the Commission issued Mandate M/425 to CEN (European Committee for Standardisation) to draft a European safety standard to address the fire risk of cigarettes.

(6) CEN adopted standard EN 16156:2010 ‘Cigarettes — Assessment of the ignition propensity — Safety requirement’ in response to the Commission’s mandate. That standard refers to standard EN ISO 12863:2010 ‘Standard test method for assessing the ignition propensity of cigarettes’. Therefore, reference should also be made to the EN ISO standard when publishing the reference to EN 16156:2010.

(7) EN ISO 12863:2010 was amended by a technical corrigendum⁽³⁾. The corrigendum was endorsed by CEN without any modification⁽⁴⁾ and thus included in standard EN 16156:2010.

(8) Standards EN 16156:2010 and EN ISO 12863:2010 fulfil Mandate M/425 and comply with the general safety requirement of Directive 2001/95/EC. Their references should be published in the *Official Journal of the European Union*.

(9) In order to ensure a successful introduction of the standards, industry should be given sufficient time to adapt their production to the safety level provided for in the standards. The publication of the references of the standards in the *Official Journal of the European Union* 12

⁽¹⁾ OJ L 11, 15.1.2002, p. 4.

⁽²⁾ OJ L 204, 21.7.1998, p. 37.

⁽³⁾ Technical corrigendum 1. Reference number ISO 12863:2010/Cor.1:2011(E).

⁽⁴⁾ Reference: EN ISO 12863:2010/AC:2011.

months after the standards were made available on 17 November 2010 by CEN is intended to ensure that thereafter in all Member States the presumption of fire safety would be based on common criteria. In order to ensure clarity and legal certainty on the internal market, market surveillance authorities in all Member States should take into account the European standards mentioned in recital 8 when assessing the fire safety of cigarettes, including at the stage of cigarette sales to consumers.

- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

Standard EN 16156:2010 'Cigarettes — Assessment of the ignition propensity — Safety requirement' and standard EN ISO 12863:2010 'Standard test method for assessing the

ignition propensity of cigarettes' meet the general safety requirement of Directive 2001/95/EC for the risk they cover.

Article 2

The references of standards EN 16156:2010 and EN ISO 12863:2010 shall be published in the C series of the *Official Journal of the European Union* on 17 November 2011.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 9 August 2011.

For the Commission

John DALLI

Member of the Commission

COMMISSION IMPLEMENTING DECISION

of 9 August 2011

authorising the placing on the market of fermented black bean extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council*(notified under document C(2011) 5645)***(Only the English text is authentic)**

(2011/497/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 8 July 2008 the company Cantox Health Sciences International on behalf of CBC Co. Ltd (Japan) made a request to the competent authorities of United Kingdom to place fermented black bean extract on the market as a novel food ingredient for use in food supplements.
- (2) On 28 January 2009 the competent food assessment body of United Kingdom issued its initial assessment report. In that report it came to the conclusion that fermented black bean extract was acceptable as a novel food ingredient provided that the product specifications and use levels are maintained.
- (3) The Commission forwarded the initial assessment report to all Member States on 5 February 2009.
- (4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.
- (5) Therefore the European Food Safety Authority (EFSA) was consulted on 19 August 2009.
- (6) On 8 April 2011, EFSA in the 'Scientific Opinion on the safety of a "fermented black bean extract" (Touchi) as a Novel Food ingredient' ⁽²⁾ came to the conclusion that fermented black bean extract was safe under the proposed use and conditions of use.
- (7) On the basis of the scientific assessment, it is established that fermented black bean extract complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97, without prejudice to the specific provisions of Directive 2002/46/EC of the European Parliament and of

the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽³⁾ and to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and certain other substances to foods ⁽⁴⁾.

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

HAS ADOPTED THIS DECISION:

Article 1

Fermented black bean extract as specified in the Annex may be placed on the market in the Union as a novel food ingredient in food supplements without prejudice to the specific provisions of Directive 2002/46/EC and Regulation (EC) No 1925/2006, with a maximum intake of 4,5 g per day.

Article 2

The designation of the authorised fermented black bean extract by this Decision on the labelling of the foodstuff containing it shall be 'fermented black bean (Soya) extract' or 'fermented Soya extract'.

Article 3

This Decision is addressed to CBC Co. Ltd, 2-15-13, Tsukima, Chuo-ku, Tokyo 104-0052, JAPAN.

Done at Brussels, 9 August 2011.

For the Commission

John DALLI

Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ EFSA Journal 2011; 9(5):2136. [20 pp.]

⁽³⁾ OJ L 183, 12.7.2002, p. 51.

⁽⁴⁾ OJ L 404, 30.12.2006, p. 26.

ANNEX

SPECIFICATIONS OF FERMENTED BLACK BEAN EXTRACT

Description:

Fermented black bean extract (Touchi extract) is a fine light-brown protein-rich powder obtained by water extraction of small soybeans (*Glycine max*) fermented with *Aspergillus oryzae*. The extract contains an α -glucosidase inhibitor.

Chemical characteristics of fermented black bean extract	
fat	Not more than 1 %
protein	Not less than 55 %
water	Not more than 7 %
ash	Not more than 10 %
carbohydrate	Not less than 20 %
α -glucosidase inhibitory activity	IC ₅₀ min 0,025 mg/ml
Soy isoflavone	Not more than 0,3 g/100 g

COMMISSION DECISION

of 9 August 2011

terminating the anti-dumping proceeding concerning imports of tris(2-chloro-1-methylethyl)phosphate originating in the People's Republic of China

(2011/498/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community⁽¹⁾ (the basic Regulation), and in particular Article 9 thereof,

After consulting the Advisory Committee,

Whereas:

A. PROCEDURE

1. Initiation

- (1) On 23 July 2010, the European Commission (the Commission) announced, by a notice published in the *Official Journal of the European Union*⁽²⁾ (the notice of initiation), the initiation of an anti-dumping proceeding pursuant to Article 5 of the basic Regulation with regard to imports into the Union of tris(2-chloro-1-methylethyl)phosphate (TCPP) originating in the People's Republic of China (the 'country concerned' or 'the PRC').
- (2) The proceeding was initiated following a complaint lodged on 9 June 2010 by the European Chemical Industry Council (CEFIC) (the complainant) on behalf of producers representing a major proportion, in this case more than 25 %, of the total Union production of TCPP. The complaint contained evidence of dumping of TCPP from the PRC and of material injury resulting therefrom, which was considered sufficient to justify the initiation of a proceeding.

2. Parties concerned by the proceeding

- (3) The Commission officially advised the complainant, other known Union producers, the exporting producers, importers and users known to be concerned as well as their associations, and the representatives of the exporting country, of the initiation of the proceeding.

Interested parties were given an opportunity to make their views known in writing and to request a hearing within the time limit set in the notice of initiation. All interested parties, who so requested and showed that there were particular reasons why they should be heard, were granted a hearing.

- (4) In view of the apparent high number of exporting producers and importers, sampling was envisaged in the notice of initiation for the determination of dumping and injury, in accordance with Article 17 of the basic Regulation. In order to enable the Commission to decide whether sampling would be necessary and, if so, to select a sample, all exporting producers and importers were asked to make themselves known to the Commission and to provide, as specified in the notice of initiation, basic information on their activities related to the product concerned during the investigation period (1 July 2009 to 30 June 2010).
- (5) After examination of the information submitted, and given the high number of importers which indicated their willingness to cooperate, it was decided that sampling was necessary with regard to unrelated importers. Whereas, given the limited number of exporting producers that indicated their willingness to cooperate, it was decided that sampling was not necessary with regard to exporting producers.
- (6) Six unrelated importers, accounting for 25 % of imports to the Union, agreed to be included in the sample. Two importers, accounting for around 20 % of imports from the PRC and over 80 % of imports of the importers that agreed to be included in the sample, were included in the sample. In accordance with Article 17(2) of the basic Regulation, the parties concerned were given the opportunity to comment on the selection of the sample. No objection was raised with regards to the selection of the sample.
- (7) The Commission sent questionnaires to the exporting producers, sampled importers, the Union producers, to all known users in the Union, and to known analogue country producers in the United States of America (USA). Questionnaire replies were received from four exporting producers in the PRC, one analogue country producer, three Union producers, two sampled importers and 35 users in the EU. However, one of the four Chinese exporting producers supplied a highly deficient questionnaire reply, and was subsequently considered as non-cooperating.

⁽¹⁾ OJ L 343, 22.12.2009, p. 51.

⁽²⁾ OJ C 201, 23.7.2010, p. 5.

- (8) In order to allow exporting producers in the PRC to submit a claim for market economy treatment (MET) or individual treatment (IT), if they so wished, the Commission sent claim forms to the exporting producers that made themselves known within the deadlines set out in the notice of initiation. Two (groups of) companies requested MET pursuant to Article 2(7) of the basic Regulation or IT pursuant to Article 9(5) of the basic Regulation should the investigation establish that they did not meet the conditions for MET. One company claimed only IT.
- (9) The Commission sought and verified the information deemed necessary for a determination of dumping, resulting injury and Union interest. Verification visits were carried out at the premises of the following companies:

Exporting producers in the PRC

- Albemarle Chemicals (Nanjing), Nanjing, PRC,
- Jiangsu Yoke Technology Co. Ltd, Yixing, PRC;

Related importers in the EU

- Albemarle Europe, Louvain-La-Neuve, Belgium,
- Shekoy Chemicals Europe BV, Breda, the Netherlands;

Union producers

- ICL-IP Bitterfeld GmbH, Bitterfeld-Wolfen, Germany,
- LANXESS Deutschland GmbH, Leverkusen, Germany,
- PCC Rokita SA, Brzeg Dolny, Poland.

- (10) In view of the need to establish a normal value for exporting producers in the PRC to which MET might not be granted and the exporting producer that requested only IT, a verification to establish normal value on the basis of data from the USA as analogue country took place at the premises of the following company:
- ICL-IP America Inc., St Louis, Missouri, USA.

2.1. Investigation period and period considered

- (11) The investigation of dumping and injury covered the period from 1 July 2009 to 30 June 2010 ('investigation period' or 'IP'). The examination of trends relevant for the assessment of injury covered the period from 1 January 2007 to the end of the investigation period (period considered).

3. Product concerned and like product

3.1. Product concerned

- (12) The product concerned is tris(2-chloro-1-methylethyl)phosphate originating in the PRC currently falling within CN code ex 2919 90 00.

The product has as Customs and Statistics (CUS) number 0024577-2. It is also called 'TCPP' and is also known under the following synonyms:

- 2-Propanol, 1-chloro, phosphate (3:1),
- tris(monochloroisopropyl)phosphate (TMCP),
- tris(2-chloroisopropyl)phosphate (TCIP),
- phosphoric acid, tris(2-chloro-1-methylethyl)ester,
- tris(beta-chloroisopropyl)phosphate,
- 1-chloro-2-propanol phosphate (3:1).

- (13) The product concerned is a flame retardant mainly used in the production of polyurethane (PUR) for use in construction and furniture.

3.2. Like product

- (14) The investigation has shown that TCPP produced and sold on the domestic market of the PRC and TCPP imported into the Union from the PRC, and that produced and sold on the domestic market of the USA, which served as an analogue country, as well as the TCPP produced and sold in the Union by the Union industry have the same basic physical, chemical and technical characteristics and uses. Therefore, these products are considered to be alike within the meaning of Article 1(4) of the basic Regulation.

4. Preliminary findings and subsequent procedure

- (15) On 27 April 2011, the Commission disclosed to interested parties an information document setting out its preliminary findings with respect to this proceeding. Given the need to examine certain aspects of the investigation further, it was considered appropriate not to impose any provisional measures and to continue the investigation. All parties were given the opportunity to submit relevant evidence and comments on the preliminary findings. The parties which so requested were also granted the opportunity to be heard. The Commission continued to seek and verify all information it deemed necessary for its final findings.

**B. WITHDRAWAL OF THE COMPLAINT AND
TERMINATION OF THE PROCEEDING**

- (16) By a letter dated 16 June 2011 addressed to the Commission, the complainant formally withdrew its complaint.
- (17) In accordance with Article 9(1) of the basic Regulation, the proceeding may be terminated where the complaint is withdrawn unless such termination would not be in the Union interest.
- (18) The Commission considered that the present proceeding should be terminated since the investigation had not brought to light any consideration showing that such termination would not be in the Union interest. Interested parties were informed accordingly and were given the opportunity to comment. However, no comments that could alter that decision were received.
- (19) The Commission therefore concludes that the anti-dumping proceeding concerning imports into the Union of tris(2-chloro-1-methylethyl)phosphate originating in the PRC should be terminated without the imposition of measures,

HAS ADOPTED THIS DECISION:

Article 1

The anti-dumping proceeding concerning imports of tris(2-chloro-1-methylethyl)phosphate originating in the People's Republic of China currently falling within CN code ex 2919 90 00 is hereby terminated.

Article 2

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

Done at Brussels, 9 August 2011.

For the Commission

The President

José Manuel BARROSO

CORRIGENDA**Corrigendum to Regulation (EC) No 1717/2006 of the European Parliament and of the Council of 15 November 2006 establishing an Instrument for Stability**

(Official Journal of the European Union L 327 of 24 November 2006)

On page 4, Article 4, introductory wording:

for: 'The Community shall provide technical and financial assistance in pursuit of the specific aims set out in Article 2(b) in the following areas:'

read: 'The Community shall provide technical and financial assistance in pursuit of the specific aims set out in point (b) of Article 1(2) in the following areas:'.

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