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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notice concerning the provisional application of the Agreement between the European Union and the Swiss Confederation establishing the terms and conditions for the participation of the Swiss Confederation in the 'Youth in Action' programme and in the action programme in the field of lifelong learning (2007 to 2013)

The Agreement between the European Union and the Swiss Confederation establishing the terms and conditions for the participation of the Swiss Confederation in the 'Youth in Action' programme and in the action programme in the field of lifelong learning (2007 to 2013) ⁽¹⁾, signed in Brussels on 15 February 2010, will be provisionally applied, by virtue of Article 5, second subparagraph of the Agreement, as of 1 January 2011.

⁽¹⁾ OJ L 87, 7.4.2010, p. 9.

REGULATIONS

COUNCIL REGULATION (EU) No 1137/2010

of 7 December 2010

amending Regulation (EC) No 147/2003 concerning certain restrictive measures in respect of Somalia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215(1) thereof,

Having regard to Council Decision 2010/231/CFSP of 26 April 2010 concerning restrictive measures against Somalia ⁽¹⁾,

Having regard to the joint proposal from the High Representative of the Union for Foreign Affairs and Security Policy and the European Commission,

Whereas:

- (1) Council Regulation (EC) No 147/2003 ⁽²⁾ imposes a general ban on the provision of technical advice, assistance, training, financing or financial assistance related to military activities, to any person, entity or body in Somalia.
- (2) By paragraph 7 of Resolution 1907 (2009), the UN Security Council calls upon Member States to inspect all cargo going to or coming from Somalia, where they believe that the cargo contains items prohibited either by paragraphs 5 and 6 of that Resolution or the general and complete arms embargo to Somalia, for the purpose of ensuring strict implementation of those provisions.
- (3) Decision 2010/231/CFSP provides for the inspection of certain cargoes to and from Somalia and, in the case of aircraft and vessels, for the supply of additional pre-arrival and pre-departure information in respect of goods brought into or out of the Union. That information must be provided in accordance with the provisions on entry and exit summary declarations of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽³⁾.
- (4) This measure falls within the scope of the Treaty and, therefore, notably with a view to ensuring its uniform application by economic operators in all Member States, Union legislation is necessary in order to implement it.

- (5) Regulation (EC) No 147/2003 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The following Article is inserted in Regulation (EC) No 147/2003:

'Article 3a

1. In order to ensure the strict implementation of Articles 1 and 3 of Council Decision 2010/231/CFSP of 26 April 2010 concerning restrictive measures against Somalia ^(*), all goods brought into or leaving the customs territory of the Union to and from Somalia shall be made subject to pre-arrival or pre-departure information to be submitted to the competent authorities of the Member States concerned.
2. The rules governing the obligation to provide pre-arrival or pre-departure information, in particular regarding the person who provides that information, the time-limits to be respected and the data required, shall be as determined in the relevant provisions concerning entry and exit summary declarations as well as customs declarations in Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ^(**) and Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 ^(***).
3. Furthermore, the person who provides the information referred to in paragraph 2, shall declare whether the goods are covered by the Common Military List of the European Union ^(****) and, if their export is subject to an exemption, specify the particulars of the export licence granted.
4. Until 31 December 2010 the entry and exit summary declarations and the required additional elements as referred to in this Article may be submitted in written form using commercial, port or transport documentation, provided that it contains the necessary particulars.

⁽¹⁾ OJ L 105, 27.4.2010, p. 17.

⁽²⁾ OJ L 24, 29.1.2003, p. 2.

⁽³⁾ OJ L 302, 19.10.1992, p. 1.

5. As from 1 January 2011 the required additional elements, as referred to in paragraph 3, shall be submitted either in written form or using a customs declaration as appropriate.

(*) OJ L 105, 27.4.2010, p. 17.

(**) OJ L 302, 19.10.1992, p. 1.

(***) OJ L 253, 11.10.1993, p. 1.

(****) OJ C 69, 18.3.2010, p. 19.

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, 7 December 2010.

For the Council

The President

D. REYNDEERS

COMMISSION REGULATION (EU) No 1138/2010

of 7 December 2010

amending for the 140th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with Usama bin Laden, the Al-Qaida network and the Taliban

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 Usama bin Laden, the Al-Qaida network and the Taliban, and repealing Council Regulation (EC) No 467/2001 prohibiting the export of certain goods and services to Afghanistan, strengthening the flight ban and extending the freeze of funds and other financial resources in respect of the Taliban of Afghanistan,⁽¹⁾ and in particular Articles 7(1)(a) and 7c(3) 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. By means of Commission Regulation (EC) No 246/2006⁽²⁾ Sanabel Relief Agency Limited (Sanabel) was added to Annex I.
- (2) On 29 September 2010 the General Court annulled Regulation (EC) No 881/2002 in so far as it concerned Sanabel⁽³⁾ holding that the rights of the defence, the right to judicial review and the right to property had not been respected.
- (3) Following receipt of a statement of reasons from the UN Al Qaida and Taliban Sanctions Committee, the Commission communicated this statement to Sanabel in August 2009. In July 2010 it has communicated a related statement of reasons which it had just received from the Sanctions Committee. Sanabel has submitted its observations on these statements of reasons.

- (4) The list of persons, groups and entities to whom the freezing of funds and economic resources should apply, drawn up by the UN Al Qaida and Taliban Sanctions Committee, currently comprises Sanabel.
- (5) Pursuant to Article 7c(3) of Regulation (EC) No 881/2002, after having carefully considered the observations received from Sanabel, and given the preventive nature of the freezing of funds and economic resources, the Commission considers that the listing of Sanabel is justified for reasons of its association with the Taliban, Usama bin Laden or the Al-Qaida network.
- (6) In view of this, the listing decision concerning Sanabel should be replaced by a new decision confirming its inclusion in Annex I to Regulation (EC) No 881/2002.
- (7) This new decision should apply from 11 February 2006, given the preventive nature and objectives of the freezing of funds and economic resources under Regulation (EC) No 881/2002 and the need to protect legitimate interests of the economic operators, who have been relying on the decision made in 2006.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Review of Listings under Regulation 881/2002,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is hereby amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 9 December 2010.

It shall apply from 11 February 2006.

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

Done at Brussels, 7 December 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

⁽²⁾ OJ L 40, 11.2.2006, p. 13.

⁽³⁾ Case T-136/06 (Judgment in joint cases T-135/06 to T-138/06).

ANNEX

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

The following entry under the heading 'Legal persons, groups and entities' is confirmed:

'Sanabel Relief Agency Limited (*alias* (a) Sanabel Relief Agency (b) Sanabel L'il-Igatha, (c) SRA, (d) Sara, (e) Al-Rahama Relief Foundation Limited). Address: (a) 63 South Rd, Sparkbrook, Birmingham B 111 EX, United Kingdom (b) 1011 Stockport Rd, Levenshulme, Manchester M9 2TB, United Kingdom (c) P.O. Box 50, Manchester M19 25P, United Kingdom (d) 98 Gresham Road, Middlesbrough, United Kingdom (e) 54 Anson Road, London NW2 6AD, United Kingdom. Other information: (a) charity number: 1083469, (b) registration number: 3713110. Date of designation referred to in Article 2a (4) (b): 7.2.2006.'

COMMISSION REGULATION (EU) No 1139/2010**of 7 December 2010****amending for the 141st time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with Usama bin Laden, the Al-Qaida network and the Taliban**

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 Usama bin Laden, the Al-Qaida network and the Taliban, and repealing Council Regulation (EC) No 467/2001 prohibiting the export of certain goods and services to Afghanistan, strengthening the flight ban and extending the freeze of funds and other financial resources in respect of the Taliban of Afghanistan,⁽¹⁾ and in particular Articles 7(1)(a) and 7a(1) 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. By means of Regulation (EC) No 246/2006⁽²⁾ Ghunia Abdrabbah, Al-Bashir Mohammed Al-Faqih and Tahir Nasuf were added to Annex 1. This followed the decision of the United Nations Sanctions Committee, established pursuant to Security Council Resolution 1267(1999) concerning Al-Qaida and the Taliban and Associated Individuals and Entities, to add them to its Consolidated List.

(2) On 29 September 2010 the General Court⁽³⁾ annulled Regulation (EC) No 881/2002 in so far as it concerned Mr Abdrabbah, Mr Al-Faqih and Mr Nasuf, holding that the rights of the defence, the right to judicial review and the right to property had not been respected.

(3) A statement of reasons was provided by the Commission to Mr Abdrabbah, Mr Al-Faqih and Mr Nasuf, respectively, on 22 September 2009, 7 August 2009 and 11 August 2009, after commencement of the Court proceedings referred to above. Accordingly the failure identified by the General Court has been addressed.

(4) In view of this, the listing decision concerning Mr Abdrabbah, Mr Al-Faqih and Mr Nasuf should therefore be replaced by a new decision made pursuant to Article 7a(1) of Regulation (EC) No 881/2002, in order to ensure consistency with the decision of the United Nations Sanctions Committee and taking into account the objectives of the freezing of funds and economic resources under Regulation (EC) No 881/2002.

(5) This new decision should apply from 11 February 2006, given the preventative nature and objectives of the freezing of funds and economic resources under Regulation (EC) No 881/2002 and the need to protect legitimate interests of the economic operators, who have been relying on the decision made in 2006.

(6) Mr Abdrabbah, Mr Al-Faqih and Mr Nasuf have already had an opportunity to submit observations on the statements of reasons provided to them as envisaged by Articles 7a(3) and 7c(3) of Regulation (EC) No 881/2002. The Commission has communicated those observations to the Sanctions Committee and is in the process of conducting its review of its decisions to impose restrictive measures on them, which is being conducted under the procedure referred to in Article 7b(2) of Regulation (EC) No 881/2002. The results of the review will be communicated to Mr Abdrabbah, Mr Al-Faqih and Mr Nasuf.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is hereby amended as set out in 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*.

It shall apply from 11 February 2006.

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

⁽²⁾ OJ L 40, 11.2.2006, p. 13.

⁽³⁾ Joint cases T-135/06 to T-138/06.

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

Done at Brussels, 7 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

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

The following entries under the heading 'Natural persons' are confirmed:

- (a) Ghuma **Abd'rabbah** (*alias* (a) Ghunia Abdurabba, (b) Ghoma Abdrabba, (c) Abd'rabbah, (d) Abu Jamil, (e) Ghunia Abdrabba). Address: Birmingham, United Kingdom. Date of birth: 2.9.1957. Place of birth: Benghazi, Libya. Nationality: British. Date of designation referred to in Article 2a (4) (b): 7.2.2006.
 - (b) Abd Al-Rahman **Al-Faqih** (*alias* (a) Mohammed Albashir, (b) Muhammad Al-Bashir, (c) Bashir Mohammed Ibrahim Al-Faqi, (d) Al-Basher Mohammed, (e) Abu Mohammed, (f) Mohammed Ismail, (g) Abu Abd Al Rahman, (h) Abd Al Rahman Al-Khatib, (i) Mustafa, (j) Mahmud, (k) Abu Khalid). Address: Birmingham, United Kingdom. Date of birth: 15.12.1959. Place of birth: Libya. Date of designation referred to in Article 2a (4) (b): 7.2.2006.
 - (c) Tahir **Nasuf** (*alias* (a) Tahir Mustafa Nasuf, (b) Tahar Nasoof, (c) Taher Nasuf, (d) Al-Qa'qa, (e) Abu Salima El Libi, (f) Abu Rida, (g) Tahir Moustafa Nasuf, (h) Tahir Moustafa Mohamed Nasuf). Address: Manchester, United Kingdom. Date of birth: (a) 4.11.1961, (b) 11.4.1961. Place of birth: Tripoli, Libya. Nationality: Libyan. Passport No.: RP0178772 (Libyan passport number). National identification No.: PW548083D (British National Insurance Number). Other information: Resident in the United Kingdom as at January 2009. Date of designation referred to in Article 2a (4) (b): 7.2.2006.
-

COMMISSION REGULATION (EU) No 1140/2010

of 7 December 2010

apportioning, for the 2010/2011 marketing year, 5 000 tonnes of short flax fibre and hemp fibre as national guaranteed quantities between Denmark, Greece, Ireland, Italy and Luxembourg

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 ⁽¹⁾, and in particular Article 95 in conjunction with Article 4 thereof,

Whereas:

- (1) Article 8(1) of Commission Regulation (EC) No 507/2008 of 6 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1673/2000 on the common organisation of the markets in flax and hemp grown for fibre ⁽²⁾ lays down that the apportioning of 5 000 tonnes of short flax fibre and hemp fibre as national guaranteed quantities, as provided for in Article 94 (1a), of Regulation (EC) No 1234/2007 for the marketing year 2010/2011, must be effected before 16 November of the marketing year in progress.
- (2) To that end, Denmark has sent the Commission information relating to areas covered by sale/purchase contracts, processing commitments and processing contracts, and estimated flax and hemp straw and fibre yields.
- (3) Conversely, no flax or hemp fibre will be produced for the 2010/2011 marketing year in Italy, Greece, Ireland or Luxembourg.
- (4) On the basis of estimates of production resulting from the information provided, total production in the five Member States concerned will not reach the overall

quantity of 5 000 tonnes allocated to them, and the national guaranteed quantities as set out below should be set.

- (5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the 2010/2011 marketing year, the apportionment in national guaranteed quantities provided for in Article 94 (1a) in conjunction with Annex XI A.II.(b) of Regulation (EC) No 1234/2007 shall be as follows:

— Denmark	84 tonnes;
— Greece	0 tonnes;
— Ireland	0 tonnes;
— Italy	0 tonnes;
— Luxembourg	0 tonnes.

Article 2

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

It shall apply from 16 November 2010.

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

Done at Brussels, 7 December 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 149, 7.6.2008, p. 38.

COMMISSION REGULATION (EU) No 1141/2010**of 7 December 2010****laying down the procedure for the renewal of the inclusion of a second group of active substances
in Annex I to Council Directive 91/414/EEC and establishing the list of those substances****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

submission of joint dossiers and to avoid, whenever possible, duplication of studies involving vertebrate animals.

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 6(5) thereof,

(7) In order to ensure the efficiency of renewal procedures, rapporteur Member States should organise, prior to the submission of the dossiers, a meeting to discuss the state of the art of the active substance and consider whether and, if necessary, how the dossiers submitted for the first inclusion are to be updated.

Whereas:

(1) Directive 91/414/EEC provides that, on request, the inclusion of an active substance may be renewed.

(2) The Commission has received letters from several producers requesting a renewal for active substances included in Annex I to Directive 91/414/EEC and for which the inclusion period is to expire in 2011 and 2012.

(3) It is necessary to provide for a procedure for the submission and appraisal of applications for the renewal of the inclusion in Annex I to Directive 91/414/EEC of those active substances.

(4) Periods should be set for the different steps of that procedure to ensure that they are carried out rapidly.

(5) Producers wishing to secure the renewal of active substances covered by this Regulation should be required to apply to the relevant rapporteur Member State.

(6) Where two or more applications for the same active substance have been submitted separately and fulfil the requirements, the rapporteur Member States should communicate the updated contact details of each applicant to the other applicants to facilitate the

(8) The dossiers submitted for renewal should include new data relevant to the active substance and new risk assessments to reflect any changes in data requirements and any changes in scientific or technical knowledge since the active substance was first included in Annex I to Directive 91/414/EEC, as reflected in guidance documents published by the Commission and in relevant opinions from the Scientific Committee on Plants or the European Food Safety Authority (hereinafter 'the Authority'). The range of uses submitted should reflect the representative uses. The applicant should demonstrate, on the basis of the data submitted, that for one or more preparations the requirements of Article 5 of Directive 91/414/EEC will be fulfilled.

(9) The applicants should list separately vertebrate studies to be submitted with the dossier and the rapporteur Member States should make such lists available on request to promote early discussions on the sharing of vertebrates data to avoid duplication of vertebrate studies.

(10) Technical or scientific information about an active substance, in particular with regard to potentially dangerous effects, submitted within the relevant period by third parties should be taken into consideration in the evaluations. The applicants should be given the opportunity to comment on such information.

(11) The renewal assessment reports prepared by the rapporteur Member States may, where necessary, be the subject of a consultation of experts organised by the Authority on request of the Commission before they are submitted to the Standing Committee on the Food Chain and Animal Health.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

- (12) The rules on data protection of Article 13 of Directive 91/414/EEC are intended to provide an incentive to applicants to assemble the detailed studies required under Annexes II and III to that Directive. However, data protection should not be extended artificially by the production of new studies which are not needed to decide on the renewal of an active substance. To this end, applicants should be required to identify explicitly which studies are new compared to the original dossier used for the first inclusion of the substance in Annex I to Directive 91/414/EC and to provide justification for their submission.
- (13) In view of the particular situation, where parts of the renewal procedure still take place while Directive 91/414/EEC applies while the decisions on the renewals will be taken under 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⁾, applicants are encouraged, as regards the format of the updating statement and the format and content of the dossier, to pay particular attention to the specific guidance documents published by the Commission.
- (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,
- (c) 'rapporteur Member State' means the Member State which evaluates an active substance, as listed in column B of Annex I for the respective active substance;
- (d) 'co-rapporteur Member State' means a Member State which cooperates in the evaluation carried out by the rapporteur Member State, as listed in column C of Annex I for the respective active substance;
- (e) 'inclusion' means inclusion of an active substance in Annex I to Directive 91/414/EEC;
- (f) 'renewal' means renewal of the inclusion of an active substance in Annex I to Directive 91/414/EEC.

Article 3

Coordinating authority of the Member State

Each Member State shall appoint an authority, hereinafter 'the coordinating authority', which coordinates and ensures contacts with applicants, other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', in accordance with this Regulation. Each Member State shall communicate the name and the contact details of its coordinating authority and any modifications to the Commission.

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation lays down the procedure for the renewal of the inclusion in Annex I to Directive 91/414/EEC of the active substances listed in Annex I to this Regulation.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

- (a) 'producer' means the person who manufactures the active substance on his own or who contracts out the manufacturing to another party or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;
- (b) 'applicant' means a producer who applies for the renewal of the inclusion of an active substance referred to in column A of Annex I;

The Commission shall publish a list including the names and the contact details of the coordinating authorities of the Member States. It shall keep that list updated according to the modifications communicated to it.

Article 4

Submission of application

1. A producer wishing to renew the inclusion in Annex I to Directive 91/414/EEC of an active substance referred to in column A of Annex I to this Regulation, or any variants thereof, shall, for each active substance separately, submit an application to the rapporteur Member State and to the co-rapporteur Member State by 28 March 2011 at the latest.

2. When submitting an application, the applicant may, pursuant to Article 14 of Directive 91/414/EEC, request certain parts of the information to be kept confidential. It shall present such parts of the application separately, setting out the reasons for requesting confidentiality.

At the same time, the applicant shall submit any data protection claims pursuant to Article 13 of Directive 91/414/EEC.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

3. The applicant shall send a copy of the application, without the updating statement referred to in Article 5(2), to the Commission and to the Authority.

4. Where several producers wish to renew the inclusion of the same active substance in Annex I to Directive 91/414/EEC, a joint application may be submitted by a joint representative.

5. Where applicable, a fee, as referred to in Article 19, shall be paid upon submission of an application.

Article 5

Format and content of application

1. An application shall be submitted in the format set out in Annex II.

2. The application shall state which sections of the dossiers submitted for the first inclusion of the active substance require updating with new information.

Hereinafter, that part of the application is referred to as 'the updating statement'.

3. The updating statement shall list the new information the applicant intends to submit and demonstrate that such information is necessary, because of data requirements or criteria which were not applicable at the time of the first inclusion of the active substance or because of changes in the representative uses or because the application is for an amended renewal.

The updating statement shall separately list new studies the applicant intends to submit on vertebrate animals.

4. Upon request from any interested party, the rapporteur Member State shall make available the information listed by the applicant as referred to in paragraph 3.

Article 6

Checking of application

1. Within 1 month of receipt of the application, the rapporteur Member State shall check whether the application fulfils the requirements of Articles 4 and 5.

2. Where the rapporteur Member State considers that the application fulfils the requirements of Articles 4 and 5, it shall, within the period of 1 month provided for in paragraph 1, inform the applicant, the Commission and the Authority of the date of receipt and that the application fulfils the requirements.

3. Where the rapporteur Member State considers that the application does not fulfil the requirements of Articles 4 and 5, it shall, within the period of 1 month provided for in paragraph 1, inform the applicant of the date of receipt and explain which requirements have not been fulfilled. It shall at the same time set the applicant a period of 14 days to render the application compliant. That period shall extend the period of 1 month provided for in paragraph 1. Where, at the end of the period set for rendering the application compliant, the rapporteur Member States considers that the application fulfils the requirements of Articles 4 and 5, paragraph 2 shall apply.

Where, at the end of the period set for rendering the application compliant, the rapporteur Member States considers that the application still does not fulfil the requirements of Articles 4 and 5, it shall, stating its reasons, immediately so inform the applicant, the Commission and the Authority.

Upon receiving the communication from the rapporteur Member State, the Commission shall, taking into account the view of the rapporteur Member State, decide whether the application fulfils the requirements of Articles 4 and 5 and inform the rapporteur Member State, the other Member States and the Authority of its decision. The rapporteur Member State shall immediately inform the applicant of that decision.

4. Where for an active substance no application fulfils the requirements of Articles 4 and 5, in accordance with Directive 91/414/EEC, the active substance shall be removed from Annex I to that Directive. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

5. Where two or more applications for the same active substance have been submitted separately and each is considered to fulfil the requirements of Articles 4 and 5, the rapporteur Member State shall communicate the contact details of each applicant to the other applicants.

6. The Commission shall publish, for each active substance, the names and the addresses of the applicants whose applications are considered to fulfil the requirements of Articles 4 and 5.

*Article 7***Pre-submission contacts**

Where an application fulfils the requirements of Articles 4 and 5, the applicant may request a meeting with the rapporteur Member State and the co-rapporteur Member State to discuss the updating statement. If requested, such pre-submission contacts shall take place prior to the submission of supplementary dossiers, as provided for in Article 9.

*Article 8***Access to the application**

Upon request from any interested party, the rapporteur Member State shall make available the application, excluding any information for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

*Article 9***Submission of supplementary dossiers**

1. Where the rapporteur Member State has informed the applicant in accordance with Article 6(2) that its application fulfils the requirements of Articles 4 and 5, the applicant shall submit to the rapporteur Member State and the co-rapporteur Member State a supplementary summary dossier and a supplementary complete dossier, hereinafter 'the supplementary dossiers'. The supplementary dossiers shall be added to the dossiers submitted for the first inclusion, with their subsequent updates, hereinafter 'the original dossiers'.

2. The contents of the supplementary dossiers shall comply with Article 10.

3. The supplementary dossiers shall be submitted by the date set out for the respective active substance in column D of Annex I.

4. At the request of the Authority or a Member State, the applicant shall make available the original dossiers where it has access to them.

5. Where there is more than one applicant requesting renewal of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly. Where dossiers are not submitted jointly by all applicants concerned, the reasons shall be set out in the dossiers. For each study involving vertebrate animals, the applicants concerned shall detail the attempts made to avoid duplication of testing and justify, if applicable, the need for conducting a duplicate study.

*Article 10***Contents of supplementary dossiers**

1. The supplementary summary dossier shall include the following:

- (a) a copy of the application, where the applicant is joined by another applicant the name and address of that applicant and of the joint representative, provided for in Article 4(4), where the applicant is replaced by another applicant the name and address of that applicant;
- (b) information with respect to one or more representative uses on a widely grown crop of at least one plant protection product containing the active substance, demonstrating that the inclusion requirements provided for in Article 5(1) and (2) of Directive 91/414/EEC are fulfilled; where the information submitted does not concern a widely grown crop, a justification shall be submitted;
- (c) data and risk assessments which were not part of the original dossiers and which are necessary to reflect changes:
 - (i) in requirements under Annexes II and III to Directive 91/414/EEC;
 - (ii) in scientific and technical knowledge since the first inclusion of the active substance concerned; or
 - (iii) to representative uses;
- (d) for each point of the requirements for the active substance, as set out in Annex II to Directive 91/414/EEC, for which new data are necessary within the meaning of point (c), the summaries and results of tests and studies, the name of their owner and of the person or institute having carried these out and the reason why each test or study is necessary either in the light of current scientific and technical knowledge or with a view to an amended renewal;
- (e) for each point of the requirements for the plant protection product, as set out in Annex III to Directive 91/414/EEC, for which new data are necessary within the meaning of point (c), the summaries and results of tests and studies, the name of their owner and of the person or institute having carried out the tests and studies, for one or more plant protection products which are representative of the supported uses, and the reason why each test or study is necessary either in the light of current scientific and technical knowledge or with a view to an amended renewal of the active substance;

- (f) for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;
 - (g) where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽¹⁾;
 - (h) an assessment of all information submitted;
 - (i) a checklist demonstrating that the supplementary dossiers referred to in paragraph 3 are complete, indicating which data are new.
2. The uses referred to in point (b) of paragraph 1 shall, where appropriate, include the uses evaluated for the first inclusion. At least one plant protection product referred to in that point (b) shall contain no other active substance, where such a product exists for a representative use.
3. The complete supplementary dossiers shall contain the full text of each test and study report referred to in points (d) and (e) of paragraph 1.

Article 11

Checking of supplementary dossiers

1. Within 1 month of receipt of the supplementary dossiers, the rapporteur Member State shall check whether the supplementary dossiers have been submitted by the date set in column D of Annex I for the respective active substance and whether they contain all the elements provided for in Article 10(1) and 10(3), using the checklist referred to in Article 10(1)(i).
2. Where the supplementary dossiers have been submitted by the applicable date and contain all the elements provided for in Article 10(1) and 10(3), the rapporteur Member State shall, within the period provided for in paragraph 1, inform the applicant, the Commission and the Authority of the date of receipt and that the dossiers are considered to be complete.
- The rapporteur Member State shall then start assessing the active substance.
3. Where the supplementary dossiers have not been submitted by the applicable date or do not contain all the elements provided for in Article 10(1) and 10(3), the rapporteur Member State shall, within the period provided for in paragraph 1, inform the applicant of the date of receipt and explain which

elements are missing. It shall at the same time set the applicant a period of 14 days to render the dossier compliant. That period shall extend the period of 1 month provided for in paragraph 1.

Where, at the end of the period set for rendering the supplementary dossiers compliant, the dossiers contain all the elements provided for in Article 10(1) and 10(3), paragraph 2 shall apply.

Where, at the end of the period set for rendering the supplementary dossiers compliant, the dossiers still do not contain all the elements provided for in Article 10(1) and 10(3), the rapporteur Member State shall immediately inform the applicant, the Commission and the Authority that the application is rejected, explaining the reasons for its decision.

4. Where for an active substance no supplementary dossiers that fulfil the requirements of Article 10(1) and 10(3) have been submitted by the applicable date, in accordance with Directive 91/414/EEC, the active substance shall be removed from Annex I to that Directive. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

Article 12

Withdrawal and replacement of the applicant

1. An applicant may withdraw its application by informing the rapporteur Member State. In that case the applicant shall at the same time inform the co-rapporteur Member State, the Commission, the Authority and any other applicants having submitted an application for the same active substance of the withdrawal.
2. An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the rapporteur Member State, through a joint declaration by the applicant and the other producer. In that case the applicant and the other producer shall at the same time inform the co-rapporteur Member State, the Commission, the Authority and any other applicants having submitted an application for the same active substance of the replacement.
3. Where an applicant withdraws its application and where no other application has been submitted for the same active substance fulfilling the requirements of Articles 4, 5, 9 and 10, the active substance shall be removed from Annex I to Directive 91/414/EEC. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

4. Paragraph 3 shall not apply where several applicants have jointly submitted their dossiers and not all of these applicants have withdrawn their application. In such a case the procedure for the renewal of the inclusion of the active substance shall continue on the basis of the submitted dossiers.

Article 13

Submission of information by third parties

Any person or Member State wishing to submit information which might contribute to the assessment, in particular with regard to the potentially dangerous effects of the active substance or its residues on human and animal health and on the environment, shall do so to the rapporteur Member State by the date set out for the respective active substance in column D of Annex I.

The rapporteur Member State shall, without delay, communicate any information received to the co-rapporteur Member State, the Authority, and the applicant. The applicant may send its comments on the submitted information to the rapporteur Member State and the other parties concerned at the latest by 2 months after receipt.

Article 14

Assessment by the rapporteur Member State and the co-rapporteur Member State

1. Within 11 months of informing the applicant that the supplementary dossiers are considered to be complete in accordance with Article 11(2), the rapporteur Member State shall, after consulting the co-rapporteur Member State, prepare and submit to the Commission, with a copy to the Authority, a report assessing whether the active substance can be expected to continue to meet the requirements for inclusion, as provided for in Article 5(1) and (2) of Directive 91/414/EEC, hereinafter 'the renewal assessment report'.

The renewal assessment report shall also include the following:

- (a) a recommendation with regard to the renewal of the inclusion;
- (b) where relevant, a suggestion for maximum residue levels to be set;
- (c) a conclusion on which of the new studies included in the supplementary dossiers are relevant for the assessment;
- (d) a recommendation as to the parts of the report on which a consultation of experts is to be organised in accordance with Article 16(2);

- (e) the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant.

2. For the assessment, the rapporteur Member State shall take into account the supplementary dossiers, any information submitted by a third party, comments on such information received from the applicant and, where appropriate, the original dossiers.

3. Where the rapporteur Member State needs additional information, it shall set a period for the applicant to supply that information. That period shall not lead to an extension of the period of 11 months provided for in paragraph 1.

4. The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States. Such consultations and requests shall not lead to an extension of the period of 11 months provided for in paragraph 1.

5. Information submitted by the applicant without having been requested, or after expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3, shall not be taken into account, unless submitted in accordance with Article 7 of Directive 91/414/EEC.

6. When submitting the renewal assessment report to the Commission, the rapporteur Member State shall request the applicant to submit the supplementary summary dossier, updated to include the additional information requested by the rapporteur Member State in accordance with paragraph 3 or submitted in accordance with Article 7 of Directive 91/414/EEC, to the Authority, the other Member States and, on request, to the Commission.

Article 15

Comments upon the renewal assessment report and access to that report and to the supplementary summary dossiers

1. After receiving the renewal assessment report, the Authority shall immediately communicate it for comments to the applicant and to the Member States. Such comments shall be communicated to the Authority within 2 months, which shall collate and forward those comments, including its own, to the Commission.

2. Upon request from any interested party, the Authority shall make the renewal assessment report available, excluding any information for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

3. The Authority shall make the supplementary summary dossier available to the public, with the exception of parts of it for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

Article 16

Evaluation of the renewal assessment report

1. The Commission shall, without delay, examine the renewal assessment report and the comments received in accordance with Article 15(1).

2. The Commission may consult the Authority asking it for a conclusion on the entire risk assessment or on specific points thereof. Such consultation may include a request to organise a consultation of experts. The Authority shall use the guidance documents available at the time of the entry into force of this Regulation.

The Authority shall deliver its conclusion at the latest 6 months after receipt of the request.

Where paragraph 3 applies, that period shall be extended by the periods referred to in the first and the second subparagraph of that paragraph.

3. Where the Authority considers that additional information or data from the applicant is necessary to comply with a request made by the Commission pursuant to paragraph 2, it shall in consultation with the rapporteur Member State, set a period of maximum 1 month for the applicant to supply it. It shall at the same time inform the Commission and the Member States. The applicant shall communicate the requested information to the Authority, the rapporteur Member State and the co-rapporteur Member State.

The rapporteur Member State shall, within 2 months of receipt, evaluate the information received and send its evaluation to the Authority.

4. Information submitted by the applicant without having been requested, or after expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3, shall not be taken into account, unless submitted in accordance with Article 7 of Directive 91/414/EEC.

Article 17

Review report and presentation of draft acts

1. The Commission shall draft a review report, hereinafter 'the review report', taking into account the renewal assessment

report by the rapporteur Member State, the comments referred to in Article 15(1) and, where applicable, the conclusion of the Authority.

The applicant shall be given the possibility to submit comments on the draft review report within a period set by the Commission.

The Commission shall present to the Committee referred to in Article 19(1) of Directive 91/414/EEC the draft review report within 6 months of receipt of the comments referred to in Article 15(1) or, where the Commission has consulted it in accordance with Article 16(2), of receipt of the conclusion of the Authority.

2. On the basis of the review report and taking into account any comments submitted by the applicant within the period set by the Commission pursuant to the second subparagraph of paragraph 1, the Commission shall submit to the Committee:

- (a) a draft act renewing the inclusion of the active substance concerned in Annex I to Directive 91/414/EEC, setting out, where appropriate, the conditions and restrictions, including the period for such inclusion; or
- (b) a draft act removing the active substance from Annex I to Directive 91/414/EEC and providing for its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance.

3. The draft acts referred to in paragraph 2 shall be adopted in accordance with the procedure referred to in Article 19(2) of Directive 91/414/EEC.

Article 18

Access to review report

The Commission shall make the review report available to the public, with the exception of parts of it for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

Article 19

Fees and charges

1. Member States may recover the costs associated with any work they carry out within the scope of this Regulation, by means of fees or charges.

2. Member States shall ensure that the fees or charges referred to in paragraph 1:

- (a) are established in a transparent manner; and
- (b) correspond to the actual total cost of the work involved except if it is in public interest to lower the fees or charges.

The fees or charges may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

Article 20

Other charges, levies or fees

Article 19 is without prejudice to Member States' rights to maintain or introduce, in accordance with the Treaty, charges, levies or fees with regard to the authorisation, placing on the market, use and control of active substances and plant protection products other than the fee provided for in Article 19.

Article 21

Entry into force

This Regulation shall enter into force on the 20th 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, 7 December 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX I

List of active substances referred to in Article 1 and their rapporteur Member States (RMS), co-rapporteur Member States (Co-RMS) and of the final dates for submission of dossiers

Column A		Column B	Column C	Column D
Substance		New RMS	Co-RMS	Deadline for submission of dossier
2,4-D	2012	EL	PL	29 February 2012
Amitrole	2011	FR	HU	29 February 2012
Esfenvalerate	2011	UK	PT	29 February 2012
Flumioxazine	2012	CZ	FR	29 February 2012
Lambda-Cyhalothrin	2011	SE	ES	29 February 2012
Acibenzolar-s-methyl	2011	FR	ES	29 February 2012
Bentazone	2011	NL	DE	29 February 2012
Cyclanilide	2011	AT	EL	29 February 2012
Fenhexamid	2011	UK	IT	29 February 2012
Ferric phosphate	2011	DE	PL	29 February 2012
Pymetrozine	2011	DE	BE	29 February 2012
Flupyrsulfuron-methyl	2011	FR	DK	31 May 2012
Diquat	2011	UK	SE	31 May 2012
Glyphosate	2012	DE	SK	31 May 2012
Iprovalicarb	2012	IE	IT	31 May 2012
Paecilomyces fumosoroseus	2011	BE	NL	31 May 2012
Thiabendazole	2011	ES	NL	31 May 2012
Pyridate	2011	AT	LV	31 May 2012
Sulfosulfuron	2012	SE	IE	31 May 2012
Pyraflufen-ethyl	2011	NL	LT	31 May 2012
Prosulfuron	2012	FR	SK	31 May 2012
Thifensulfuron-methyl	2012	UK	AT	31 August 2012
Cinidon-ethyl	2012	HU	UK	31 August 2012
Cyhalofop butyl	2012	IT	AT	31 August 2012
Florasulam	2012	PL	BE	31 August 2012
Metalaxyl-M	2012	BE	EL	31 August 2012
Picolinafen	2012	DE	LV	31 August 2012
Isoproturon	2012	DE	CZ	31 August 2012
Metsulfuron methyl	2011	SI	SE	31 August 2012
Triasulfuron	2011	FR	DK	31 August 2012
Famoxadone	2012	UK	FI	31 August 2012

ANNEX II

Format for application, as provided for in Article 5(1)

The application shall be in writing, signed by the applicant, and sent by registered mail to the rapporteur Member State listed in column B of Annex I and to the co-rapporteur Member State listed in column C of Annex I.

A copy of the application without the updating statement shall be sent to the European Commission, DG Health and Consumers, unit E3, 1049 Brussels, Belgium and to the Authority, European Food Safety Authority, Largo N. Palli 5/A, 43121 Parma, Italy.

The application shall be submitted in accordance with the following model.

MODEL1. *Information concerning the applicant*

1.1. Name and address of the applicant including the name of the natural person responsible for the application and further engagements resulting from this Regulation:

1.2.1.

(a) Telephone No:

(b) Fax No:

(c) E-mail address:

1.2.2.

(a) Contact:

(b) Alternative:

2. *Information to facilitate identification*

2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer.

2.2. Chemical name (IUPAC and CAS nomenclature).

2.3. CAS, CIPAC and EEC numbers (if available).

2.4. Empirical and structural formula, molecular mass.

2.5. Specification of purity of the active substance in g/kg which should be whenever possible identical or already accepted as equivalent to the one included in Annex I to Directive 91/414/EEC.

2.6. Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁽¹⁾ (health and environment effects).

An updating statement, as provided for in Article 5(2), shall be attached as an Annex to the application.

The applicant confirms that the above information submitted on (date) is correct.

Signature (of the person competent to act for the applicant referred to under 1.1)

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

COMMISSION REGULATION (EU) No 1142/2010**of 7 December 2010****amending Regulation (EC) No 1266/2007 as regards the period of application of the transitional measures concerning the conditions for exempting certain animals from the exit ban provided for in Council Directive 2000/75/EC****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue ⁽¹⁾, and in particular Article 9(1)(c), Articles 11 and 12 and the third paragraph of Article 19 thereof,

Whereas:

- (1) Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue ⁽²⁾ lays down rules for the control, monitoring, surveillance and restrictions on movements of animals, in relation to bluetongue, in and from the restricted zones.
- (2) Article 8 of Regulation (EC) No 1266/2007 lays down conditions for exemption from the exit ban provided for in Directive 2000/75/EC. Article 8(1) of that Regulation provides that movements of animals, their semen, ova and embryos, from a holding or semen collection or storage centre located in a restricted zone to another holding or semen collection or storage centre are to be exempted from that exit ban provided that they comply with the conditions set out in Annex III to that Regulation or with any other appropriate animal health guarantees based on a positive outcome of a risk assessment of measures against the spread of the bluetongue virus and protection against attacks by vectors, required by the competent authority of the place of origin and approved by the competent authority of the place of destination, prior to the movement of such animals.
- (3) Article 9(a) of Regulation (EC) No 1266/2007 provides that, until 31 December 2010, and by way of derogation from the conditions set out in Annex III to that Regulation, Member States of destination may require that the movement of certain animals which are covered by the exemption, provided for in Article 8(1) thereof, be subjected to additional conditions, on the basis of a

risk assessment taking into account the entomological and epidemiological conditions in which animals are being introduced. Those additional conditions specify that the animals must be less than 90 days old, they must have been kept since birth in vector protected confinement and they must have been subject to certain tests referred to in Annex III to that Regulation.

- (4) Fifteen Member States and Norway have notified the Commission that they have applied that transitional measure. The outcomes of the risk assessments that were carried out, which are publicly available on the Commission's website, show that the introduction of bluetongue in those Member States and in Norway as a result of animal movements from restricted zones could have a major negative impact.
- (5) The overall disease situation as regards bluetongue has improved considerably since 2008. However the virus is still present in parts of the Union.
- (6) For the sake of harmonized implementation, Member States have requested for specific criteria for the 'vector proof establishment' which is an important requirement for a number of the conditions set out in Annex III of Regulation (EC) No 1266/2007 and aims at the protection of animals against attacks by vectors. Currently, the World Organization for Animal Health (OIE) is working on a definition of a vector-protected establishment or facility. The outcome of this work shall serve as input for the Commission to define criteria for the vector proof establishment as referred to in Annex III of the Regulation.
- (7) Pending the development of the criteria for a vector proof establishment, the period of application of the transitional measures provided for in Article 9(a) of Regulation (EC) No 1266/2007 should be prolonged for another six months.
- (8) Regulation (EC) No 1266/2007 should therefore be amended accordingly.
- (9) 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 327, 22.12.2000, p. 74.

⁽²⁾ OJ L 283, 27.10.2007, p. 37.

HAS ADOPTED THIS REGULATION:

Article 1

In the introductory phrase of Article 9a(1) of Regulation (EC) No 1266/2007, the date '31 December 2010' is replaced by '30 June 2011'.

Article 2

This Regulation shall enter into force on the third day following that 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, 7 December 2010.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 1143/2010**of 7 December 2010****amending Regulation (EC) No 1251/2008 as regards the period of application of the transitional provisions for certain ornamental aquatic animals intended for closed ornamental facilities****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals⁽¹⁾, and in particular Article 17(2), Articles 22 and 25 and Article 61(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species⁽²⁾ lays down the animal health conditions and certification requirements for imports into the Union of ornamental aquatic animals intended for closed ornamental facilities.
- (2) Article 11 of Regulation (EC) No 1251/2008 provides that ornamental fish of species susceptible to one or more of the diseases listed in Part II of Annex IV to Directive 2006/88/EC and intended for closed ornamental facilities are only to be imported into the Union from third countries, territories, zones or compartments listed in Annex III to that Regulation. Epizootic ulcerative syndrome (EUS) is listed in Part II of Annex IV to Directive 2006/88/EC as an exotic disease of certain susceptible species of fish.
- (3) Article 20(5) of Regulation (EC) No 1251/2008 provides that for a transitional period until 31 December 2010, Member States may authorise the import of ornamental aquatic animals of species susceptible to EUS intended solely for closed ornamental facilities from third countries or territories that are members of the World Organisation for Animal Health (OIE).
- (4) Part II.2 of the model animal health certificate applicable to ornamental aquatic animals intended for closed facilities set out in Part B of Annex IV to Regulation (EC) No 1251/2008 sets out certain import requirements

related to EUS. The second sub-paragraph of Article 20(5) of that Regulation provides that these requirements shall not apply during the transitional period referred to above.

- (5) Further studies are needed at present to assess more precisely the risks associated with the import into the Union of such ornamental aquatic animals. In order not to disrupt trade in those animals, it is appropriate to prolong until 31 December 2012 the period of application of the transitional measures currently laid down in Article 20(5) of Regulation (EC) No 1251/2008.
- (6) In addition, certain other transitional provisions currently laid down in Article 20 of that Regulation are no longer applicable. In the interests of conciseness and clarity of Union legislation, it is appropriate to delete those provisions.
- (7) Regulation (EC) No 1251/2008 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,

HAS ADOPTED THIS REGULATION:

Article 1

Article 20 of Regulation (EC) No 1251/2008 is replaced by the following:

'Article 20

For a transitional period until 31 December 2012, Member States may authorise the import of ornamental aquatic animals of species susceptible to epizootic ulcerative syndrome (EUS) intended solely for closed ornamental facilities from third countries or territories that are Members of the World Organisation for Animal Health (OIE).

During that transitional period, the requirements concerning EUS set out in Part II.2 of the model animal health certificate set out in Part B of Annex IV, shall not apply to ornamental aquatic animals intended solely for closed ornamental facilities.'

⁽¹⁾ OJ L 328, 24.11.2006, p. 14.

⁽²⁾ OJ L 337, 16.12.2008, p. 41.

Article 2

In note (3) to Part II.2 of the model animal health certificate set out in Part B of Annex IV, the date '1 January 2011' is replaced by '1 January 2013'.

For a transitional period until 31 December 2012, consignments of ornamental aquatic animals accompanied by animal health certificates issued in accordance with Part B of Annex IV to Regulation (EC) No 1251/2008 before the

amendments introduced by the present Regulation, may continue to be imported into or transited through the Union.

Article 3

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

It shall apply from 1 January 2011.

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

Done at Brussels, 7 December 2010.

For the Commission

The President

José Manuel BARROSO

COMMISSION REGULATION (EU) No 1144/2010**of 3 December 2010****establishing a prohibition of fishing for tusk in EU and international waters of V, VI and VII by vessels flying the flag of the United Kingdom**

THE EUROPEAN COMMISSION,

(3) It is therefore necessary to prohibit fishing activities for that stock,

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

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy⁽¹⁾, and in particular Article 36(2) thereof,

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2010 shall be deemed to be exhausted from the date set out in that Annex.

Whereas:

*Article 2***Prohibitions**(1) Council Regulation (EU) No 53/2010 of 14 January 2010 fixing for 2010 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in EU waters and, for EU vessels, in waters where catch limitations are required⁽²⁾, lays down quotas for 2010.

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2010.

*Article 3***Entry into force**This Regulation shall enter into force on the day following that 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, 3 December 2010.

*For the Commission,
On behalf of the President,*

Lowri EVANS

Director-General for Maritime Affairs and Fisheries⁽¹⁾ OJ L 343, 22.12.2009, p. 1.⁽²⁾ OJ L 21, 26.1.2010, p. 1.

ANNEX

No	23/T&Q
Member State	UNITED KINGDOM/GBR
Stock	USK/567EI.
Species	Tusk (<i>Brosme brosme</i>)
Zone	EU and international waters of V, VI and VII
Date	21.5.2010

COMMISSION REGULATION (EU) No 1145/2010**of 3 December 2010****establishing a prohibition of fishing for tusk in EU and international waters of V, VI and VII by vessels flying the flag of Spain**

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

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

*Article 1***Quota exhaustion**

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, and in particular Article 36(2) thereof,

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2010 shall be deemed to be exhausted from the date set out in that Annex.

Whereas:

*Article 2***Prohibitions**

(1) Council Regulation (EU) No 53/2010 of 14 January 2010 fixing for 2010 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in EU waters and, for EU vessels, in waters where catch limitations are required ⁽²⁾, lays down quotas for 2010.

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2010.

*Article 3***Entry into force**

(3) It is therefore necessary to prohibit fishing activities for that stock,

This Regulation shall enter into force on the day following that 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, 3 December 2010.

*For the Commission,
On behalf of the President,*

Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 21, 26.1.2010, p. 1.

ANNEX

No	22/T&Q
Member state	Spain
Stock	USK/567El.
Species	Tusk (<i>Brosme brosme</i>)
Zone	EU and international waters of V, VI and VII
Date	27.6.2010

COMMISSION REGULATION (EU) No 1146/2010**of 3 December 2010****establishing a prohibition of fishing for plaice in VIII, IX and X; EU waters of CECAF 34.1.1 by vessels flying the flag of Spain**

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

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

*Article 1***Quota exhaustion**

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, and in particular Article 36(2) thereof,

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2010 shall be deemed to be exhausted from the date set out in that Annex.

Whereas:

*Article 2***Prohibitions**

(1) Council Regulation (EU) No 53/2010 of 14 January 2010 fixing for 2010 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in EU waters and, for EU vessels, in waters where catch limitations are required ⁽²⁾, lays down quotas for 2010.

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2010.

*Article 3***Entry into force**

(3) It is therefore necessary to prohibit fishing activities for that stock,

This Regulation shall enter into force on the day following that 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, 3 December 2010.

*For the Commission,
On behalf of the President,*

Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 21, 26.1.2010, p. 1.

ANNEX

No	24/T&Q
Member State	Spain
Stock	PLE/8/3411
Species	Plaice (<i>Pleuronectes platessa</i>)
Zone	VIII, IX and X; EU waters of CECAF 34.1.1
Date	27.6.2010

COMMISSION REGULATION (EU) No 1147/2010**of 3 December 2010****establishing a prohibition of fishing for cod in NAFO 3M by vessels flying the flag of Estonia**

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

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

*Article 1***Quota exhaustion**

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy⁽¹⁾, and in particular Article 36(2) thereof,

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2010 shall be deemed to be exhausted from the date set out in that Annex.

Whereas:

*Article 2***Prohibitions**

(1) Council Regulation (EU) No 53/2010 of 14 January 2010 fixing for 2010 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in EU waters and, for EU vessels, in waters where catch limitations are required⁽²⁾, lays down quotas for 2010.

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2010.

*Article 3***Entry into force**

(3) It is therefore necessary to prohibit fishing activities for that stock,

This Regulation shall enter into force on the 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, 3 December 2010.

*For the Commission,
On behalf of the President,*

Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 21, 26.1.2010, p. 1.

ANNEX

No	28/T&Q
Member State	Estonia
Stock	COD/N3M.
Species	Cod (<i>Gadus morhua</i>)
Zone	NAFO 3M
Date	1.8.2010

COMMISSION REGULATION (EU) No 1148/2010**of 3 December 2010****establishing a prohibition of fishing for cod in NAFO 3M by vessels flying the flag of Spain**

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

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

*Article 1***Quota exhaustion**

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, and in particular Article 36(2) thereof,

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2010 shall be deemed to be exhausted from the date set out in that Annex.

Whereas:

*Article 2***Prohibitions**

(1) Council Regulation (EU) No 53/2010 of 14 January 2010 fixing for 2010 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in EU waters and, for EU vessels, in waters where catch limitations are required ⁽²⁾, lays down quotas for 2010.

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2010.

*Article 3***Entry into force**

(3) It is therefore necessary to prohibit fishing activities for that stock,

This Regulation shall enter into force on the day following that 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, 3 December 2010.

*For the Commission,
On behalf of the President,*

Lowri EVANS
Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 21, 26.1.2010, p. 1.

ANNEX

No	48/T&Q
Member State	Spain
Stock	COD/N3M.
Species	Cod (<i>Gadus morhua</i>)
Zone	NAFO 3M
Date	7.10.2010

COMMISSION REGULATION (EU) No 1149/2010**of 3 December 2010****establishing a prohibition of fishing for black scabbardfish in Community waters and waters not under the sovereignty or jurisdiction of third countries of V, VI, VII and XII by vessels flying the flag of Spain**

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

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

*Article 1***Quota exhaustion**Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, and in particular Article 36(2) thereof,

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2010 shall be deemed to be exhausted from the date set out in that Annex.

Whereas:

*Article 2***Prohibitions**(1) Council Regulation (EC) No 1359/2008 of 28 November 2008 fixing for 2009 and 2010 the fishing opportunities for Community fishing vessels for certain deep-sea fish stocks ⁽²⁾ lays down quotas for 2009 and 2010.

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2010.

*Article 3***Entry into force**

(3) It is therefore necessary to prohibit fishing activities for that stock,

This Regulation shall enter into force on the day following that 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, 3 December 2010.

*For the Commission,
On behalf of the President,*

Lowri EVANS

Director-General for Maritime Affairs and Fisheries⁽¹⁾ OJ L 343, 22.12.2009, p. 1.⁽²⁾ OJ L 352, 31.12.2008, p. 1.

ANNEX

No	25/T&Q
Member State	Spain
Stock	BSF/56712-
Species	Black scabbardfish (<i>Aphanopus carbo</i>)
Zone	Community waters and waters not under the sovereignty or jurisdiction of third countries of V, VI, VII and XII
Date	27.6.2010

COMMISSION REGULATION (EU) No 1150/2010**of 7 December 2010****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 Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 8 December 2010.

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

Done at Brussels, 7 December 2010.

*For the Commission,
On behalf of the President,*

Jean-Luc DEMARTY
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, 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
0702 00 00	AL	63,0
	MA	88,9
	MK	66,1
	TR	139,6
	ZZ	89,4
0707 00 05	EG	145,5
	TR	89,1
	ZZ	117,3
0709 90 70	MA	87,7
	TR	81,1
	ZZ	84,4
0805 10 20	AR	50,8
	BR	57,8
	MA	57,1
	TR	50,8
	ZA	51,6
	ZW	48,4
	ZZ	52,8
0805 20 10	MA	68,5
	ZZ	68,5
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	72,2
	TR	68,8
	ZZ	70,5
0805 50 10	AR	45,9
	TR	52,3
	UY	57,1
	ZZ	51,8
0808 10 80	AR	74,9
	AU	187,9
	BR	50,3
	CA	100,0
	CL	84,2
	CN	95,3
	MK	26,7
	NZ	99,2
	US	116,9
	ZA	113,0
	ZZ	94,8
0808 20 50	CN	84,3
	US	125,5
	ZA	143,3
	ZZ	117,7

⁽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'.

DIRECTIVES

COMMISSION DIRECTIVE 2010/90/EU

of 7 December 2010

amending Council Directive 91/414/EEC to include pyridaben as active substance and amending 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 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Commission Regulations (EC) No 451/2000 ⁽²⁾ and (EC) No 1490/2002 ⁽³⁾ lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included pyridaben.
- (2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the applicant withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within two months from receipt of the draft assessment report. 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 ⁽⁴⁾ was adopted on the non-inclusion of pyridaben.
- (3) 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 Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council 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⁾.

- (4) The application was submitted to the Netherlands, which had been designated rapporteur Member State by Regulation (EC) No 451/2000. 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.
- (5) The Netherlands 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 15 June 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 pyridaben to the Commission on 28 May 2010 ⁽⁶⁾. 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 28 October 2010 in the format of the Commission review report for pyridaben.
- (6) It has appeared from the various examinations made that plant protection products containing pyridaben may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include pyridaben in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.
- (7) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EC provides that inclusion of a substance in Annex I may be subject to

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.⁽²⁾ OJ L 55, 29.2.2000, p. 25.⁽³⁾ OJ L 224, 21.8.2002, p. 23.⁽⁴⁾ OJ L 333, 11.12.2008, p. 11.⁽⁵⁾ OJ L 15, 18.1.2008, p. 5.⁽⁶⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance pyridaben. EFSA Journal 2010; 8(6):1632. [70 pp.]. doi:10.2903/j.efsa.2010.1632. Available online: www.efsa.europa.eu

conditions. Therefore, it is appropriate to require that the applicant submit further information to confirm the results of the risk assessment on the basis of most recent scientific knowledge as regards the exposure to the aqueous photolysis metabolites W-1 and B-3, the long term risk for mammals, the assessment of fat soluble residues.

- (8) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.
- (9) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing pyridaben to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 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.
- (11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (12) Decision 2008/934/EC provides for the non-inclusion of pyridaben and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning pyridaben in the Annex to that Decision.

(13) It is therefore appropriate to amend Decision 2008/934/EC accordingly.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

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

Article 3

Member States shall adopt and publish by 31 October 2011 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 November 2011.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing pyridaben as an active substance by 1 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to pyridaben are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing pyridaben as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 30 April 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning pyridaben. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

Following that determination Member States shall:

Article 5

This Directive shall enter into force on 1 May 2011.

Article 6

This Directive is addressed to the Member States.

- (a) in the case of a product containing pyridaben as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2015 at the latest; or
- (b) in the case of a product containing pyridaben as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Done at Brussels, 7 December 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
'318	Pyridaben CAS No: 96489-71-3 CIPAC No: 583	2- <i>tert</i> -butyl-5-(4- <i>tert</i> -butylbenzylthio)-4-chloropyrididazin-3(2H)-one	> 980 g/kg	1 May 2011	30 April 2021	<p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyridaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the risk to aquatic organisms and mammals, — the risk to non target arthropods including honeybees. <p>Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify the real exposure of honeybees to pyridaben in areas extensively used by such bees for foraging or by beekeepers, where and as appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — the risks for the water compartment resulting from the exposure to aqueous photolysis metabolites W-1 and B-3, — the potential long term risk for mammals, — the assessment of fat soluble residues. <p>They shall ensure that the applicant provides such confirmatory information to the Commission by 30 April 2013.'</p>

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

DECISIONS

COUNCIL DECISION

of 18 November 2010

designating the European Capital of Culture for the year 2015 in Belgium

(2010/757/EU)

THE COUNCIL OF THE EUROPEAN UNION,

HAS ADOPTED THIS DECISION:

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

Article 1

Mons is designated as 'European Capital of Culture 2015' in Belgium.

Having regard to Decision No 1622/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Community action for the European Capital of Culture event for the years 2007 to 2019 ⁽¹⁾, and in particular Article 9(3) thereof,

Article 2

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

Having regard to the recommendation from the European Commission,

Having regard to the Selection Panel reports of February 2010 regarding the selection process of the European Capitals of Culture in Belgium,

Done at Brussels, 18 November 2010.

Whereas:

Considering that the criteria referred to in Article 4 of Decision No 1622/2006/EC are entirely fulfilled,

For the Council

The President

F. LAANAN

⁽¹⁾ OJ L 304, 3.11.2006, p. 1.

COUNCIL DECISION**of 2 December 2010****on the launch of automated data exchange with regard to dactyloscopic data in Bulgaria**

(2010/758/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime ⁽¹⁾, in particular Article 25 thereof,

Having regard to Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA ⁽²⁾, in particular Article 20 and Chapter 4 of the Annex thereto,

Whereas:

- (1) According to the Protocol on Transitional Provisions annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community, the legal effects of the acts of the institutions, bodies, offices and agencies of the Union adopted prior to the entry into force of the Treaty of Lisbon are preserved until those acts are repealed, annulled or amended in implementation of the Treaties.
- (2) Accordingly, Article 25 of Decision 2008/615/JHA is applicable and the Council must unanimously decide whether the Member States have implemented the provisions of Chapter 6 of that Decision.
- (3) Article 20 of Decision 2008/616/JHA provides that decisions referred to in Article 25(2) of Decision 2008/615/JHA are to be taken on the basis of an evaluation report based on a questionnaire. With respect to automated data exchange in accordance with Chapter 2 of Decision 2008/615/JHA, the evaluation report is to be based on an evaluation visit and a pilot run.
- (4) According to Chapter 4, point 1.1 of the Annex to Decision 2008/616/JHA, the questionnaire drawn up by the relevant Council Working Group concerns each of

the automated data exchanges and has to be answered by a Member State as soon as it believes it fulfils the prerequisites for sharing data in the relevant data category.

- (5) Bulgaria has completed the questionnaire on data protection and the questionnaire on dactyloscopic data exchange.
- (6) A successful pilot run has been carried out by Bulgaria with Austria.
- (7) An evaluation visit has taken place in Bulgaria and a report on the evaluation visit has been produced by the Austrian/Spanish evaluation team and forwarded to the relevant Council Working Group.
- (8) An overall evaluation report, summarising the results of the questionnaire, the evaluation visit and the pilot run concerning dactyloscopic data exchange has been presented to the Council,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of automated searching of dactyloscopic data, Bulgaria has fully implemented the general provisions on data protection of Chapter 6 of Decision 2008/615/JHA and is entitled to receive and supply personal data pursuant to Article 9 of that Decision as from the date of the entry into force of this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 2 December 2010.

For the Council
The President
M. WATHELET

⁽¹⁾ OJ L 210, 6.8.2008, p. 1.

⁽²⁾ OJ L 210, 6.8.2008, p. 12.

COUNCIL DECISION

of 2 December 2010

on submitting 4-methylmethcathinone (mephedrone) to control measures

(2010/759/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances ⁽¹⁾, and in particular Article 8(3) thereof,

Having regard to the initiative of the European Commission,

Whereas:

- (1) A Risk Assessment Report on 4-methylmethcathinone (mephedrone) was drawn up on the basis of Article 6 of Decision 2005/387/JHA by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction, and was subsequently received by the Commission on 3 August 2010.
- (2) Mephedrone is a synthetic cathinone which is legally produced and distributed mainly in Asia, while final packaging seems to occur in Europe. Mephedrone is mostly sold as powder, but also as capsules or tablets. It is commercially available on the Internet, from 'head shops' and from street-level dealers. On the Internet, mephedrone is often marketed as 'plant food', 'bath salt', or 'research chemical'. It is very rarely marketed as a 'legal high' (licit psychoactive substance) and there is usually no reference or concrete information about its potential psychoactive effects.
- (3) Mephedrone's specific effects are difficult to assess because it is primarily used in combination with substances like alcohol and other stimulants. Mephedrone is deemed to have similar physical effects to other stimulant drugs, in particular ecstasy (MDMA). However, its relatively short duration of action, leading to repeated dosing, is more analogous to cocaine. Some evidence suggests that it may be used as an alternative to illicit stimulants, that it has a high abuse liability and a potential to cause dependency. More in-depth studies would be required to explore in detail the dependence potential of this drug.
- (4) There are two reported fatalities in the Union in which mephedrone appears to be the sole cause of death. There are at least another 37 deaths in which mephedrone has been detected in post-mortem samples.
- (5) Twenty two Member States have reported seizures of mephedrone in powder or tablets. There is little information that may suggest large-scale processing or distribution of mephedrone and the involvement of organised crime. Some evidence suggests that where mephedrone has been controlled, the drug continues to be available on the illicit market.
- (6) Mephedrone has no established or acknowledged medical value or use in the Union and there is no indication that it may be used for any other legitimate purposes.
- (7) Mephedrone is currently not under assessment and has not been under assessment by the United Nations system. Eleven Member States control mephedrone under drug control legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances. Two Member States apply control measures to mephedrone under their medicines legislation.
- (8) The Risk Assessment reveals limited scientific evidence and points out that further studies are needed on the overall health and social risks of mephedrone. However, because of its stimulant properties, its ability to produce dependence in users, its potential attractiveness, the risk to health, the lack of medical benefits, and therefore the need to apply precaution, mephedrone should be controlled.
- (9) Since eleven Member States already control mephedrone, placing it under control across the Union may help avoid problems in cross-border law enforcement and judicial cooperation,

HAS ADOPTED THIS DECISION:

Article 1

Member States shall take the necessary measures, in accordance with their national law, to submit 4-methylmethcathinone (mephedrone) to control measures and criminal penalties, as provided for under their legislation complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances.

⁽¹⁾ OJ L 127, 20.5.2005, p. 32.

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, 2 December 2010.

For the Council
The President
M. WATHELET

COMMISSION DECISION

of 6 December 2010

on the duty-free importation of goods intended to be distributed or made available free of charge to victims of the floods which occurred in Spring 2010 in Hungary

*(notified under document C(2010) 8482)***(Only the Hungarian text is authentic)**

(2010/760/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1186/2009 of 16 November 2009 setting up a Community system of reliefs from customs duty ⁽¹⁾, and in particular Article 76 thereof,

Having regard to the request, made by the Government of Hungary dated 2 June 2010 seeking the duty-free importation of goods intended to be made available free of charge to victims of the floods which occurred in Spring 2010 in Hungary,

Whereas:

- (1) A flood constitutes a disaster within the meaning of Title XVII C of Regulation (EC) No 1186/2009; whereas there is consequently reason to authorize the duty-free importation of goods which satisfy the requirements of Articles 74 to 80 of the abovementioned Regulation (EC) No 1186/2009.
- (2) In order that the Commission may be suitably informed of the use made of the goods admitted duty-free, the Government of Hungary must communicate the measures taken to prevent such goods imported duty-free from being employed otherwise than for the use laid down.
- (3) The Commission should also be informed of the extent and the nature of the importations made.
- (4) Other Member States have been consulted as laid down in Article 76 of Regulation (EC) No 1186/2009,

HAS ADOPTED THIS DECISION:

Article 1

1. Goods imported for release for free circulation by State bodies or by organizations approved by the competent Hungarian authorities for the purpose of being distributed by them free of charge to the victims of the floods which occurred in Spring 2010 in Hungary, or made available to them free of

charge while remaining the property of the organizations in question shall be admitted free of import duties within the meaning of Article 2(1)(a) of Regulation (EC) No 1186/2009.

2. Goods imported for release for free circulation by relief agencies in order to meet their needs during the period of their activity shall also be admitted duty-free.

Article 2

The Government of Hungary shall communicate to the Commission at the latest on 31 January 2011 the list of approved organizations referred to in Article 1(1).

Article 3

The Government of Hungary shall communicate to the Commission at the latest on 31 January 2011 by broad category of products, all information regarding the nature and quantities of the various goods admitted free of duty in pursuance of Article 1.

Article 4

The Government of Hungary shall communicate to the Commission at the latest on 31 January 2011 the measures which it takes to ensure that Articles 78, 79 and 80 of Regulation (EC) No 1186/2009 are respected.

Article 5

Article 1 of this Decision shall apply to importations made on or after 1 May 2010 and not later than 31 December 2010.

Article 6

This Decision is addressed to Hungary.

Done at Brussels, 6 December 2010.

For the Commission

Algirdas ŠEMETA

Member of the Commission

⁽¹⁾ OJ L 324, 10.12.2009, p. 23.

COMMISSION DECISION

of 7 December 2010

amending Annexes I and II to Decision 2010/221/EU as regards approved national measures by Hungary and the United Kingdom for spring viraemia of carp

*(notified under document C(2010) 8617)***(Text with EEA relevance)**

(2010/761/EU)

THE EUROPEAN COMMISSION,

listed in Annex I, instead of in Annex II, to that Decision as regards that disease.

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

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ⁽¹⁾, and in particular Article 43(2) thereof,

(4) Hungary has submitted to the Commission applications for the approval of national measures as regards SVC. Hungary has also conducted targeted surveillance of SVC for the last two years which has demonstrated that its entire territory is free of SVC. Hungary should therefore be listed in Annex I to Decision 2010/221/EU as free of SVC.

Whereas:

(5) Annexes I and II to Decision 2010/221/EU should therefore be amended accordingly.

(1) Commission Decision 2010/221/EU of 15 April 2010 approving national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Council Directive 2006/88/EC ⁽²⁾ allows certain Member States to apply placing on the market and import restrictions on consignments of those animals in order to prevent the introduction of certain diseases, including spring viraemia of carp (SVC), provided that the Member States have either demonstrated that they, or certain demarcated areas, are free of the disease in question ('disease-free areas') or that they have established an eradication programme to obtain such freedom.

(6) 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

Annexes I and II to Decision 2010/221/EU are replaced by the text in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

(2) Annex I to Decision 2010/221/EU lists the disease-free areas and Annex II thereto lists the areas with approved eradication programmes.

Done at Brussels, 7 December 2010.

(3) Annex II to Decision 2010/221/EU currently lists Great Britain as an area of the United Kingdom with approved eradication programme for SVC. That Member State has now submitted information demonstrating that its eradication programme has been successfully completed and that Great Britain should be regarded as free of SVC and

For the Commission

John DALLI

Member of the Commission

⁽¹⁾ OJ L 328, 24.11.2006, p. 14.

⁽²⁾ OJ L 98, 20.4.2010, p. 7.

ANNEX

Annexes I and II to Decision 2010/221/EU are replaced by the following:

‘ANNEX I

Member States and areas regarded as being free of the diseases listed in the table and approved to take national measures to prevent the introduction of those diseases in accordance with Article 43(2) of Directive 2006/88/EC

Disease	Member State	Code	Geographical demarcation of the area with approved national measures
Spring viraemia of carp (SVC)	Denmark	DK	Whole territory
	Ireland	IE	Whole territory
	Hungary	HU	Whole territory
	Finland	FI	Whole territory
	Sweden	SE	Whole territory
	United Kingdom	UK	The whole territory of the United Kingdom; the territories of Guernsey, Jersey and the Isle of Man
Bacterial kidney disease (BKD)	Ireland	IE	Whole territory
	United Kingdom	UK	The territory of Northern Ireland; the territories of Jersey and the Isle of Man.
Infectious pancreatic necrosis virus (IPN)	Finland	FI	The continental parts of the territory
	Sweden	SE	The continental parts of the territory
	United Kingdom	UK	The territory of the Isle of Man
Infection with <i>Gyrodactylus salaris</i> (GS)	Ireland	IE	The whole territory
	Finland	FI	The water catchment areas of the Tenojoki and Nääämönjoki; the water catchment areas of the Paatsjoki, Luttojoki, and Uutuanjoki are considered as buffer zones.
	United Kingdom	UK	The whole territory of the United Kingdom; the territories of Guernsey, Jersey and the Isle of Man

ANNEX II

Member States and areas with eradication programmes as regards certain diseases in aquaculture animals, and approved to take national measures to control those diseases in accordance with Article 43(2) of Directive 2006/88/EC

Disease	Member State	Code	Geographical demarcation of the area with approved national measures
Bacterial kidney disease (BKD)	Finland	FI	The continental parts of the territory
	Sweden	SE	The continental parts of the territory
	United Kingdom	UK	The territory of Great Britain
Infectious pancreatic necrosis virus (IPN)	Sweden	SE	The coastal parts of the territory'

CORRIGENDA**Corrigendum to Commission Directive 2010/89/EU of 6 November 2010 amending Council Directive 91/414/EEC to include quinmerac as active substance and amending Decision 2008/934/EC**

(Official Journal of the European Union L 320 of 7 December 2010)

In the title on the cover page and on page 3, and in the signature on page 5:

for: '6 November 2010',

read: '6 December 2010'.

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- ★ **Commission Directive 2010/90/EU of 7 December 2010 amending Council Directive 91/414/EEC to include pyridaben as active substance and amending Decision 2008/934/EC ⁽¹⁾** 38

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⁽¹⁾ Text with EEA relevance

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