

# Official Journal

## of the European Union

L 104



English edition

Legislation

Volume 53

24 April 2010

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Price: EUR 4

(Continued overleaf)

<sup>(1)</sup> Text with EEA relevance

EN

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

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<sup>(1)</sup> Text with EEA relevance

## II

*(Non-legislative acts)*

## REGULATIONS

## COMMISSION REGULATION (EU) No 346/2010

of 15 April 2010

**amending Regulation (EC) No 1251/2008 as regards the placing on the market and import requirements for consignments of aquaculture animals intended for Member States or parts thereof with national measures approved by Decision 2010/221/EU**

*(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<sup>(1)</sup>, and in particular Article 25 and Article 61(3) thereof,

Whereas:

- (1) Commission Decision 2010/221/EU 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<sup>(2)</sup> allows certain Member States to impose requirements on the introduction into their territories or parts thereof of consignments of certain aquaculture animals in order to prevent the introduction of or to control spring viraemia of carp (SVC), bacterial kidney disease (BKD), infectious pancreatic necrosis virus (IPN) and infection with *Gyrodactylus salaris* (GS). That Decision replaces Commission Decision 2004/453/EC of 29 April 2004 implementing Council Directive 91/67/EEC as regards measures against certain diseases in aquaculture animals<sup>(3)</sup>.
- (2) To prevent the introduction of or to control the spread of those diseases, consignments of aquaculture animals intended for farming, relaying areas, put and take fisheries, open ornamental facilities, or restocking introduced into a Member State or part thereof listed in Annexes I and II to Decision 2010/221/EU of species susceptible to the diseases for which the

Member State or part thereof is regarded as disease-free or for which it has an eradication programme, should originate from an area with an equivalent health status.

- (3) To ensure that those requirements are complied with, such consignments should be accompanied by an animal health certificate providing the necessary attestations.
- (4) For movements of aquaculture animals within the European Union (placing on the market), specific animal health certificates are laid down in Decision 2004/453/EC. In the interest of simplification of Union legislation, the necessary animal health conditions as regards the diseases covered by the approved national measures should now be included in the animal health certificates for placing on the market laid down in 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<sup>(4)</sup>. Annex II to that Regulation should therefore be amended accordingly.
- (5) The relevant model animal health certificates for imports of aquaculture animals into the Union, laid down in Regulation (EC) No 1251/2008 already include attestations as regards those diseases. However, those attestations should be amended to take account of the principles for imports of aquaculture animals laid down in Directive 2006/88/EC and the Aquatic Animal Health Code of the World Organisation for Animal Health (OIE). Annex IV to that Regulation should therefore be amended accordingly.

<sup>(1)</sup> OJ L 328, 24.11.2006, p. 14.

<sup>(2)</sup> OJ L 98, 20.4.2010, p. 7.

<sup>(3)</sup> OJ L 202, 7.6.2004, p. 4.

<sup>(4)</sup> OJ L 337, 16.12.2008, p. 41.

- (6) The placing on the market and import requirements for consignments of aquaculture animals intended for Member States and parts thereof with national measures approved by Decision 2010/221/EU should only apply to species susceptible to the relevant diseases. Consequently, a list of species susceptible to those diseases should be set out in Annex II to Regulation (EC) No 1251/2008.
- (7) However, as fish of any species that are present in waters where fish of species infected with GS are present, may spread that disease, the placing on the market and import requirements related to GS should also apply to consignments of fish of any species introduced into Member States or parts thereof listed in Decision 2010/221/EU as free of that disease.
- (8) As the model animal health certificates laid down in Regulation (EC) No 1251/2008, as amended by this Regulation, cover all the national measures approved in accordance with Article 43 of Directive 2006/88/EC and Decision 2004/453/EC is repealed by Decision 2010/221/EU, Article 18 of Regulation (EC) No 1251/2008 should be deleted.
- (9) It is appropriate to provide for transitional measures to allow Member States and the industry to take the necessary measures to comply with the requirements laid down in this Regulation.
- (10) To ensure that animal health certificates are correctly issued in those cases where certain statements of the model animal health certificates set out in Regulation (EC) No 1251/2008 are not relevant and in those cases where they consist of more than one sheet of paper, further clarification should be provided for in the explanatory notes. Annex V to that Regulation should therefore be amended accordingly.
- (11) Regulation (EC) No 1251/2008 should therefore be amended accordingly.
- (12) 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

Regulation (EC) No 1251/2008 is amended as follows:

#### 1. In Article 1, point (b) is replaced by the following:

‘(b) animal health conditions for the placing on the market of:

- (i) ornamental aquatic animals either originating from or intended for closed ornamental facilities; and
- (ii) aquaculture animals intended for farming, relaying areas, put and take fisheries, open ornamental

facilities and restocking in Member States and parts thereof with national measures approved by Commission Decision 2010/221/EU (\*);

(\*) OJ L 98, 20.4.2010, p. 7.’

#### 2. The following Article 8a is inserted:

##### ‘Article 8a

**Aquaculture animals intended for farming, relaying areas, put and take fisheries, open ornamental facilities and restocking in Member States and parts thereof with national measures approved by Decision 2010/221/EU**

1. Consignments of aquaculture animals intended for farming, relaying areas, put and take fisheries, open ornamental facilities, or restocking shall be accompanied by an animal health certificate completed in accordance with the model set out in Part A of Annex II and the explanatory notes set out in Annex V, where the animals:

- (a) are introduced into Member States or parts thereof listed in the second and fourth column of the table set out in:
  - (i) Annex I to Decision 2010/221/EU as free of one or more of the diseases listed in the first column of that table; or
  - (ii) Annex II to Decision 2010/221/EU as subject to an eradication programme for one or more of the diseases listed in the first column of that table;
- (b) are of species which are listed in Part C of Annex II as species susceptible to the diseases, for which the Member State concerned or part thereof is regarded as disease-free, or for which an eradication programme applies in accordance with Decision 2010/221/EU, as referred to in point (a).

2. Consignments of animals referred to in paragraph 1 shall comply with the animal health requirements set out in the model animal health certificate and explanatory notes as referred to in paragraph 1.

3. Paragraph 1 and 2 shall apply to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with *Gyrodactylus salaris*, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of *Gyrodactylus salaris* (GS).’

#### 3. Article 18 is deleted.

#### 4. Annexes II, IV and V are amended in accordance with the Annex to this Regulation.

*Article 2***Transitional provisions**

1. For a transitional period until 31 July 2010, consignments of aquaculture animals accompanied by animal health certificates issued in accordance with Parts A or 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.

2. For a transitional period until 31 July 2011, consignments of aquaculture animals accompanied by animal health certificates issued in accordance with Part A or 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 provided that the animal health attestations as regards spring viraemia of carp (SVC), bacterial kidney disease (BKD), infectious pancreatic necrosis virus (IPN) and Infection with *Gyrodactylus salaris* (GS) set out in Part II of those certificates are not applicable.

*Article 3***Entry into force and applicability**

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

It shall apply from 15 May 2010.

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

Done at Brussels, 15 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX

Annexes II, IV and V are amended as follows:

(1) Annex II is amended as follows:

(a) Part A is replaced by the following:

## PART A

**Model animal health certificate for the placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking**

## EUROPEAN UNION

## Intra trade certificate

|                                                                                                                                                 |                                                                                                                                                                                                                                                                    |                                                                                                                                                  |                                                                                                                                                                            |                                |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------|
| Part I: Details of consignment presented                                                                                                        | I.1. Consignor<br>Name<br>Address<br>Postal code                                                                                                                                                                                                                   |                                                                                                                                                  | I.2. Certificate reference number                                                                                                                                          | I.2.a. Local reference number: |          |
|                                                                                                                                                 |                                                                                                                                                                                                                                                                    |                                                                                                                                                  | I.3. Central Competent Authority                                                                                                                                           |                                |          |
|                                                                                                                                                 |                                                                                                                                                                                                                                                                    |                                                                                                                                                  | I.4. Local Competent Authority                                                                                                                                             |                                |          |
|                                                                                                                                                 | I.5. Consignee<br>Name<br>Address<br>Postal code                                                                                                                                                                                                                   |                                                                                                                                                  | I.6.                                                                                                                                                                       |                                |          |
|                                                                                                                                                 |                                                                                                                                                                                                                                                                    |                                                                                                                                                  | I.7.                                                                                                                                                                       |                                |          |
|                                                                                                                                                 | I.8. Country of origin                                                                                                                                                                                                                                             | ISO code                                                                                                                                         | I.9.                                                                                                                                                                       | I.10. Country of destination   | ISO code |
|                                                                                                                                                 |                                                                                                                                                                                                                                                                    |                                                                                                                                                  | I.11.                                                                                                                                                                      |                                |          |
|                                                                                                                                                 | I.12. Place of origin/Place of harvest<br>Approved aquaculture holding <input type="checkbox"/><br>Other <input type="checkbox"/><br>Name<br>Address<br>Postal code<br>Approval number                                                                             |                                                                                                                                                  | I.13. Place of destination<br>Approved aquaculture holding <input type="checkbox"/><br>Other <input type="checkbox"/><br>Name<br>Address<br>Postal code<br>Approval number |                                |          |
|                                                                                                                                                 | I.14. Place of loading<br>Postal code                                                                                                                                                                                                                              |                                                                                                                                                  | I.15. Date and time of departure                                                                                                                                           |                                |          |
|                                                                                                                                                 | I.16. Means of transport<br>Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/><br>Road vehicle <input type="checkbox"/> Other <input type="checkbox"/><br>Identification:                                     |                                                                                                                                                  | I.17. Transporter<br>Name<br>Address<br>Postal code<br>Approval number<br>Member State                                                                                     |                                |          |
|                                                                                                                                                 | I.18. Animal species/product                                                                                                                                                                                                                                       |                                                                                                                                                  | I.19. Commodity code (CN code)                                                                                                                                             |                                |          |
|                                                                                                                                                 |                                                                                                                                                                                                                                                                    |                                                                                                                                                  | I.20. Number/quantity                                                                                                                                                      |                                |          |
|                                                                                                                                                 | I.21.                                                                                                                                                                                                                                                              |                                                                                                                                                  | I.22. Number of packages                                                                                                                                                   |                                |          |
|                                                                                                                                                 | I.23. Identification of container/seal number                                                                                                                                                                                                                      |                                                                                                                                                  | I.24. Type of packaging                                                                                                                                                    |                                |          |
|                                                                                                                                                 | I.25. Animals certified as/products certified for<br>Breeding <input type="checkbox"/> Game restocking <input type="checkbox"/> Relaying <input type="checkbox"/> Pets <input type="checkbox"/> Quarantine <input type="checkbox"/> Other <input type="checkbox"/> |                                                                                                                                                  |                                                                                                                                                                            |                                |          |
| I.26. Transit through third country <input type="checkbox"/><br>Third country<br>Exit point<br>Entry point<br>ISO code<br>Code<br>BIP unit no.: |                                                                                                                                                                                                                                                                    | I.27. Transit through Member States <input type="checkbox"/><br>Member State<br>Member State<br>Member State<br>ISO code<br>ISO code<br>ISO code |                                                                                                                                                                            |                                |          |
| I.28. Export <input type="checkbox"/><br>Third country<br>Exit point<br>ISO code<br>Code                                                        |                                                                                                                                                                                                                                                                    | I.29.                                                                                                                                            |                                                                                                                                                                            |                                |          |
| I.30.                                                                                                                                           |                                                                                                                                                                                                                                                                    |                                                                                                                                                  |                                                                                                                                                                            |                                |          |
| I.31. Identification of the animals<br>Species (Scientific name) Quantity                                                                       |                                                                                                                                                                                                                                                                    |                                                                                                                                                  |                                                                                                                                                                            |                                |          |

| EUROPEAN UNION                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking                                                                                                                                          |                              |
|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|                                                  | II. Health attestation                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | II.a. Certificate reference number                                                                                                                                                                                                                                             | II.b. Local reference number |
| Part II: Certification                           | <b>II.1 General requirements</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                |                              |
|                                                  | I, the undersigned official inspector, hereby certify that the aquaculture animals referred to in Part I of this certificate:                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                |                              |
|                                                  | II.1.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <i>either</i> <sup>(1)</sup> [have been inspected within <sup>(1)(2)</sup> [72] <sup>(2)</sup> [24] hours of loading, and showed no clinical signs of disease;]                                                                                                                |                              |
|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <i>or</i> <sup>(1)</sup> [in the case of eggs and molluscs, come from a farm or mollusc farming area where, according to the records of the farm or mollusc farming area, there is no indication of disease problems;]                                                         |                              |
|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <i>or</i> <sup>(1)(3)</sup> [in the case of wild aquatic animals, according to the best of my knowledge and belief are clinically healthy;]                                                                                                                                    |                              |
|                                                  | II.1.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | are not subject to any prohibitions due to unresolved increased mortality;                                                                                                                                                                                                     |                              |
|                                                  | II.1.3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | are not intended for destruction or slaughter for the eradication of diseases;                                                                                                                                                                                                 |                              |
|                                                  | II.1.4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | comply with the requirements for placing on the market laid down in Directive 2006/88/EC;                                                                                                                                                                                      |                              |
|                                                  | II.1.5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <sup>(1)</sup> [in the case of molluscs, were subject to an individual visual check of each part of the consignment, and no molluscs species other than those specified in Part I of the certificate were detected.]                                                           |                              |
|                                                  | <b>II.2</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b><sup>(1)(4)(5)</sup>[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease]</b> |                              |
|                                                  | I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                |                              |
|                                                  | <i>either</i> <sup>(1)(6)</sup> [originate from a Member State, zone or compartment declared free from <sup>(1)</sup> [VHS] <sup>(1)</sup> [IHN] <sup>(1)</sup> [ISA] <sup>(1)</sup> [KHV] <sup>(1)</sup> [Marteilia refringens] <sup>(1)</sup> [Bonamia ostreae] <sup>(1)</sup> [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC.]                                                                                                                                       |                                                                                                                                                                                                                                                                                |                              |
|                                                  | <i>or</i> <sup>(1)(5)(6)</sup> [in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                |                              |
| <b>II.3</b>                                      | <b><sup>(1)(7)</sup>[Requirements for vector species to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease]</b>                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                |                              |
|                                                  | I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above which are to be regarded as possible vectors to <sup>(1)</sup> [VHS] <sup>(1)</sup> [IHN] <sup>(1)</sup> [ISA] <sup>(1)</sup> [KHV] <sup>(1)</sup> [Marteilia refringens] <sup>(1)</sup> [Bonamia ostreae] <sup>(1)</sup> [White spot disease] as they are of species listed in Column 2 and fulfil the conditions set out in Column 3 of the table in Annex I to Regulation (EC) No 1251/2008: |                                                                                                                                                                                                                                                                                |                              |
|                                                  | <i>either</i> <sup>(1)(6)</sup> [originate from a Member State, zone or compartment declared free from <sup>(1)</sup> [VHS] <sup>(1)</sup> [IHN] <sup>(1)</sup> [ISA] <sup>(1)</sup> [KHV] <sup>(1)</sup> [Marteilia refringens] <sup>(1)</sup> [Bonamia ostreae] <sup>(1)</sup> [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC.]                                                                                                                                       |                                                                                                                                                                                                                                                                                |                              |
|                                                  | <i>or</i> <sup>(1)(6)(7)</sup> [have been subject to quarantine in accordance with Decision 2008/946/EC.]]                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                |                              |
| <b>II.4 Transport and labelling requirements</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                |                              |
|                                                  | I, the undersigned official inspector, hereby certify that:                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                |                              |
| II.4.1                                           | the aquaculture animals referred to above,                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                |                              |
|                                                  | (i) are placed under conditions, including with a water quality, that do not alter their health status,                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                |                              |
|                                                  | (ii) as appropriate, comply with the general conditions for the transport of animals laid down in Article 3 of Regulation (EC) No 1/2005;                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                |                              |

| EUROPEAN UNION |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking |                              |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| II.            | Health attestation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | II.a. Certificate reference number                                                                                                    | II.b. Local reference number |
| II.4.2         | the transport container or well boat prior to loading is clean and disinfected or previously unused; and                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                       |                              |
| II.4.3         | the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement:<br><br><i>either</i> <sup>(1)</sup> [" <sup>(1)</sup> [Wild] <sup>(1)</sup> [Fish] <sup>(1)</sup> [Molluscs] <sup>(1)</sup> [Crustaceans] intended for farming in the European Union"],<br><br><i>or</i> <sup>(1)</sup> [" <sup>(1)</sup> [Wild] <sup>(1)</sup> [Molluscs] intended for relaying in the European Union"],<br><br><i>or</i> <sup>(1)</sup> [" <sup>(1)</sup> [Wild] <sup>(1)</sup> [Fish] <sup>(1)</sup> [Molluscs] <sup>(1)</sup> [Crustaceans] intended for put and take fisheries in the European Union"],<br><br><i>or</i> <sup>(1)</sup> [" <sup>(1)</sup> [Wild] <sup>(1)</sup> [Ornamental fish] <sup>(1)</sup> [Ornamental molluscs] <sup>(1)</sup> [Ornamental crustaceans] intended for open ornamental facilities in the European Union"],<br><br><i>or</i> <sup>(1)</sup> [" <sup>(1)</sup> [Fish] <sup>(1)</sup> [Molluscs] <sup>(1)</sup> [Crustaceans] intended for restocking in the European Union"],<br><br><i>or</i> <sup>(1)</sup> [" <sup>(1)</sup> [Wild] <sup>(1)</sup> [Fish] <sup>(1)</sup> [Molluscs] <sup>(1)</sup> [Crustaceans] intended for quarantine in the European Union"],                                                                                                                                                                                                                                                           |                                                                                                                                       |                              |
| II.5           | <sup>(1)(8)</sup> <b>[Attestation for consignments originating from an area subject to disease control measures as provided for in Section 3 to 6 of Chapter V of Directive 2006/88/EC]</b><br><br>I, the undersigned official inspector, hereby certify that:<br><br>II.5.1 the animals referred to above originate from an area subject to disease control measures regarding <sup>(1)</sup> [Epizootic ulcerative syndrome (EUS)] <sup>(1)</sup> [Epizootic haematopoietic necrosis (EHN)] <sup>(1)</sup> [Viral haemorrhagic septicaemia (VHS)] <sup>(1)</sup> [Infectious haematopoietic necrosis (IHN)] <sup>(1)</sup> [Infectious salmon anaemia (ISA)] <sup>(1)</sup> [Koi herpes virus (KHV)] <sup>(1)</sup> [Bonamia exitiosa] <sup>(1)</sup> [Perkinsus marinus] <sup>(1)</sup> [Mikrocytos mackini] <sup>(1)</sup> [Martellia refringens] <sup>(1)</sup> [Bonamia ostreae] <sup>(1)</sup> [Taura syndrome] <sup>(1)</sup> [Yellowhead disease] <sup>(1)</sup> [White spot disease] <sup>(1)(9)</sup> [the following emerging disease .....];<br><br>II.5.2 the animals referred to above are allowed to be placed on the market according to the control measures laid down; and<br><br>II.5.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.8 to I.13 of Part I of this certificate, and the following statement:<br><br>" <sup>(1)</sup> [Wild] <sup>(1)</sup> [Fish] <sup>(1)</sup> [Molluscs] <sup>(1)</sup> [Crustaceans] originating from an area subject to disease control measures".] |                                                                                                                                       |                              |
| II.6           | <sup>(1)(10)</sup> <b>[Requirements for species susceptible to Spring vireamia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN) and Infection with <i>Gyrodactylus salaris</i> (GS)]</b><br><br>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,<br><br><i>either</i> <sup>(1)</sup> [originate from a Member State or part thereof:<br><br>(a) where <sup>(1)</sup> [SVC] <sup>(1)</sup> [GS] <sup>(1)</sup> [BKD] <sup>(1)</sup> [IPN] are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,<br><br>(b) where all aquaculture animals of species susceptible to the relevant disease(s) introduced into that Member State or part thereof comply with the requirements set out in II.6 of this certificate,<br><br>(c) where species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s), and                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                       |                              |

## EUROPEAN UNION

## Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking

| II. Health attestation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | II.a. Certificate reference number | II.b. Local reference number |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------|
| <p>(d) <i>either</i> <sup>(1)</sup>[which, in the case of <sup>(1)</sup>[IPN] <sup>(1)</sup>[BKD], complies with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC.]</p> <p><i>and/or</i> <sup>(1)</sup>[which, in the case of <sup>(1)</sup>[SVC] <sup>(1)</sup>[GS], complies with requirements for disease freedom laid down in the relevant OIE Standard.]</p> <p><i>and/or</i> <sup>(1)</sup>[which, in the case of <sup>(1)</sup>[SVC] <sup>(1)</sup>[IPN] <sup>(1)</sup>[BKD], comprises one individual farm which under the supervision of the competent authority:</p> <p style="padding-left: 40px;">(i) has been emptied, cleansed and disinfected, and fallowed in at least 6 weeks,</p> <p style="padding-left: 40px;">(ii) has been restocked with animals from areas certified free from the relevant disease by the competent authority.]]</p> <p><i>and/or</i> <sup>(1)</sup>[in the case of wild aquatic animals susceptible to <sup>(1)</sup>[SVC] <sup>(1)</sup>[IPN] <sup>(1)</sup>[BKD], have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]</p> <p><i>and/or</i> <sup>(1)</sup>[in the case of consignments for which GS requirements apply, have been held, immediately prior to the placing on the market, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days and no other live aquatic animals of the species susceptible to GS have been introduced during that period.]</p> <p><i>and/or</i> <sup>(1)</sup>[in the case of eyed fish eggs for which GS requirements apply, have been disinfected by a method demonstrated to be effective against GS.]]</p> |                                    |                              |
| <b>Notes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                    |                              |
| <b>Part I:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                    |                              |
| <p>— Box I.12: If appropriate, use the authorisation number for the farm or mollusc farming area in question. Use “other” if wild aquatic animals.</p> <p>— Box I.13: If appropriate, use the authorisation number for the farm or mollusc farming area in question. Use “other” if intended for restocking.</p> <p>— Box I.19: Use the appropriate HS codes: 0301, 0306, 0307, 030110 or 030270.</p> <p>— Box I.20 and I.31: As regards quantity, give the total number.</p> <p>— Box I.25: Use the option “Breeding” if intended for farming, “Relaying” if intended for relaying, “Pets” if intended for open ornamental facilities, “Game restocking” if intended for restocking, “Quarantine” if the aquaculture animals are intended for a quarantine facility, and “Other” if intended for put and take fisheries.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                    |                              |
| <b>Part II:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                    |                              |
| <p>(1) Keep as appropriate.</p> <p>(2) The 24-hour option applies only to consignments of aquaculture animals which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive. In all other cases the 72-hour option applies.</p> <p>(3) Only applicable to consignments of aquaculture animals caught in the wild and immediately transported to a farm or mollusc farming area without any temporary storage.</p> <p>(4) Part II.2 of this certificate applies to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                    |                              |

**Placing on the market of aquaculture animals for farming, relaying, put and take fisheries, open ornamental facilities and restocking**

**EUROPEAN UNION**

| II. Health attestation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | II.a. Certificate reference number | II.b. Local reference number |                            |                          |                        |                        |       |            |        |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------|----------------------------|--------------------------|------------------------|------------------------|-------|------------|--------|--|
| <p>(5) Consignments of wild aquatic animals may be placed on the market regardless of the requirements in Part II.2 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> <p>(6) To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, <i>Marteilia refringens</i>, <i>Bonamia ostreae</i>, or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain susceptible or vector species to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Union are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a></p> <p>(7) Part II.3 of this certificate applies to vector species to one or more of the diseases referred to in the title. Possible vector species and the conditions, under which consignments of such species are to be considered vector species, are listed in Annex I to Regulation (EC) No 1251/2008. Consignments of possible vector species may be placed on the market regardless of the requirements in Part II.3 if the conditions set out in Column 4 of the table in Annex I to Regulation (EC) No 1251/2008 are not fulfilled or they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> <p>(8) Part II.5 of this certificate applies to consignments of aquaculture animals which according to Article 8 of Regulation (EC) No 1251/2008 must be accompanied by a certificate and which in compliance with the placing on the market requirements of Directive 2006/88/EC are allowed by the competent authority to leave an area subject to control provisions provided for in Sections 3 to 6 of Chapter V of Directive 2006/88/EC or a Member State, zone or compartment with an eradication programme approved in accordance with Article 44(2) of that Directive.</p> <p>(9) Applicable when measures are taken in accordance with Article 41 of Directive 2006/88/EC.</p> <p>(10) Part II.6 of this certificate only applies to consignments intended for a Member State or part thereof which is regarded as disease-free, or for which a programme is approved by Decision 2010/221/EU as regards SVC, BKD, IPN or GS, and the consignment comprises species listed in Part C of Annex II as susceptible to the disease(s) for which the disease-free status or programme(s) apply(ies).</p> <p>Part II.6 shall also apply to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with GS, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of GS.</p> <p>Consignments of wild aquatic animals for which SVC, IPN and/or BKD related requirements are applicable, may be placed on the market regardless of the requirements in Part II.6 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> |                                    |                              |                            |                          |                        |                        |       |            |        |  |
| <p>Official inspector</p> <table border="0"> <tr> <td>Name (in capital letters):</td> <td>Qualification and title:</td> </tr> <tr> <td>Local Veterinary Unit:</td> <td>N° of the related LVU:</td> </tr> <tr> <td>Date:</td> <td>Signature:</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                    |                              | Name (in capital letters): | Qualification and title: | Local Veterinary Unit: | N° of the related LVU: | Date: | Signature: | Stamp: |  |
| Name (in capital letters):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Qualification and title:           |                              |                            |                          |                        |                        |       |            |        |  |
| Local Veterinary Unit:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | N° of the related LVU:             |                              |                            |                          |                        |                        |       |            |        |  |
| Date:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Signature:                         |                              |                            |                          |                        |                        |       |            |        |  |
| Stamp:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                    |                              |                            |                          |                        |                        |       |            |        |  |

(b) the following Part C is added:

PART C

**List of species susceptible to diseases for which national measures are approved under Decision 2010/221/EU**

| Disease                                    | Susceptible species                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Spring Viraemia of Carp (SVC)              | Bighead carp ( <i>Aristichthys nobilis</i> ), goldfish ( <i>Carassius auratus</i> ), crucian carp ( <i>Carassius carassius</i> ), grass carp ( <i>Ctenopharyngodon idellus</i> ), common carp and koi carp ( <i>Cyprinus carpio</i> ), silver carp ( <i>Hypophthalmichthys molitrix</i> ), sheatfish ( <i>Silurus glanis</i> ), and tench ( <i>Tinca tinca</i> ), Orfe ( <i>Leuciscus idus</i> ) |
| Bacterial kidney disease (BKD)             | Family: <i>Salmonidae</i>                                                                                                                                                                                                                                                                                                                                                                        |
| Infectious pancreatic necrosis virus (IPN) | Rainbow trout ( <i>Oncorhynchus mykiss</i> ), brook trout ( <i>Salvelinus fontinalis</i> ), brown trout ( <i>Salmo trutta</i> ), Atlantic salmon ( <i>Salmo salar</i> ), and Pacific salmon ( <i>Oncorhynchus spp.</i> ) and whitefish ( <i>Coregonus lavaretus</i> )                                                                                                                            |
| Infection with <i>Gyrodactylus salaris</i> | Atlantic salmon ( <i>Salmo salar</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> ), Arctic char ( <i>Salvelinus alpinus</i> ), North American brook trout ( <i>Salvelinus fontinalis</i> ), grayling ( <i>Thymallus thymallus</i> ), North American lake trout ( <i>Salvelinus namaycush</i> ) and brown trout ( <i>Salmo trutta</i> ).                                                        |

(2) Annex IV is amended as follows:

(a) Part A is replaced by the following:

**PART A**

**Model animal health certificate for the import into the European Union of aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities**

| COUNTRY                                                                                                                                |                        |                                |                                   | Veterinary certificate to EU                                   |                             |                   |                             |      |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------------|-----------------------------------|----------------------------------------------------------------|-----------------------------|-------------------|-----------------------------|------|
| Part I: Details of dispatched consignment                                                                                              | I.1. Consignor<br>Name |                                | I.2. Certificate reference number |                                                                | I.2.a.                      |                   |                             |      |
|                                                                                                                                        | Address                |                                | I.3. Central Competent Authority  |                                                                |                             |                   |                             |      |
|                                                                                                                                        | Tel. N°                |                                | I.4. Local Competent Authority    |                                                                |                             |                   |                             |      |
|                                                                                                                                        | I.5. Consignee<br>Name |                                | I.6.                              |                                                                |                             |                   |                             |      |
|                                                                                                                                        | Address                |                                |                                   |                                                                |                             |                   |                             |      |
|                                                                                                                                        | Postal code            |                                |                                   |                                                                |                             |                   |                             |      |
|                                                                                                                                        | Tel. N°                |                                |                                   |                                                                |                             |                   |                             |      |
|                                                                                                                                        | I.7. Country of origin | ISO code                       | I.8. Region of origin             | Code                                                           | I.9. Country of destination | ISO code          | I.10. Region of destination | Code |
|                                                                                                                                        | I.11. Place of origin  |                                |                                   |                                                                | I.12.                       |                   |                             |      |
|                                                                                                                                        | Name                   |                                | Approval number                   |                                                                |                             |                   |                             |      |
| Address                                                                                                                                |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Name                                                                                                                                   |                        | Approval number                |                                   |                                                                |                             |                   |                             |      |
| Address                                                                                                                                |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Name                                                                                                                                   |                        | Approval number                |                                   |                                                                |                             |                   |                             |      |
| Address                                                                                                                                |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.13. Place of loading                                                                                                                 |                        | Approval number                |                                   | I.14. Date of departure                                        |                             | time of departure |                             |      |
| Address                                                                                                                                |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.15. Means of transport                                                                                                               |                        |                                |                                   | I.16. Entry BIP in EU                                          |                             |                   |                             |      |
| Aeroplane <input type="checkbox"/>                                                                                                     |                        | Ship <input type="checkbox"/>  |                                   | Railway wagon <input type="checkbox"/>                         |                             |                   |                             |      |
| Road vehicle <input type="checkbox"/>                                                                                                  |                        | Other <input type="checkbox"/> |                                   |                                                                |                             |                   |                             |      |
| Identification:                                                                                                                        |                        |                                |                                   | I.17. No.(s) of CITES                                          |                             |                   |                             |      |
| Documentary references:                                                                                                                |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.18. Description of commodity                                                                                                         |                        |                                |                                   | I.19. Commodity code (HS code)                                 |                             |                   |                             |      |
|                                                                                                                                        |                        |                                |                                   | I.20. Quantity                                                 |                             |                   |                             |      |
| I.21.                                                                                                                                  |                        |                                |                                   | I.22. Number of packages                                       |                             |                   |                             |      |
| I.23. Identification of container/seal number                                                                                          |                        |                                |                                   | I.24.                                                          |                             |                   |                             |      |
| I.25. Commodities certified for:                                                                                                       |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Breeding <input type="checkbox"/> Quarantine <input type="checkbox"/> Relaying <input type="checkbox"/> Other <input type="checkbox"/> |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Pets <input type="checkbox"/> Circus/exhibition <input type="checkbox"/>                                                               |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.26.                                                                                                                                  |                        |                                |                                   | I.27. For import or admission into EU <input type="checkbox"/> |                             |                   |                             |      |
| I.28. Identification of the commodities                                                                                                |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Species (Scientific name)                                                                                                              |                        |                                |                                   | Quantity                                                       |                             |                   |                             |      |

| COUNTRY                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities |       |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------|
| II.                    | Health information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | II.a. Certificate reference number                                                               | II.b. |
| Part II: Certification | <b>II.1 General requirements</b><br><br>I, the undersigned official inspector, hereby certify that the aquaculture animals, referred to in Part I of this certificate:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                  |       |
|                        | II.1.1 have been inspected within 72 hours of loading, and showed no clinical signs of disease;<br><br>II.1.2 are not subject to any prohibitions due to unresolved increased mortality;<br><br>II.1.3 are not intended for destruction or slaughter for the eradication of diseases; and<br><br>II.1.4 originate from aquaculture farms who are all under the supervision of the competent authority;<br><br>II.1.5 <sup>(1)</sup> [in the case of molluscs, were subject to an individual visual check of each part of the consignment, and no molluscs species other than those specified in Part I of the certificate were detected.]                                                                                                                                               |                                                                                                  |       |
|                        | <b>II.2 <sup>(1)(2)(3)</sup>[Requirements for species susceptible to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Bonamia exitiosa, Perkinsus marinus, Mikrocystos mackini, Taura syndrome and/or Yellowhead disease]</b><br><br>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                  |       |
|                        | <i>either</i> <sup>(1)(5)</sup> [originate from a country/territory, zone or compartment declared free from <sup>(1)</sup> [EUS] <sup>(1)</sup> [EHN] <sup>(1)</sup> [Bonamia exitiosa] <sup>(1)</sup> [Perkinsus marinus] <sup>(1)</sup> [Mikrocystos mackini] <sup>(1)</sup> [Taura syndrome] <sup>(1)</sup> [Yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and                                                                                                                                                                                                                                                                                                |                                                                                                  |       |
|                        | (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                  |       |
|                        | (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                  |       |
|                        | (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s);                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                  |       |
|                        | <i>or</i> <sup>(1)(3)(5)</sup> [in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                  |       |
|                        | <b>II.3 <sup>(1)(4)</sup>[Requirements for vector species to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Bonamia exitiosa, Perkinsus marinus, Mikrocystos mackini, Taura syndrome and/or Yellowhead disease]</b><br><br>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above which are to be regarded as possible vectors to <sup>(1)</sup> [EUS] <sup>(1)</sup> [EHN] <sup>(1)</sup> [Bonamia exitiosa] <sup>(1)</sup> [Perkinsus marinus] <sup>(1)</sup> [Mikrocystos mackini] <sup>(1)</sup> [Taura syndrome] <sup>(1)</sup> [Yellowhead disease] as they are of species listed in Column 2 and fulfil the conditions set out in Column 3 of the table in Annex I to Regulation (EC) No 1251/2008: |                                                                                                  |       |
|                        | <i>either</i> <sup>(1)(5)</sup> [originate from a country/territory, zone or compartment declared free from <sup>(1)</sup> [EUS] <sup>(1)</sup> [EHN] <sup>(1)</sup> [Bonamia exitiosa] <sup>(1)</sup> [Perkinsus marinus] <sup>(1)</sup> [Mikrocystos mackini] <sup>(1)</sup> [Taura syndrome] <sup>(1)</sup> [Yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and                                                                                                                                                                                                                                                                                                |                                                                                                  |       |
|                        | (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                  |       |
|                        | (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                  |       |
|                        | (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s);                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                  |       |
|                        | <i>or</i> <sup>(1)(5)</sup> [have been subject to quarantine in accordance with Decision 2008/946/EC.]]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                  |       |

| COUNTRY |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities |       |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------|
| II.     | Health information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | II.a. Certificate reference number                                                               | II.b. |
| II.4    | <p><sup>(1)(2)(3)</sup>[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), <i>Marteilia refringens</i>, <i>Bonamia ostreae</i>, and/or White spot disease]</p> <p>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above:</p> <p><i>either</i> <sup>(1)(6)</sup>[originate from a country/territory, zone or compartment declared free from <sup>(1)</sup>[VHS] <sup>(1)</sup>[IHN] <sup>(1)</sup>[ISA] <sup>(1)</sup>[KHV] <sup>(1)</sup>[<i>Marteilia refringens</i>] <sup>(1)</sup>[<i>Bonamia ostreae</i>] <sup>(1)</sup>[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and</p> <ul style="list-style-type: none"> <li>(i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority,</li> <li>(ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and</li> <li>(iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s)]</li> </ul> <p><i>or</i> <sup>(1)(3)(6)</sup>[in the case of wild aquatic animals, have been subject to quarantine in accordance with Decision 2008/946/EC.]]</p>                                                                                                                                                                                                                                                                                                                                                       |                                                                                                  |       |
| II.5    | <p><sup>(1)(4)</sup>[Requirements for vector species to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV), <i>Marteilia refringens</i>, <i>Bonamia ostreae</i>, and/or White spot disease]</p> <p>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above which are to be regarded as possible vectors to <sup>(1)</sup>[VHS] <sup>(1)</sup>[IHN] <sup>(1)</sup>[ISA] <sup>(1)</sup>[KHV] <sup>(1)</sup>[<i>Marteilia refringens</i>] <sup>(1)</sup>[<i>Bonamia ostreae</i>] <sup>(1)</sup>[White spot disease] as they are of species listed in Column 2 and fulfil the conditions set out in Column 3 of the table in Annex I to Regulation (EC) No 1251/2008:</p> <p><i>either</i> <sup>(1)(6)</sup>[originate from a country/territory, zone or compartment declared free from <sup>(1)</sup>[VHS] <sup>(1)</sup>[IHN] <sup>(1)</sup>[ISA] <sup>(1)</sup>[KHV] <sup>(1)</sup>[<i>Marteilia refringens</i>] <sup>(1)</sup>[<i>Bonamia ostreae</i>] <sup>(1)</sup>[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and</p> <ul style="list-style-type: none"> <li>(i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority,</li> <li>(ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and</li> <li>(iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s)]</li> </ul> <p><i>or</i> <sup>(1)(6)</sup>[have been subject to quarantine in accordance with Decision 2008/946/EC.]]</p> |                                                                                                  |       |
| II.6    | <p><b>Transport and labelling requirements</b></p> <p>I, the undersigned official inspector, hereby certify that:</p> <p>II.6.1 the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;</p> <p>II.6.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and</p> <p>II.6.3 the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.13 of Part I of this certificate, and the following statement:</p> <p><i>either</i> <sup>(1)</sup>["<sup>(1)</sup>[Wild] <sup>(1)</sup>[Fish] <sup>(1)</sup>[Molluscs] <sup>(1)</sup>[Crustaceans] intended for farming in the European Union"]</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                  |       |

| COUNTRY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities |       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------|
| II.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Health information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | II.a. Certificate reference number                                                               | II.b. |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>or <sup>(1)</sup>["<sup>(1)</sup>[Wild] <sup>(1)</sup>[Molluscs] intended for relaying in the European Union"],</p> <p>or <sup>(1)</sup>["<sup>(1)</sup>[Wild] <sup>(1)</sup>[Fish] <sup>(1)</sup>[Molluscs] <sup>(1)</sup>[Crustaceans] intended for put and take fisheries in the European Union"]</p> <p>or <sup>(1)</sup>["Ornamental <sup>(1)</sup>[fish] <sup>(1)</sup>[molluscs] <sup>(1)</sup>[crustaceans] intended for open ornamental facilities in the European Union"]</p> <p>or <sup>(1)</sup>(3)["<sup>(1)</sup>[Wild] <sup>(1)</sup>[Fish] <sup>(1)</sup>[Molluscs] <sup>(1)</sup>[Crustaceans] intended for quarantine in the European Union"].</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                  |       |
| <b>II.7</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p><sup>(1)</sup>(7)[Requirements for species susceptible to Spring vireamia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN) and Infection with <i>Gyrodactylus salaris</i> (GS)]</p> <p>I, the undersigned official inspector, hereby certify that the aquaculture animals referred to above,</p> <p>either <sup>(1)</sup>[originate from a country/territory or part thereof:</p> <p>(a) where <sup>(1)</sup>[SVC] <sup>(1)</sup>[GS] <sup>(1)</sup>[BKD] <sup>(1)</sup>[IPN] is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority,</p> <p>(b) where all aquaculture animals of species susceptible to the relevant disease(s) introduced into that country/territory or part thereof comply with the requirements set out in II.7 of this certificate,</p> <p>(c) where species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s), and</p> <p>(d) either <sup>(1)</sup>[which, in the case of <sup>(1)</sup>[IPN] <sup>(1)</sup>[BKD], complies with requirements for disease freedom equivalent to those laid down in Chapter VII of Directive 2006/88/EC.],</p> <p>and/or <sup>(1)</sup>[which, in the case of <sup>(1)</sup>[SVC] <sup>(1)</sup>[GS], complies with requirements for disease freedom laid down in the relevant OIE Standard.]</p> <p>and/or <sup>(1)</sup>[which, in the case of <sup>(1)</sup>[SVC] <sup>(1)</sup>[IPN] <sup>(1)</sup>[BKD], comprises one individual farm which under the supervision of the competent authority</p> <p>(i) has been emptied, cleansed and disinfected, and fallowed in at least 6 weeks,</p> <p>(ii) has been restocked with animals from areas certified free from the relevant disease by the competent authority.]]</p> <p>and/or <sup>(1)</sup>[in the case of wild aquatic animals susceptible to <sup>(1)</sup>[SVC] <sup>(1)</sup>[IPN] <sup>(1)</sup>[BKD], have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]</p> <p>and/or <sup>(1)</sup>[in the case consignments for which GS requirements apply, have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days and no other live aquatic animals of the species susceptible to GS have been introduced during that period.]</p> <p>and/or <sup>(1)</sup>[in the case of eyed fish eggs for which GS requirements apply, have been disinfected by a method demonstrated to be effective against GS.]]</p> |                                                                                                  |       |
| <p><b>Notes</b></p> <p><b>Part I:</b></p> <p>— Box I.19: Use the appropriate HS codes: 0301, 0306, 0307, 030110 or 030270.</p> <p>— Box I.20 and I.28: As regards quantity, give the total number.</p> <p>— Box I.25: Use the option "Breeding" if intended for farming, "Relaying" if intended for relaying, "Pets" for ornamental aquatic animals intended for pet shops or similar businesses for further sale, "Circus/exhibition" for ornamental aquatic animals intended for exhibition aquaria or similar businesses not for further sale, "Quarantine" if the aquaculture animals are intended for a quarantine facility, and "Other" if intended for put and take fisheries.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                  |       |

| COUNTRY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                    | Aquaculture animals for farming, relaying, put and take fisheries and open ornamental facilities |       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------|-------|
| II.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Health information | II.a. Certificate reference number                                                               | II.b. |
| <p><b>Part II:</b></p> <p>(1) Keep as appropriate.</p> <p>(2) Part II.2 and II.4 of this certificate only applies to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC.</p> <p>(3) Consignments of wild aquatic animals may be imported regardless of the requirements in Part II.2 and II.4 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> <p>(4) Part II.3 and II.5 of this certificate only applies to vector species to one or more of the diseases referred to in the title. Possible vector species and the conditions, under which consignments of such species are to be considered vector species, are listed in Annex I to Regulation (EC) No 1251/2008. Consignments of possible vector species may be imported regardless of the requirements in Parts II.3 and II.5 if the conditions set out in Column 4 of the table in Annex I to Regulation (EC) No 1251/2008 are not fulfilled or they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> <p>(5) To be authorised into the Union one of these statements must be kept if the consignments contain susceptible or vector species to EUS, EHN, Bonamia exitiosa, Perkinsus marinus, Mikrocytos mackini, Taura syndrome and/or Yellowhead disease.</p> <p>(6) To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, Marteilia refringens, Bonamia ostreae, or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain susceptible or vector species to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Union are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a></p> <p>(7) Part II.7 of this certificate only applies to consignments intended for a Member State or part thereof which is regarded as disease-free, or for which a programme is approved by Decision 2010/221/EU as regards SVC, BKD, IPN or GS, and the consignment comprises species listed in Part C of Annex II as susceptible to the disease(s) for which the disease-free status or programme(s) apply(ies).</p> <p>Part II.7 shall also apply to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with GS, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of GS.</p> <p>Consignments of wild aquatic animals for which SVC, IPN and/or BKD related requirements are applicable, may be imported regardless of the requirements in Part II.7 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> |                    |                                                                                                  |       |
| <p>Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                    |                                                                                                  |       |

(b) Part B is replaced by the following:

## PART B

**Model animal health certificate for the import into the European Union of ornamental aquatic animals intended for closed ornamental facilities****COUNTRY****Veterinary certificate to EU**

|                                                                                                              |                        |                                |                                   |                                                                |                             |                   |                             |      |
|--------------------------------------------------------------------------------------------------------------|------------------------|--------------------------------|-----------------------------------|----------------------------------------------------------------|-----------------------------|-------------------|-----------------------------|------|
| <b>Part I: Details of dispatched consignment</b>                                                             | I.1. Consignor<br>Name |                                | I.2. Certificate reference number |                                                                | I.2.a.                      |                   |                             |      |
|                                                                                                              | Address                |                                | I.3. Central Competent Authority  |                                                                |                             |                   |                             |      |
|                                                                                                              | Tel. N°                |                                | I.4. Local Competent Authority    |                                                                |                             |                   |                             |      |
|                                                                                                              | I.5. Consignee<br>Name |                                | I.6.                              |                                                                |                             |                   |                             |      |
|                                                                                                              | Address                |                                |                                   |                                                                |                             |                   |                             |      |
|                                                                                                              | Postal code            |                                |                                   |                                                                |                             |                   |                             |      |
|                                                                                                              | Tel. N°                |                                |                                   |                                                                |                             |                   |                             |      |
|                                                                                                              | I.7. Country of origin | ISO code                       | I.8. Region of origin             | Code                                                           | I.9. Country of destination | ISO code          | I.10. Region of destination | Code |
|                                                                                                              | I.11. Place of origin  |                                | Approval number                   |                                                                | I.12.                       |                   |                             |      |
|                                                                                                              | Name                   |                                | Approval number                   |                                                                |                             |                   |                             |      |
| Address                                                                                                      |                        | Approval number                |                                   |                                                                |                             |                   |                             |      |
| Name                                                                                                         |                        | Approval number                |                                   |                                                                |                             |                   |                             |      |
| Address                                                                                                      |                        | Approval number                |                                   |                                                                |                             |                   |                             |      |
| I.13. Place of loading                                                                                       |                        | Approval number                |                                   | I.14. Date of departure                                        |                             | time of departure |                             |      |
| Address                                                                                                      |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.15. Means of transport                                                                                     |                        | I.16. Entry BIP in EU          |                                   |                                                                |                             |                   |                             |      |
| Aeroplane <input type="checkbox"/>                                                                           |                        | Ship <input type="checkbox"/>  |                                   | Railway wagon <input type="checkbox"/>                         |                             |                   |                             |      |
| Road vehicle <input type="checkbox"/>                                                                        |                        | Other <input type="checkbox"/> |                                   |                                                                |                             |                   |                             |      |
| Identification:                                                                                              |                        | I.17. No.(s) of CITES          |                                   |                                                                |                             |                   |                             |      |
| Documentary references:                                                                                      |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.18. Description of commodity                                                                               |                        |                                |                                   | I.19. Commodity code (HS code)                                 |                             |                   |                             |      |
|                                                                                                              |                        |                                |                                   | I.20. Quantity                                                 |                             |                   |                             |      |
| I.21.                                                                                                        |                        |                                |                                   | I.22. Number of packages                                       |                             |                   |                             |      |
| I.23. Identification of container/seal number                                                                |                        |                                |                                   | I.24.                                                          |                             |                   |                             |      |
| I.25. Commodities certified for:                                                                             |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Pets <input type="checkbox"/> Quarantine <input type="checkbox"/> Circus/exhibition <input type="checkbox"/> |                        |                                |                                   |                                                                |                             |                   |                             |      |
| I.26.                                                                                                        |                        |                                |                                   | I.27. For import or admission into EU <input type="checkbox"/> |                             |                   |                             |      |
| I.28. Identification of the commodities                                                                      |                        |                                |                                   |                                                                |                             |                   |                             |      |
| Species (Scientific name)                                                                                    |                        |                                |                                   | Quantity                                                       |                             |                   |                             |      |

## COUNTRY

## Ornamental aquatic animals intended for closed ornamental facilities

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                         |                                    |       |  |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------|--|
| Part II: Certification | II.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Health information                                                                                                                                                      | II.a. Certificate reference number | II.b. |  |
|                        | II.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>General requirements</b><br><br>I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to in Part I of this certificate: |                                    |       |  |
|                        | II.1.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | have been inspected within 72 hours of loading, and showed no clinical signs of disease;                                                                                |                                    |       |  |
|                        | II.1.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | are not subject to any prohibitions due to unresolved increased mortality; and                                                                                          |                                    |       |  |
|                        | II.1.3                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | are not intended for destruction or slaughter for the eradication of diseases.                                                                                          |                                    |       |  |
| II.2                   | <sup>(1)(2)(3)(4)</sup> <b>Requirements for species susceptible to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Bonamia exitiosa, Perkinsus marinus, Mikrocystos mackini, Taura syndrome and/or Yellowhead disease</b><br><br>I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to above:                                                                                                          |                                                                                                                                                                         |                                    |       |  |
|                        | either <sup>(1)(5)</sup> [originate from a country/territory, zone or compartment declared free from <sup>(1)(3)</sup> [EUS] <sup>(1)</sup> [EHN] <sup>(1)</sup> [Bonamia exitiosa] <sup>(1)</sup> [Perkinsus marinus] <sup>(1)</sup> [Mikrocystos mackini] <sup>(1)</sup> [Taura syndrome] <sup>(1)</sup> [Yellowhead disease] in accordance with Chapter VII of Council Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and |                                                                                                                                                                         |                                    |       |  |
|                        | (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority;                                                                                                                                                                                                                                                                       |                                                                                                                                                                         |                                    |       |  |
|                        | (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s); and                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                         |                                    |       |  |
|                        | (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s);                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                         |                                    |       |  |
|                        | or <sup>(1)(4)(5)</sup> [have been subject to quarantine in accordance with Decision 2008/946/EC].]                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                         |                                    |       |  |
| II.3                   | <sup>(1)(2)(4)</sup> <b>Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Kol herpes virus (KHV), Marteilia refringens, Bonamia ostreae, and/or White spot disease</b><br><br>I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to above:                                                                                    |                                                                                                                                                                         |                                    |       |  |
|                        | either <sup>(1)(6)</sup> [originate from a country/territory, zone or compartment declared free from <sup>(1)</sup> [VHS] <sup>(1)</sup> [IHN] <sup>(1)</sup> [ISA] <sup>(1)</sup> [KHV] <sup>(1)</sup> [Marteilia refringens] <sup>(1)</sup> [Bonamia ostreae] <sup>(1)</sup> [White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of the country of origin, and                                     |                                                                                                                                                                         |                                    |       |  |
|                        | (i) where the relevant disease(s) is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority,                                                                                                                                                                                                                                                                       |                                                                                                                                                                         |                                    |       |  |
|                        | (ii) all introduction of species susceptible to the relevant disease(s) come from an area declared free of the disease(s), and                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                         |                                    |       |  |
|                        | (iii) species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s)]                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                         |                                    |       |  |
|                        | or <sup>(1)(4)(6)</sup> [have been subject to quarantine in accordance with Decision 2008/946/EC].]                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                         |                                    |       |  |
| II.4                   | <b>Transport and labelling requirements</b><br><br>I, the undersigned official inspector, hereby certify that:                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                         |                                    |       |  |
| II.4.1                 | the ornamental aquatic animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                         |                                    |       |  |
| II.4.2                 | the transport container is clean and disinfected or previously unused; and                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |                                    |       |  |

## COUNTRY

## Ornamental aquatic animals intended for closed ornamental facilities

| II.    | Health information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | II.a. Certificate reference number | II.b. |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------|
| II.4.3 | <p>the consignment is identified by a legible label on the exterior of the container with the relevant information referred to in boxes I.7 to I.13 of Part I of this certificate, and the following statement:</p> <p><i>either</i> <sup>(1)</sup>["Ornamental <sup>(1)</sup>[fish] <sup>(1)</sup>[molluscs] <sup>(1)</sup>[crustaceans] intended for closed ornamental facilities in the European Union"]</p> <p><i>or</i> <sup>(1)(3)</sup>["Ornamental <sup>(1)</sup>[fish] <sup>(1)</sup>[molluscs] <sup>(1)</sup>[crustaceans] intended for quarantine in the European Union"].</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                    |       |
| II.5   | <p><sup>(1)(4)(7)</sup><b>[Requirements for species susceptible to Spring vireamia of carp (SVC), Bacterial kidney disease (BKD), Infectious pancreatic necrosis virus (IPN) and Infection with <i>Gyrodactylus salaris</i> (GS)]</b></p> <p>I, the undersigned official inspector, hereby certify that the ornamental aquatic animals referred to above:</p> <p><i>either</i> <sup>(1)</sup>[originate from a country/territory or part thereof:</p> <p>(a) where <sup>(1)</sup>[SVC] <sup>(1)</sup>[GS] <sup>(1)</sup>[BKD] <sup>(1)</sup>[IPN] is (are) notifiable to the competent authority and reports of suspicion of infection of the relevant disease(s) must be immediately investigated by the competent authority;</p> <p>(b) where all aquaculture animals of species susceptible to the relevant disease(s) introduced into that country/territory or part thereof comply with the requirements set in Part II.5 of this certificate;</p> <p>(c) where species susceptible to the relevant disease(s) are not vaccinated against the relevant disease(s); and</p> <p>(d) which comply with the requirements for disease freedom as regards <sup>(1)</sup>[SVC] <sup>(1)</sup>[GS] <sup>(1)</sup>[BKD] <sup>(1)</sup>[IPN] laid down in the relevant OIE standard or at least equivalent to those laid down in Chapter VII of Directive 2006/88/EC.]</p> <p><i>or</i> <sup>(1)(4)</sup>[have been subject to quarantine under conditions at least equivalent to those laid down in Decision 2008/946/EC.]]</p> <p><b>Notes</b></p> <p><b>Part I:</b></p> <p>— Box I.19: Use the appropriate HS codes: 0306, 0307 or 030110.</p> <p>— Box I.20 and I.28: As regards quantity, give the total number.</p> <p>— Box I.25: Use the option "Pets" for ornamental aquatic animals intended for pet shops or similar businesses for further sale, "Circus/exhibition" for ornamental aquatic animals intended for exhibition aquaria or similar businesses not for further sale and "Quarantine" if the ornamental aquatic animals are intended for a quarantine facility.</p> <p><b>Part II:</b></p> <p>(1) Keep as appropriate.</p> <p>(2) Part II.2 and II.3 of this certificate only applies to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Part II of Annex IV to Directive 2006/88/EC.</p> <p>(3) The requirements in Part II.2 of this certificate on ornamental aquatic animals susceptible to epizootic ulcerative syndrome (EUS) as regards that disease laid down shall only apply from 1 January 2011 and until that date the reference to EUS shall be deleted.</p> <p>(4) Consignments of ornamental aquatic animals may be imported regardless of the requirements in Part II.2 and II.3 if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> <p>(5) To be authorised into the Union one of these statements must be kept if the consignments contain species susceptible to EUS (see note 3), EHN, <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i>, <i>Mikrocytos mackini</i>, Taura syndrome and/or Yellowhead disease.</p> |                                    |       |

**COUNTRY****Ornamental aquatic animals intended for closed ornamental facilities**

| II. Health information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | II.a. Certificate reference number | II.b. |                            |                          |       |             |        |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------|----------------------------|--------------------------|-------|-------------|--------|--|
| <p>(6) To be authorised into a Member State, zone or compartment declared free from VHS, IHN, ISA, KHV, Marteilia refringens, Bonamia ostreae, or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or surveillance or eradication programme(s) apply(ies). Data on the disease status in different parts of the Union are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a></p> <p>(7) Part II.5 of this certificate only applies to consignments intended for a Member State or part thereof which is regarded as disease-free, or for which a programme is approved by Decision 2010/221/EU as regards SVC, BKD, IPN or GS, and the consignment comprises species listed in Part C of Annex II as susceptible to the disease(s) for which the disease-free status or programme(s) apply(ies).</p> <p>Part II.5 shall also apply to consignments of fish of any species originating from waters where species listed in Part C of Annex II as species susceptible to infection with GS, are present, where those consignments are intended for a Member State or part thereof listed in Annex I to Decision 2010/221/EU as free of GS.</p> <p>Consignments of ornamental aquatic animals for which SVC, IPN and/or BKD related requirements are applicable, may be imported regardless of the requirements in Part II.5 of this certificate if they are intended for a quarantine facility complying with the requirements laid down in Decision 2008/946/EC.</p> |                                    |       |                            |                          |       |             |        |  |
| <p>Official inspector</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;">Name (in capital letters):</td> <td style="width: 40%;">Qualification and title:</td> </tr> <tr> <td>Date:</td> <td>Signature:'</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                    |       | Name (in capital letters): | Qualification and title: | Date: | Signature:' | Stamp: |  |
| Name (in capital letters):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Qualification and title:           |       |                            |                          |       |             |        |  |
| Date:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Signature:'                        |       |                            |                          |       |             |        |  |
| Stamp:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                    |       |                            |                          |       |             |        |  |

(3) Annex V is replaced by the following:

‘ANNEX V

**Explanatory notes**

- (a) Certificates shall be issued by the competent authorities of the country of origin, based on the appropriate model set out in Annex II and IV to this Regulation taking into account the place of destination and use of the consignment after the arrival at the destination.
- (b) Considering the status of the place of destination as regards non-exotic diseases referred to in Part II of Annex IV to Directive 2006/88/EC in the EU Member State or diseases for which the place of destination has measures approved by Decision 2010/221/EU approving national measures in accordance with Article 43 of Council Directive 2006/88/EC, the appropriate specific requirements shall be incorporated and completed in the certificate.
- (c) The “Place of origin” shall be the localisation of the farm or mollusc farming area where the aquaculture animals were reared reaching their commercial size relevant for the consignment covered by this certificate. For wild aquatic animals “place of origin” shall be the place of harvest.
- (d) Where the model certificate states that certain statements shall be kept as appropriate, statements which are not relevant, may be crossed out and initialled and stamped by the certifying officer, or completely deleted from the certificate.
- (e) The original of each certificate shall consist of a single sheet of paper, or, where more text is required it must be in such a form that all sheets of paper required are part of an integrated whole and indivisible.
- (f) For import into the Union from third countries, the original of the certificate and the labels referred to in the model certificate shall be drawn up in at least one of the official languages of the Member State of the border inspection post of introduction of the consignment into the Union and of the Member State of destination. However, those Member States may authorise the certificate to be drawn up in the official language of another Member State, and accompanied, if necessary, by an official translation.
- (g) Where additional sheets are attached to the certificate for the purpose of identifying the items making up the consignment, such additional sheets shall also be considered to form part of the original of the certificate, provided the signature and stamp of the certifying official inspector appear on each page.
- (h) When the certificate, including any additional sheets as referred to in (g), comprises more than one page, each page shall be numbered “-x(page number) of y(total number of pages)-” on the bottom and shall bear the certificate reference number allocated by the competent authority on the top.
- (i) The original of the certificate must be completed and signed by an official inspector not more than 72 hours prior to loading of the consignment, or not more than 24 hours in those cases where the aquaculture animals must be inspected within 24 hours of loading. The competent authorities of the country of origin shall ensure that principles of certification equivalent to those laid down in Directive 96/93/EC are followed.
- (j) The colour of the signature shall be different from that of the printing. The same requirement shall apply to stamps other than embossed stamps or watermarks.
- (k) For import into the Union from third countries, the original of the certificate must accompany the consignment until it reaches the EU border inspection post. For consignments placed on the market within the Union, the original of the certificate must accompany the consignment until it reaches its final destination.
- (l) A certificate issued for live aquaculture animals shall be valid for 10 days from the date of issue. In the case of transport by ship, the time of validity is prolonged by the time of journey at sea. To that end, the original of a declaration by the ship’s master, drawn up in accordance with the addendum drawn up in conformity with the model laid down in Part D of Annex IV, shall be attached to the animal health certificate.
- (m) Please note that the general conditions on the transport of animals laid down in Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 may, where applicable, require measures to be taken after entry into the Union if the requirements of that Regulation are not fulfilled.’

**COMMISSION REGULATION (EU) No 347/2010****of 21 April 2010****amending Commission Regulation (EC) No 245/2009 as regards the ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products <sup>(1)</sup>, and in particular Article 15(1) thereof,

After consulting the Ecodesign Consultation Forum,

Whereas:

- (1) After the adoption of Commission Regulation (EC) No 245/2009 of 18 March 2009 implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps, and repealing Directive 2000/55/EC of the European Parliament and of the Council <sup>(2)</sup>, it appeared that certain provisions of that Regulation should be amended in order to avoid unintended impacts on the availability and performance of the products covered by that Regulation.

- (2) In addition, it is necessary to improve coherence, as regards the requirements on product information, between on the one hand Regulation (EC) No 245/2009 and on the other hand Commission Regulation (EC) No 244/2009 of 18 March 2009 implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for non-directional household lamps <sup>(3)</sup>.

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 19(1) of Directive 2009/125/EC,

HAS ADOPTED THIS REGULATION:

*Article 1***Amendments to Regulation (EC) No 245/2009**

Annexes I, II, III and IV to Regulation (EC) No 245/2009 are amended as set out in the Annex to this Regulation.

*Article 2***Entry into force**

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

It shall apply from 13 April 2010.

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

Done at Brussels, 21 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

<sup>(1)</sup> OJ L 285, 31.10.2009, p. 10.

<sup>(2)</sup> OJ L 76, 24.3.2009, p. 17.

<sup>(3)</sup> OJ L 76, 24.3.2009, p. 3.

## ANNEX

**Amendments in Annexes I, II, III and IV to Regulation (EC) No 245/2009**

Annexes I, II, III and IV to Regulation (EC) No 245/2009 are amended as follows:

1. Annex I is amended as follows:

(a) the title is replaced by the following:

‘Exemptions’;

(b) the introductory sentence in point 1 is replaced by the following:

‘The following lamps shall be exempt from the provisions of Annex III, provided that the technical documentation file drawn up for the purposes of conformity assessment pursuant to Article 8 of Directive 2009/125/EC states which of the technical parameters listed hereunder provide(s) a basis for their exemption.’;

(c) points 1(c) and 1(d) are replaced by the following:

‘(c) blended high intensity discharge lamps having:

- 6 % or more of total radiation of the range 250-780 nm in the range of 250-400 nm; and
- 11 % or more of total radiation of the range 250-780 nm in the range of 630-780 nm; and
- 5 % or more of total radiation of the range 250-780 nm in the range of 640-700 nm;

(d) blended high intensity discharge lamps having:

- the peak of the radiation between 315-400 nm (UVA) or 280-315 nm (UVB);

(d) point 2 is replaced by the following:

‘2. The following products shall be exempt from the provisions of Annex III, provided that in all forms of product information it is stated that they are not intended for general lighting use within the meaning of this Regulation, or that they are intended for use in applications listed in points (b) to (e):

- (a) products intended for use in applications other than general lighting and products incorporated into products which do not provide a general lighting function;
- (b) lamps covered by the requirements of Directives 94/9/EC of the European Parliament and of the Council <sup>(1)</sup> or Directive 1999/92/EC of the European Parliament and of the Council <sup>(2)</sup>;
- (c) emergency lighting luminaires and emergency sign luminaires within the meaning of Directive 2006/95/EC of the European Parliament and of the Council <sup>(3)</sup>;
- (d) ballasts intended for use in luminaires defined in paragraph (c) and designed to operate lamps in emergency conditions;
- (e) luminaires covered by the requirements of Directive 94/9/EC, Directive 1999/92/EC, Directive 2006/42/EC of the European Parliament and of the Council <sup>(4)</sup>, Council Directive 93/42/EEC <sup>(5)</sup>, Council Directive 88/378/EEC <sup>(6)</sup> and luminaires integrated into equipment covered by these requirements.

The intended purpose shall be stated for each product in the product information, and the technical documentation file drawn up for the purposes of conformity assessment pursuant to Article 8 of Directive 2009/125/EC shall list the technical parameters that make the product design specific for the stated intended purpose.

<sup>(1)</sup> OJ L 100, 19.4.1994, p. 1.

<sup>(2)</sup> OJ L 23, 28.1.2000, p. 57.

<sup>(3)</sup> OJ L 374, 27.12.2006, p. 10.

<sup>(4)</sup> OJ L 157, 9.6.2006, p. 24.

<sup>(5)</sup> OJ L 169, 12.7.1993, p. 1.

<sup>(6)</sup> OL L 187, 16.7.1988, p. 1.’

## 2. Annex II is amended as follows:

- (a) the first sentence is deleted;
- (b) The following sentence is added to point 1(c):

‘For the purposes of Table 6 in Annex III, the LSF shall be measured in high frequency operating mode with a switching cycle of 11h/1h.’

- (c) The following point (o) is added to point 3:

‘(o) “Blended lamp” means a lamp containing a mercury vapour lamp and an incandescent lamp filament connected in series in the same bulb.’

## 3. Annex III is amended as follows:

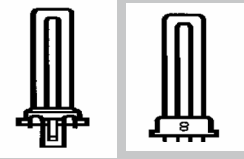
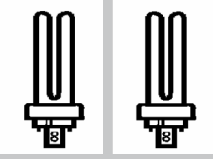
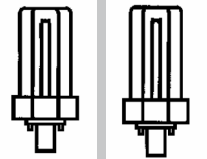
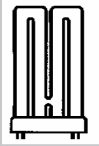
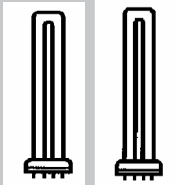
- (a) The following paragraph is added before Table 1:

‘Spiral-shaped double capped fluorescent lamps of all diameters equal to or larger than 16 mm (T5) shall comply with the requirements set out in Table 5 for T9 circular lamps.’

- (b) Table 2 is replaced by the following:

*Table 2*

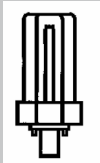
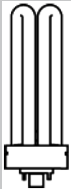
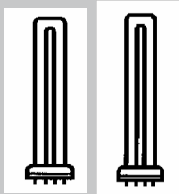
**Rated minimum efficacy values for single capped fluorescent lamps working on electromagnetic and electronic ballast**

| Small single parallel tube, lamp cap G23<br>(2 pin) or 2G7 (4 pin)                  |                                                           | Double parallel tubes, lamp cap G24d<br>(2 pin) or G24q (4 pin)                     |                                                           | Triple parallel tubes, lamp cap GX24d<br>(2 pin) or GX24q (4 pin)                     |                                                           |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------------|
|  |                                                           |  |                                                           |  |                                                           |
| Nominal wattage<br>(W)                                                              | Rated luminous<br>efficacy (lm/W),<br>100 h initial value | Nominal wattage<br>(W)                                                              | Rated luminous<br>efficacy (lm/W),<br>100 h initial value | Nominal wattage<br>(W)                                                                | Rated luminous<br>efficacy (lm/W),<br>100 h initial value |
| 5                                                                                   | 48                                                        | 10                                                                                  | 60                                                        | 13                                                                                    | 62                                                        |
| 7                                                                                   | 57                                                        | 13                                                                                  | 69                                                        | 18                                                                                    | 67                                                        |
| 9                                                                                   | 67                                                        | 18                                                                                  | 67                                                        | 26                                                                                    | 66                                                        |
| 11                                                                                  | 76                                                        | 26                                                                                  | 66                                                        |                                                                                       |                                                           |
| 4 legs in one plane, lamp cap 2G10<br>(4 pin)                                       |                                                           | Long single parallel tube, lamp cap 2G11<br>(4 pin)                                 |                                                           |                                                                                       |                                                           |
|  |                                                           |  |                                                           |                                                                                       |                                                           |
| Nominal wattage<br>(W)                                                              | Rated luminous<br>efficacy (lm/W),<br>100 h initial value | Nominal wattage<br>(W)                                                              | Rated luminous<br>efficacy (lm/W),<br>100 h initial value |                                                                                       |                                                           |
| 18                                                                                  | 61                                                        | 18                                                                                  | 67                                                        |                                                                                       |                                                           |
| 24                                                                                  | 71                                                        | 24                                                                                  | 75                                                        |                                                                                       |                                                           |
| 36                                                                                  | 78                                                        | 34                                                                                  | 82                                                        |                                                                                       |                                                           |
|                                                                                     |                                                           | 36                                                                                  | 81'                                                       |                                                                                       |                                                           |

- (c) Table 3 is replaced by the following:

Table 3

**Rated minimum efficacy values for single capped fluorescent lamps, working only on electronic ballast**

| Triple parallel tubes, lamp cap GX24q<br>(4 pin)                                  |                                                           | Four parallel tubes, lamp cap GX24q<br>(4 pin)                                    |                                                           | Long single parallel tube, lamp cap 2G11<br>(4 pin)                                 |                                                           |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------|
|  |                                                           |  |                                                           |  |                                                           |
| Nominal wattage<br>(W)                                                            | Rated luminous<br>efficacy (lm/W),<br>100 h initial value | Nominal wattage<br>(W)                                                            | Rated luminous<br>efficacy (lm/W),<br>100 h initial value | Nominal wattage<br>(W)                                                              | Rated luminous<br>efficacy (lm/W),<br>100 h initial value |
| 32                                                                                | 75                                                        | 57                                                                                | 75                                                        | 40                                                                                  | 83                                                        |
| 42                                                                                | 74                                                        | 70                                                                                | 74                                                        | 55                                                                                  | 82                                                        |
| 57                                                                                | 75                                                        |                                                                                   |                                                           | 80                                                                                  | 75                                                        |
| 70                                                                                | 74'                                                       |                                                                                   |                                                           |                                                                                     |                                                           |

- (d) Table 6 is replaced by the following:

Table 6

**Deduction percentages for rated minimum efficacy values for fluorescent lamps with high colour temperature and/or high colour rendering and/or second lamp envelope and/or long life**

| Lamp parameter                                              | Deduction from luminous efficacy at 25 °C |
|-------------------------------------------------------------|-------------------------------------------|
| $T_c \geq 5\,000\text{ K}$                                  | – 10 %                                    |
| $95 \geq R_a > 90$                                          | – 20 %                                    |
| $R_a > 95$                                                  | – 30 %                                    |
| Second lamp envelope                                        | – 10 %                                    |
| Lamp Survival Factor $\geq 0,50$ after 40 000 burning hours | – 5 %'                                    |

- (e) In Annex III.1.1.B, the sentence

'The corrections defined for the first stage (Table 6) shall continue to apply'

is replaced by

'The corrections (Table 6) and the specific requirements for spiral-shaped double capped fluorescent lamps defined for the first stage shall continue to apply.';

- (f) The title of Table 7 is replaced by the following:

Table 7

**Rated minimum efficacy values for high pressure sodium lamps with  $R_a \leq 60$ ;**

- (g) The title of Table 8 is replaced by the following:

*Table 8*

**Rated minimum efficacy values for Metal Halide Lamps with  $R_a \leq 80$  and for high pressure sodium lamps with  $R_a > 60$**

- (h) The second paragraph of Annex III.1.1.C is replaced by the following:

'Fluorescent lamps without integrated ballast shall be able to operate with ballasts of energy efficiency class A2 or more efficient ballasts in accordance with point 2.2 of Annex III. In addition they may also operate with ballasts of less efficient classes than A2.'

- (i) Table 11 is replaced by the following:

*Table 11*

**Lamp lumen maintenance factors for single and double capped fluorescent lamps — Stage 2**

| Lamp lumen maintenance factor                                                                                                                                                                                                        | Burning hours                |       |       |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-------|-------|--------|
| Lamp types                                                                                                                                                                                                                           | 2 000                        | 4 000 | 8 000 | 16 000 |
| Double-Capped Fluorescent lamps operating on non-high frequency ballasts                                                                                                                                                             | 0,95                         | 0,92  | 0,90  | —      |
| T8 Double-Capped Fluorescent lamps on high frequency ballast with warmstart                                                                                                                                                          | 0,96                         | 0,92  | 0,91  | 0,90   |
| Other Double-Capped Fluorescent lamps on high frequency ballast with warmstart                                                                                                                                                       | 0,95                         | 0,92  | 0,90  | 0,90   |
| Circular Single-Capped Fluorescent lamps operating on non-high frequency ballasts, T8 U-shaped double-capped fluorescent lamps and spiral-shaped double capped fluorescent lamps of all diameters equal to or larger than 16 mm (T5) | 0,80                         | 0,74  | —     | —      |
|                                                                                                                                                                                                                                      | 0,72 at 5 000 burning hours  |       |       |        |
| Circular Single-Capped Fluorescent lamps operating on high frequency ballasts                                                                                                                                                        | 0,85                         | 0,83  | 0,80  | —      |
|                                                                                                                                                                                                                                      | 0,75 at 12 000 burning hours |       |       |        |
| Other Single-Capped Fluorescent lamps operating on non-high frequency ballasts                                                                                                                                                       | 0,85                         | 0,78  | 0,75  | —      |
| Other Single-Capped Fluorescent lamps on high frequency ballast with warmstart                                                                                                                                                       | 0,90                         | 0,84  | 0,81  | 0,78'  |

- (j) The following introductory phrase and Table 11a is added after Table 11:

'The following cumulative deductions shall be applied to the values in Table 11:

*Table 11a*

**Deduction percentages for fluorescent lamp lumen maintenance requirements**

| Lamp parameter                                  | Deduction from lamp lumen maintenance requirement                                 |
|-------------------------------------------------|-----------------------------------------------------------------------------------|
| Lamps with $95 \geq R_a > 90$                   | At burning hours $\leq 8\,000$ h: – 5 %<br>At burning hours $> 8\,000$ h: – 10 %  |
| Lamps with $R_a > 95$                           | At burning hours $\leq 4\,000$ h: – 10 %<br>At burning hours $> 4\,000$ h: – 15 % |
| Lamps with a colour temperature $\geq 5\,000$ K | – 10 %'                                                                           |

(k) Table 12 is replaced by the following:

Table 12

**Lamp survival factors for single and double capped fluorescent lamps — Stage 2**

| Lamp survival factor                                                                                                                                                                                                                 | Burning hours                |       |       |        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-------|-------|--------|
| Lamp types                                                                                                                                                                                                                           | 2 000                        | 4 000 | 8 000 | 16 000 |
| Double-Capped Fluorescent lamps operating on non-high frequency ballasts                                                                                                                                                             | 0,99                         | 0,97  | 0,90  | —      |
| Double-Capped Fluorescent lamps on high frequency ballast with warmstart                                                                                                                                                             | 0,99                         | 0,97  | 0,92  | 0,90   |
| Circular Single-Capped Fluorescent lamps operating on non-high frequency ballasts, T8 U-shaped double-capped fluorescent lamps and spiral-shaped double capped fluorescent lamps of all diameters equal to or larger than 16 mm (T5) | 0,98                         | 0,77  | —     | —      |
|                                                                                                                                                                                                                                      | 0,50 at 5 000 burning hours  |       |       |        |
| Circular Single-Capped Fluorescent lamps operating on high frequency ballasts                                                                                                                                                        | 0,99                         | 0,97  | 0,85  | —      |
|                                                                                                                                                                                                                                      | 0,50 at 12 000 burning hours |       |       |        |
| Other Single-Capped Fluorescent lamps operating on non-high frequency ballasts                                                                                                                                                       | 0,98                         | 0,90  | 0,50  | —      |
| Other Single-Capped Fluorescent lamps on high frequency ballast with warmstart                                                                                                                                                       | 0,99                         | 0,98  | 0,88  | —      |

(l) Table 13 is replaced by the following:

Table 13

**Lamp lumen maintenance factors and lamp survival factors for high pressure sodium lamps — Stage 2**

| High pressure sodium lamp category and burning hours for measurement |                                                                                     | Lamp lumen maintenance factor | Lamp survival factor |
|----------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------|----------------------|
| P ≤ 75 W<br>LLMF and LSF measured at<br>12 000 burning hours         | Ra ≤ 60                                                                             | > 0,80                        | > 0,90               |
|                                                                      | Ra > 60                                                                             | > 0,75                        | > 0,75               |
|                                                                      | all retrofit lamps designed to operate on high pressure mercury vapour lamp ballast | > 0,75                        | > 0,80               |
| P > 75 W<br>LLMF and LSF measured at<br>16 000 burning hours         | Ra ≤ 60                                                                             | > 0,85                        | > 0,90               |
|                                                                      | Ra > 60                                                                             | > 0,70                        | > 0,65               |
|                                                                      | all retrofit lamps designed to operate on high pressure mercury vapour lamp ballast | > 0,75                        | > 0,55               |

The requirements in Table 13 for retrofit lamps designed to operate on high pressure mercury vapour lamp ballast shall be applicable until 6 years after the entry into force of this Regulation.;

(m) Annex III.1.3(i) is replaced by the following:

‘(i) Ambient temperature inside the luminaire at which the lamp was designed to maximise its luminous flux. If this temperature is equal to or lower than 0 °C or equal to or higher than 50 °C, it shall be stated that the lamp is not suitable for indoor use at standard room temperatures.’;

(n) The following point (j) is added to point 1.3 of Annex III:

‘(j) For fluorescent lamps without integrated ballast, the energy efficiency index(es) of ballasts as defined in Table 17 with which the lamp can operate.’;

(o) Table 17 is replaced by the following:

Table 17

**Energy efficiency index requirements for non-dimmable ballasts for fluorescent lamps**

| LAMP DATA    |                 |                                                      |                       |      | BALLAST EFFICIENCY (Plamp/Pinput) |        |        |        |        |
|--------------|-----------------|------------------------------------------------------|-----------------------|------|-----------------------------------|--------|--------|--------|--------|
|              |                 |                                                      |                       |      | Non-dimmable                      |        |        |        |        |
| Lamp type    | Nominal Wattage | ILCOS CODE                                           | Rated/typical wattage |      | A2 BAT                            | A2     | A3     | B1     | B2     |
|              |                 |                                                      | 50 Hz                 | HF   |                                   |        |        |        |        |
|              | W               |                                                      | W                     | W    |                                   |        |        |        |        |
| T8           | 15              | FD-15-E-G13-26/450                                   | 15                    | 13,5 | 87,8 %                            | 84,4 % | 75,0 % | 67,9 % | 62,0 % |
| T8           | 18              | FD-18-E-G13-26/600                                   | 18                    | 16   | 87,7 %                            | 84,2 % | 76,2 % | 71,3 % | 65,8 % |
| T8           | 30              | FD-30-E-G13-26/900                                   | 30                    | 24   | 82,1 %                            | 77,4 % | 72,7 % | 79,2 % | 75,0 % |
| T8           | 36              | FD-36-E-G13-26/1200                                  | 36                    | 32   | 91,4 %                            | 88,9 % | 84,2 % | 83,4 % | 79,5 % |
| T8           | 38              | FD-38-E-G13-26/1050                                  | 38,5                  | 32   | 87,7 %                            | 84,2 % | 80,0 % | 84,1 % | 80,4 % |
| T8           | 58              | FD-58-E-G13-26/1500                                  | 58                    | 50   | 93,0 %                            | 90,9 % | 84,7 % | 86,1 % | 82,2 % |
| T8           | 70              | FD-70-E-G13-26/1800                                  | 69,5                  | 60   | 90,9 %                            | 88,2 % | 83,3 % | 86,3 % | 83,1 % |
| TC-L         | 18              | FSD-18-E-2G11                                        | 18                    | 16   | 87,7 %                            | 84,2 % | 76,2 % | 71,3 % | 65,8 % |
| TC-L         | 24              | FSD-24-E-2G11                                        | 24                    | 22   | 90,7 %                            | 88,0 % | 81,5 % | 76,0 % | 71,3 % |
| TC-L         | 36              | FSD-36-E-2G11                                        | 36                    | 32   | 91,4 %                            | 88,9 % | 84,2 % | 83,4 % | 79,5 % |
| TCF          | 18              | FSS-18-E-2G10                                        | 18                    | 16   | 87,7 %                            | 84,2 % | 76,2 % | 71,3 % | 65,8 % |
| TCF          | 24              | FSS-24-E-2G10                                        | 24                    | 22   | 90,7 %                            | 88,0 % | 81,5 % | 76,0 % | 71,3 % |
| TCF          | 36              | FSS-36-E-2G10                                        | 36                    | 32   | 91,4 %                            | 88,9 % | 84,2 % | 83,4 % | 79,5 % |
| TC-D / DE    | 10              | FSQ-10-E-G24q=1<br>FSQ-10-I-G24d=1                   | 10                    | 9,5  | 89,4 %                            | 86,4 % | 73,1 % | 67,9 % | 59,4 % |
| TC-D / DE    | 13              | FSQ-13-E-G24q=1<br>FSQ-13-I-G24d=1                   | 13                    | 12,5 | 91,7 %                            | 89,3 % | 78,1 % | 72,6 % | 65,0 % |
| TC-D / DE    | 18              | FSQ-18-E-G24q=2<br>FSQ-18-I-G24d=2                   | 18                    | 16,5 | 89,8 %                            | 86,8 % | 78,6 % | 71,3 % | 65,8 % |
| TC-D / DE    | 26              | FSQ-26-E-G24q=3<br>FSQ-26-I-G24d=3                   | 26                    | 24   | 91,4 %                            | 88,9 % | 82,8 % | 77,2 % | 72,6 % |
| TC-T / TE    | 13              | FSM-13-E-GX24q=1<br>FSM-13-I-GX24d=1                 | 13                    | 12,5 | 91,7 %                            | 89,3 % | 78,1 % | 72,6 % | 65,0 % |
| TC-T / TE    | 18              | FSM-18-E-GX24q=2<br>FSM-18-I-GX24d=2                 | 18                    | 16,5 | 89,8 %                            | 86,8 % | 78,6 % | 71,3 % | 65,8 % |
| TC-T / TC-TE | 26              | FSM-26-E-GX24q=3<br>FSM-26-I-GX24d=3                 | 26,5                  | 24   | 91,4 %                            | 88,9 % | 82,8 % | 77,5 % | 73,0 % |
| TC-DD / DDE  | 10              | FSS-10-E-GR10q<br>FSS-10-L/P/H-GR10q                 | 10,5                  | 9,5  | 86,4 %                            | 82,6 % | 70,4 % | 68,8 % | 60,5 % |
| TC-DD / DDE  | 16              | FSS-16-E-GR10q<br>FSS-16-I-GR8<br>FSS-16-L/P/H-GR10q | 16                    | 15   | 87,0 %                            | 83,3 % | 75,0 % | 72,4 % | 66,1 % |
| TC-DD / DDE  | 21              | FSS-21-E-GR10q<br>FSS-21-L/P/H-GR10q                 | 21                    | 19,5 | 89,7 %                            | 86,7 % | 78,0 % | 73,9 % | 68,8 % |
| TC-DD / DDE  | 28              | FSS-28-E-GR10q<br>FSS-28-I-GR8<br>FSS-28-L/P/H-GR10q | 28                    | 24,5 | 89,1 %                            | 86,0 % | 80,3 % | 78,2 % | 73,9 % |
| TC-DD / DDE  | 38              | FSS-38-E-GR10q<br>FSS-38-L/P/H-GR10q                 | 38,5                  | 34,5 | 92,0 %                            | 89,6 % | 85,2 % | 84,1 % | 80,4 % |
| TC           | 5               | FSD-5-I-G23<br>FSD-5-E-2G7                           | 5,4                   | 5    | 72,7 %                            | 66,7 % | 58,8 % | 49,3 % | 41,4 % |
| TC           | 7               | FSD-7-I-G23<br>FSD-7-E-2G7                           | 7,1                   | 6,5  | 77,6 %                            | 72,2 % | 65,0 % | 55,7 % | 47,8 % |

|       |     |                                                |      |      |        |        |        |        |        |
|-------|-----|------------------------------------------------|------|------|--------|--------|--------|--------|--------|
| TC    | 9   | FSD-9-I-G23<br>FSD-9-E-2G7                     | 8,7  | 8    | 78,0 % | 72,7 % | 66,7 % | 60,3 % | 52,6 % |
| TC    | 11  | FSD-11-I-G23<br>FSD-11-E-2G7                   | 11,8 | 11   | 83,0 % | 78,6 % | 73,3 % | 66,7 % | 59,6 % |
| T5    | 4   | FD-4-E-G5-16/150                               | 4,5  | 3,6  | 64,9 % | 58,1 % | 50,0 % | 45,0 % | 37,2 % |
| T5    | 6   | FD-6-E-G5-16/225                               | 6    | 5,4  | 71,3 % | 65,1 % | 58,1 % | 51,8 % | 43,8 % |
| T5    | 8   | FD-8-E-G5-16/300                               | 7,1  | 7,5  | 69,9 % | 63,6 % | 58,6 % | 48,9 % | 42,7 % |
| T5    | 13  | FD-13-E-G5-16/525                              | 13   | 12,8 | 84,2 % | 80,0 % | 75,3 % | 72,6 % | 65,0 % |
| T9-C  | 22  | FSC-22-E-G10q-29/200                           | 22   | 19   | 89,4 % | 86,4 % | 79,2 % | 74,6 % | 69,7 % |
| T9-C  | 32  | FSC-32-E-G10q-29/300                           | 32   | 30   | 88,9 % | 85,7 % | 81,1 % | 80,0 % | 76,0 % |
| T9-C  | 40  | FSC-40-E-G10q-29/400                           | 40   | 32   | 89,5 % | 86,5 % | 82,1 % | 82,6 % | 79,2 % |
| T2    | 6   | FDH-6-L/P-W4,3x8,5d-7/220                      |      | 5    | 72,7 % | 66,7 % | 58,8 % |        |        |
| T2    | 8   | FDH-8-L/P-W4,3x8,5d-7/320                      |      | 7,8  | 76,5 % | 70,9 % | 65,0 % |        |        |
| T2    | 11  | FDH-11-L/P-W4,3x8,5d-7/420                     |      | 10,8 | 81,8 % | 77,1 % | 72,0 % |        |        |
| T2    | 13  | FDH-13-L/P-W4,3x8,5d-7/520                     |      | 13,3 | 84,7 % | 80,6 % | 76,0 % |        |        |
| T2    | 21  | FDH-21-L/P-W4,3x8,5d-7/                        |      | 21   | 88,9 % | 85,7 % | 79,2 % |        |        |
| T2    | 23  | FDH-23-L/P-W4,3x8,5d-7/                        |      | 23   | 89,8 % | 86,8 % | 80,7 % |        |        |
| T5-E  | 14  | FDH-14-G5-L/P-16/550                           |      | 13,7 | 84,7 % | 80,6 % | 72,1 % |        |        |
| T5-E  | 21  | FDH-21-G5-L/P-16/850                           |      | 20,7 | 89,3 % | 86,3 % | 79,6 % |        |        |
| T5-E  | 24  | FDH-24-G5-L/P-16/550                           |      | 22,5 | 89,6 % | 86,5 % | 80,4 % |        |        |
| T5-E  | 28  | FDH-28-G5-L/P-16/1150                          |      | 27,8 | 89,8 % | 86,9 % | 81,8 % |        |        |
| T5-E  | 35  | FDH-35-G5-L/P-16/1450                          |      | 34,7 | 91,5 % | 89,0 % | 82,6 % |        |        |
| T5-E  | 39  | FDH-39-G5-L/P-16/850                           |      | 38   | 91,0 % | 88,4 % | 82,6 % |        |        |
| T5-E  | 49  | FDH-49-G5-L/P-16/1450                          |      | 49,3 | 91,6 % | 89,2 % | 84,6 % |        |        |
| T5-E  | 54  | FDH-54-G5-L/P-16/1150                          |      | 53,8 | 92,0 % | 89,7 % | 85,4 % |        |        |
| T5-E  | 80  | FDH-80-G5-L/P-16/1150                          |      | 80   | 93,0 % | 90,9 % | 87,0 % |        |        |
| T5-E  | 95  | FDH-95-G5-L/P-16/1150                          |      | 95   | 92,7 % | 90,5 % | 84,1 % |        |        |
| T5-E  | 120 | FDH-120-G5-L/P-16/1450                         |      | 120  | 92,5 % | 90,2 % | 84,5 % |        |        |
| T5-C  | 22  | FSCH-22-L/P-2GX13-16/225                       |      | 22,3 | 88,1 % | 84,8 % | 78,8 % |        |        |
| T5-C  | 40  | FSCH-40-L/P-2GX13-16/300                       |      | 39,9 | 91,4 % | 88,9 % | 83,3 % |        |        |
| T5-C  | 55  | FSCH-55-L/P-2GX13-16/300                       |      | 55   | 92,4 % | 90,2 % | 84,6 % |        |        |
| T5-C  | 60  | FSCH-60-L/P-2GX13-16/375                       |      | 60   | 93,0 % | 90,9 % | 85,7 % |        |        |
| TC-LE | 40  | FSDH-40-L/P-2G11                               |      | 40   | 91,4 % | 88,9 % | 83,3 % |        |        |
| TC-LE | 55  | FSDH-55-L/P-2G11                               |      | 55   | 92,4 % | 90,2 % | 84,6 % |        |        |
| TC-LE | 80  | FSDH-80-L/P-2G11                               |      | 80   | 93,0 % | 90,9 % | 87,0 % |        |        |
| TC-TE | 32  | FSMH-32-L/P-2GX24q=3                           |      | 32   | 91,4 % | 88,9 % | 82,1 % |        |        |
| TC-TE | 42  | FSMH-42-L/P-2GX24q=4                           |      | 43   | 93,5 % | 91,5 % | 86,0 % |        |        |
| TC-TE | 57  | FSM6H-57-L/P-2GX24q=5<br>FSM8H-57-L/P-2GX24q=5 |      | 56   | 91,4 % | 88,9 % | 83,6 % |        |        |
| TC-TE | 70  | FSM6H-70-L/P-2GX24q=6<br>FSM8H-70-L/P-2GX24q=6 |      | 70   | 93,0 % | 90,9 % | 85,4 % |        |        |
| TC-TE | 60  | FSM6H-60-L/P-2G8=1                             |      | 63   | 92,3 % | 90,0 % | 84,0 % |        |        |
| TC-TE | 62  | FSM8H-62-L/P-2G8=2                             |      | 62   | 92,2 % | 89,9 % | 83,8 % |        |        |
| TC-TE | 82  | FSM8H-82-L/P-2G8=2                             |      | 82   | 92,4 % | 90,1 % | 83,7 % |        |        |
| TC-TE | 85  | FSM6H-85-L/P-2G8=1                             |      | 87   | 92,8 % | 90,6 % | 84,5 % |        |        |
| TC-TE | 120 | FSM6H-120-L/P-2G8=1<br>FSM8H-120-L/P-2G8=1     |      | 122  | 92,6 % | 90,4 % | 84,7 % |        |        |
| TC-DD | 55  | FSSH-55-L/P-GRY10q3                            |      | 55   | 92,4 % | 90,2 % | 84,6 % |        |        |

4. The following paragraph is added after the first paragraph of Annex IV:

'Member States authorities shall use reliable, accurate and reproducible measurement procedures, which take into account the generally recognised state of the art measurement methods, including methods set out in documents the reference numbers of which have been published for that purpose in the *Official Journal of the European Union*.'

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**COMMISSION REGULATION (EU) No 348/2010****of 23 April 2010****concerning the authorisation of L-isoleucine as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of L-isoleucine produced by *Escherichia coli* (FERM ABP-10641) as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 9 December 2009<sup>(2)</sup> that L-isoleucine does not have an adverse effect on animal health, human health or the environment, and that this

preparation can be considered a source of available isoleucine for all animal species. The Authority recommends appropriate measures for user safety. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of L-isoleucine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.
- (6) 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*

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

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, 23 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> *The EFSA Journal* 2010; 8(1):1425.

## ANNEX

| Identification number of the additive                                                       | Name of the holder of authorisation | Additive     | Composition, chemical formula, description, analytical method                                                                                                                                                                                                                                                                                                                                                                                                            | Species or category of animal | Maximum age | Minimum content                                                | Maximum content | Other provisions                                                                                                              | End of period of authorisation |
|---------------------------------------------------------------------------------------------|-------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------|----------------------------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                                                                             |                                     |              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                               |             | mg/kg of complete feedingstuff with a moisture content of 12 % |                 |                                                                                                                               |                                |
| Category of nutritional additives. Functional group: amino acids, their salts and analogues |                                     |              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                               |             |                                                                |                 |                                                                                                                               |                                |
| 3c3.8.1                                                                                     | —                                   | L-isoleucine | Additive composition:<br><br>L-isoleucine with a purity of at least 93,4 % (on dry matter) produced by <i>Escherichia coli</i> (FERM ABP-10641)<br><br>≤ 1 % unidentified impurities (as dry matter)<br><br>Characterisation of the active substance:<br>L-isoleucine (C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub> )<br><br>Analytical method:<br><br>Method for the determination of amino acids as set out in Commission Regulation (EC) No 152/2009 <sup>(1)</sup> | All animal species            | —           | —                                                              | —               | 1. The moisture content shall be indicated.<br><br>2. For safety reasons: breathing protection shall be used during handling. | 14 May 2020                    |

<sup>(1)</sup> OJ L 54, 26.2.2009, p. 1.

**COMMISSION REGULATION (EU) No 349/2010****of 23 April 2010****concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) From the opinion of the European Food Safety Authority (the Authority) adopted on 12 November 2009<sup>(2)</sup> read in combination with that of 16 April 2008<sup>(3)</sup> it results that copper chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, human health or the environment. According to the opinion of 16 April 2008, the use of that preparation may be considered as a source of available copper and fulfils the criteria of a nutritional additive for all animal species. The Authority recommends appropriate measures for user safety. It does not consider that there

is a need for specific requirements of post market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) By Commission Regulation (EC) No 1253/2008 of 15 December 2008 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive<sup>(4)</sup> that preparation was already authorised as a feed additive for chickens for fattening. That Regulation should be repealed.

(7) 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*

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

Regulation (EC) No 1253/2008 is repealed.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> *The EFSA Journal* (2009) 7(11): 1382.

<sup>(3)</sup> *The EFSA Journal* (2008) 693, 1.

<sup>(4)</sup> OJ L 337, 16.12.2008, p. 78.

*Article 3*

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, 23 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX

| Identification number of the additive                                            | Name of the holder of authorisation | Additive                                         | Composition, chemical formula, description, analytical method.                                                                                                                                                                                                                                               | Species or category of animal | Maximum age | Minimum content                                                                           | Maximum content                                                                                                                                                                                                                                                                            | Other provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | End of period of authorisation |
|----------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                                                                  |                                     |                                                  |                                                                                                                                                                                                                                                                                                              |                               |             | Content of element (Cu) in mg/kg of complete feedingstuff with a moisture content of 12 % |                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                |
| Category of nutritional additives. Functional group: compounds of trace elements |                                     |                                                  |                                                                                                                                                                                                                                                                                                              |                               |             |                                                                                           |                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                |
| 3b4.10                                                                           | —                                   | Copper chelate of hydroxy analogue of methionine | <p>Characterisation of the additive:</p> <p>Copper chelate of hydroxy analogue of methionine containing 18 % copper and 79,5 % - 81 % (2-hydroxy-4-methylthio) butanoic acid<br/>Mineral oil: 1 %<br/>CAS: 292140-30-8</p> <p>Analytical method <sup>(1)</sup>:<br/>Atomic Absorption Spectrometry (AAS)</p> | All species                   | —           |                                                                                           | <p>Bovines</p> <p>— Bovines before the start of rumination including complementary milk replacers: 15 (total)</p> <p>— Other bovines: 35 (total).</p> <p>Ovines: 15 (total)</p> <p>Piglets up to 12 weeks: 170 (total)</p> <p>Crustaceans: 50 (total)</p> <p>Other animals: 25 (total)</p> | <p>1. The additive shall be incorporated into feed in the form of a premixture.</p> <p>2. For user safety: Breathing protection, safety glasses and gloves should be worn during handling.</p> <p>3. The following words shall be included in the labelling:</p> <p>— For feed for sheep if the level of copper in the feed exceeds 10 mg/kg:<br/>‘The level of copper in this feed may cause poisoning in certain breeds of sheep.’</p> <p>— For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg:<br/>‘The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.’</p> | 14 May 2020                    |

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Community Reference Laboratory: <http://www.irmm.jrc.be/crl-feed-additives>

**COMMISSION REGULATION (EU) No 350/2010****of 23 April 2010****concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) From the opinion of the European Food Safety Authority ('the Authority') adopted on 9 December 2009 <sup>(2)</sup>, read in combination with the opinions of 15 September 2009 <sup>(3)</sup> and 15 April 2008 <sup>(4)</sup>, it results that manganese chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, human health or the environment. According to the opinion of 15 April 2008, the use of that preparation

may be considered as a source of available manganese and fulfils the criteria of a nutritional additive for all animal species. The Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) By Commission Regulation (EU) No 103/2010 of 5 February 2010 concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for chickens for fattening <sup>(5)</sup> that preparation was already authorised as a feed additive for chickens for fattening. That Regulation should be repealed.

(7) 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*

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

Regulation (EU) No 103/2010 is repealed.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> The EFSA Journal (2010) 8(1): 1424.

<sup>(3)</sup> The EFSA Journal (2009) 7(9): 1316.

<sup>(4)</sup> The EFSA Journal (2008) 692, 1.

<sup>(5)</sup> OJ L 35, 6.2.2010, p. 1.

*Article 3*

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, 23 April 2010.

*For the Commission*  
*The President*  
José Manuel BARROSO

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## ANNEX

| Identification number of the additive                                            | Name of the holder of authorisation | Additive                                            | Composition, chemical formula, description, analytical method                                                                                                                                                                                                                                                                                  | Species or category of animal | Maximum age | Minimum content                                                                           | Maximum content                                     | Other provisions                                                                                                                                                                     | End of period of authorisation |
|----------------------------------------------------------------------------------|-------------------------------------|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                                                                                  |                                     |                                                     |                                                                                                                                                                                                                                                                                                                                                |                               |             | Content of element (Mn) in mg/kg of complete feedingstuff with a moisture content of 12 % |                                                     |                                                                                                                                                                                      |                                |
| Category of nutritional additives. Functional group: compounds of trace elements |                                     |                                                     |                                                                                                                                                                                                                                                                                                                                                |                               |             |                                                                                           |                                                     |                                                                                                                                                                                      |                                |
| 3b5.10                                                                           | —                                   | Manganese chelate of hydroxy analogue of methionine | Characterisation of the additive:<br><br>Manganese chelate of hydroxy analogue of methionine containing 15,5 %-17 % manganese and 77 %-78 % (2-hydroxy-4-methylthio) butanoic acid<br><br>Mineral oil: ≤ 1 %<br><br>Analytical method (1):<br><br>Inductively coupled plasma atomic emission spectrometry (ICP-AES) according to EN 15510:2007 | All species                   | —           | —                                                                                         | Fish: 100 (total)<br><br>Other species: 150 (total) | 1. The additive has to be incorporated into feed in the form of a premixture.<br>2. For user safety: breathing protection, safety glasses and gloves should be worn during handling. | 14 May 2020                    |

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Community Reference Laboratory: <http://irmm.jrc.ec.europa.eu/crl-feed-additives>

## COMMISSION REGULATION (EU) No 351/2010

of 23 April 2010

**implementing Regulation (EC) No 862/2007 of the European Parliament and of the Council on Community statistics on migration and international protection as regards the definitions of the categories of the groups of country of birth, groups of country of previous usual residence, groups of country of next usual residence and groups of citizenship**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 862/2007 of the European Parliament and of the Council of 11 July 2007 on Community statistics on migration and international protection and repealing Council Regulation (EEC) No 311/76 on the compilation of statistics on foreign workers<sup>(1)</sup>, and in particular Article 10(2)(b) thereof,

Whereas:

- (1) In order to ensure that data from different statistical and administrative sources in the Member States are comparable, and to allow reliable Community-wide overviews to be drawn up, the categories of groups of country of birth, groups of country of previous usual residence, groups of country of next usual residence and groups of citizenship must be defined in the same way in all Member States. Regulation (EC) No 862/2007 therefore requires the Commission to define the above categories.
- (2) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

This Regulation lays down the categories of groups of country of birth, groups of country of previous usual residence, groups of country of next usual residence and groups of citizenship as required by Regulation (EC) No 862/2007.

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

Done at Brussels, 23 April 2010.

*Article 2*

For the above categories, the following definitions shall apply:

- (a) 'country of previous usual residence' means the country in which a person was usually resident immediately prior to immigration, regardless of the person's citizenship or country of birth;
- (b) 'country of next usual residence' means the country in which a person becomes usually resident following an emigration, regardless of the person's citizenship or country of birth;
- (c) 'level of development' means the relative degree of development of a country as defined by statistical measures of life expectancy, literacy, educational attainment, and Gross Domestic Product (GDP) per capita;
- (d) 'native-born' means a person who was born in the country of current usual residence, regardless of the person's citizenship;
- (e) 'foreign-born' means a person who was born outside of the country of current usual residence, regardless of the person's citizenship.

*Article 3*

The groups of country of birth, groups of country of previous usual residence, groups of country of next usual residence and groups of citizenship according to which Member States are required to transmit data to the Commission are listed in the Annex.

*Article 4*

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

*For the Commission*

*The President*

José Manuel BARROSO

<sup>(1)</sup> OJ L 199, 31.7.2007, p. 23.

## ANNEX

The groups of countries and citizenship are as follows:

- basic groups,
- additional groups of other non-European Union (EU) countries and citizenship.

1. BASIC GROUPS OF COUNTRIES

1.1. **Groups of citizenship**

'Citizenship' shall be defined according to Article 2(1)(d) of Regulation (EC) No 862/2007.

A person with two or more citizenships shall be allocated to only one country of citizenship, to be determined in the following order of precedence:

1. reporting country; or, if the person does not have citizenship of the reporting country;
2. another EU Member State; or, if the person does not have citizenship of another EU Member State;
3. another country outside the European Union.

Where a person has two or more citizenships of EU Member States but where neither is the reporting country, Member States shall determine which is to be the country of citizenship.

Where a person has two or more citizenships of non-EU countries, Member States shall determine which is to be the country of citizenship.

The data laid down in Article 3(1)(a)(i) and (c)(i) of Regulation (EC) No 862/2007 shall be disaggregated by the following groups of citizenship:

- citizenship of reporting country (national citizens),
- citizenship of another EU Member State (other EU citizens),
- citizenship of non-EU countries (non-EU citizens), of which:
  - citizenship of EFTA countries,
  - citizenship of Candidate countries,
  - citizenship of other non-EU countries,
- unknown citizenship.

The data laid down in Article 3(1)(b)(i) of Regulation (EC) No 862/2007 shall be disaggregated by the following groups of citizenship:

- citizenship of reporting country (national citizens),
- citizenship of another EU Member State (other EU citizens),
- citizenship of non-EU countries (non-EU citizens),
- unknown citizenship.

1.2. **Groups of country of birth**

'Country of birth' shall be defined according to Article 2(1)(e) of Regulation (EC) No 862/2007.

The data laid down in Article 3(1)(a)(ii) and (c)(ii) of Regulation (EC) No 862/2007 shall be disaggregated by the following groups of country of birth:

- reporting country (native-born),
- other EU Member States (EU foreign-born),

— outside EU (non-EU foreign-born), of which:

- EFTA countries,
- Candidate countries,
- other non-EU countries,

— unknown country of birth.

### 1.3. Groups of country of previous usual residence

The data laid down in Article 3(1)(a)(iii) of Regulation (EC) No 862/2007 shall be disaggregated by the following groups of country of previous usual residence:

- other EU Member States,
- outside EU, of which:
  - EFTA countries,
  - Candidate countries,
  - other non-EU countries,
- unknown country of previous usual residence.

### 1.4. Groups of country of next usual residence

The data laid down in Article 3(1)(b)(iv) of Regulation (EC) No 862/2007 shall be disaggregated by the following groups of country of next usual residence:

- other EU Member States,
- outside EU,
- unknown country of next residence.

## 2. ADDITIONAL GROUPS OF OTHER NON-EU COUNTRIES AND CITIZENSHIP BY LEVEL OF DEVELOPMENT

For the data laid down in Article 3(1)(a)(i), (ii) and (iii) and (c)(i) and (ii) of Regulation (EC) No 862/2007, data relating to other non-EU countries and other non-EU citizenship shall also be disaggregated by the following groups of level of development:

- highly developed countries,
- medium developed countries,
- less developed countries.

## 3. LIST OF COUNTRIES AND CITIZENSHIPS IN GROUPS

Country of birth, country of previous usual residence and country of next usual residence shall refer to the countries defined by international boundaries existing on 1 January of the reference year.

The composition of the EU, EFTA and Candidate Countries shall be as at 1 January of the reference year.

The Commission will provide Member States with lists of countries and citizenships to be included in each of the basic groups. These basic group lists shall be updated as necessary.

The Commission will provide Member States with lists of countries and citizenships to be included in each of the additional groups of level of development. These additional group lists shall be updated as necessary.

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## COMMISSION REGULATION (EU) No 352/2010

of 23 April 2010

**approving minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Pomme de terre de l'île de Ré (PDO)]**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 <sup>(1)</sup>, and in particular the second sentence of Article 9(2) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 9(1) of Regulation (EC) No 510/2006, the Commission has examined France's application for approval of an amendment to details of the specification for the protected designation of origin 'Pomme de terre de l'île de Ré', registered by Commission Regulation (EC) No 2400/96 <sup>(2)</sup>, as amended by Regulation (EC) No 1187/2000 <sup>(3)</sup>.
- (2) The purpose of the application is to amend the specification by adding the Carrera variety to the list of varieties of potato allowed for the production of the PDO 'Pomme de terre de l'île de Ré' in the category 'varieties for human consumption'. The practices in question ensure that the essential characteristics of the designation are maintained.

- (3) The Commission has examined the amendments in question and concluded that they are justified. Since these are minor amendments within the meaning of Article 9 of Regulation (EC) No 510/2006, the Commission may approve them without using the procedure set out in Articles 5, 6 and 7 of that Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specification for the protected designation of origin 'Pomme de terre de l'île de Ré' is hereby amended in accordance with Annex I to this Regulation.

*Article 2*

The updated Single Document is set out in Annex II to this Regulation.

*Article 3*

This Regulation shall enter into force on the twentieth 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, 23 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

<sup>(1)</sup> OJ L 93, 31.3.2006, p. 12.

<sup>(2)</sup> OJ L 327, 18.12.1996, p. 11.

<sup>(3)</sup> OJ L 133, 6.6.2000, p. 19.

## ANNEX I

The following amendments to the specification for the protected designation of origin 'Pomme de terre de l'île de Ré' are hereby approved:

**Method of production**

The second paragraph of the 'Method of production' section of the specification is amended as follows:

instead of: 'Potatoes qualifying for the designation of origin "Pomme de terre de l'île de Ré" must come from the varieties for human consumption Alcmaria, Goulvena, Pénélope or Starlette or the varieties for human consumption with firm flesh Amandine, BF15, Charlotte or Roseval.'

read: 'Potatoes qualifying for the designation of origin "Pomme de terre de l'île de Ré" must come from the varieties for human consumption Alcmaria, Goulvena, Pénélope, Starlette or Carrera or the varieties for human consumption with firm flesh Amandine, BF15, Charlotte or Roseval.'

The seventh paragraph of the 'Method of production' section of the specification is amended as follows:

instead of: 'Irrigation is permitted up to 25 May for the varieties Alcmaria, Goulvena, Pénélope and Starlette, and up to 15 June for the varieties Amandine, BF 15, Charlotte and Roseval.'

read: 'Irrigation is permitted up to 25 May for the varieties Alcmaria, Goulvena, Pénélope, Starlette and Carrera, and up to 15 June for the varieties Amandine, BF 15, Charlotte and Roseval.'

The tenth paragraph of the 'Method of production' section of the specification is amended as follows:

instead of: 'The dry matter content of the potatoes must be between 15 and 19% for the varieties Alcmaria, Goulvena, Pénélope and Starlette, and between 16 and 19.5% for the varieties Amandine, BF15, Charlotte and Roseval.'

read: 'The dry matter content of the potatoes must be between 15 and 19% for the varieties Alcmaria, Goulvena, Pénélope, Starlette and Carrera, and between 16 and 19.5% for the varieties Amandine, BF15, Charlotte and Roseval.'

**National requirements**

Instead of: 'Decree of 5 February 1998'

read: 'Decree on the protected designation of origin "Pomme de terre de l'île de Ré".'

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## ANNEX II

## SINGLE DOCUMENT

Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

**'POMME DE TERRE DE L'ÎLE DE RÉ'**

EC No: FR-PDO-0105-0065-14.03.2008

☐ PGI ☒ PDO

**1. Name**

'Pomme de terre de l'île de Ré'

**2. Member State or third country**

France

**3. Description of the agricultural product or foodstuff****3.1. Type of product**

Class 1.6. Fruit, vegetables and cereals, fresh or processed

**3.2. Description of the product to which the name in (1) applies**

The 'pomme de terre de l'île de Ré' is an early potato which is small in size (less than 70 mm).

Potatoes qualifying for the designation of origin 'Pomme de terre de l'île de Ré' must come from the varieties for human consumption Alcmaria, Goulvena, Pénélope, Starlette or Carrera or the varieties for human consumption with firm flesh Amandine, BF15, Charlotte or Roseval.

They are known for their firm texture and specific aromas with vegetable overtones. Their dry matter content is between 15 and 19 % for the Alcmaria, Goulvena, Pénélope, Starlette and Carrera varieties and between 16 and 19,5 % for the Amandine, BF15, Charlotte and Roseval varieties.

Harvested before they are completely mature, their skin is fine and comes off easily with simple scrubbing (flaky-skinned tubers).

They are seasonal produce and can only be sold up to 31 July inclusive of the year of the harvest and they are not suitable for long-term storage.

The 'pomme de terre de l'île de Ré' is a fresh vegetable which must be marketed quickly after harvesting.

**3.3. Raw materials (for processed products only)**

Not applicable

**3.4. Feed (for products of animal origin only)**

Not applicable

**3.5. Specific steps in production that must take place in the defined geographical area**

The potatoes are produced, sorted, sized and packaged in the region.

**3.6. Specific rules concerning slicing, grating, packaging, etc.**

The 'pomme de terre de l'île de Ré' is packaged in the region in which it grows for the following reasons:

Preserving the authenticity of the product:

The 'pommes de terre de l'île de Ré' are packaged locally in distribution packaging not exceeding 25 kg. The methods of packaging ensure that the batches and their origin can be identified, thereby helping to guarantee that the potatoes are traceable.

Preserving the characteristics of the potato:

The 'pomme de terre de l'île de Ré' is a product marketed fresh only: it must therefore be packed promptly after harvesting.

Additionally the 'pomme de terre de l'île de Ré' is harvested before it is completely mature and for this reason it is a fragile product. It is therefore necessary to avoid any blows which could lead to a change in the skin, e.g. bruises and browning. As a consequence producers take particular care at the stage of harvesting, but also during sorting and packaging, to preserve the characteristics of the potato.

### 3.7. *Specific rules concerning labelling*

The labels of potatoes using the protected designation of origin 'Pomme de terre de l'île de Ré' include in the same visual field the name of the designation and the words 'appellation d'origine contrôlée' or 'AOC' which must feature directly below the name of the designation.

## 4. **Concise definition of the geographical area**

The restricted area of production for potatoes qualifying for the protected designation of origin 'Pomme de terre de l'île de Ré' is located on the île de Ré and consists of certain parcels located on the territory of the following municipalities: Canton d'Ars-en-Ré: Ars-en-Ré, La Couarde-sur-Mer, Loix, Les Portes-en-Ré, Saint-Clément-des-Baleines; Canton de Saint-Martin de Ré: Le Bois-Plage en Ré, La Flotte, Rivedoux-Plage, Sainte-Marie-de-Ré, Saint-Martin de Ré.

## 5. **Link with the geographical area**

### 5.1. *Specificity of the geographical area*

Ile de Ré, situated on the Atlantic coast, is a good location from a climatological point of view and is characterised by:

- significant amounts of sun and light,
- low rainfall between February and May,
- exposure to warm and violent winds.

These climatic factors typical of a Mediterranean-type climate are favourable for the growth of an early potato as they allow early development (thanks to light, heat and water).

The effects of less rainfall than the average for the mainland together with the evapotranspiration are compensated for by the existence of sufficient hydrogeological reserves which allow the crops to be irrigated when the tubers are forming and developing.

On Ile de Ré the land reserved for the production of potatoes is located on coastal soil which is calcosol with a sandy texture on a limestone base. This is light, dry, filtering soil which heats up quickly and this is beneficial for the early production of potatoes. The producers of 'pommes de terre de l'île de Ré' were able to take advantage of these favourable climatological and soil conditions to successfully grow the tuber in accordance with established local practices. The originality of the cultural practices is characterised by:

- fertilisation methods: adding organic material in autumn, in particular in the form of kelp (organic compost made of marine algae harvested on the beaches of the island). This organic compost, which is one of the island's veritable treasures, has for a long time been the sole organic compost used. The kelp decomposes more quickly than bovine manure and is said to lead to less disease,
- planting in close rows, not very deep, under very shallow layers of soil. The two objectives are to both protect against the wind and to promote growth.

### 5.2. *Specificity of the product*

The 'pomme de terre de l'île de Ré' owes its reputation to its early growth in comparison with the other early potatoes on the mainland.

It is characterised by its small size: 70 % of the quantities harvested are between 30 and 60 mm.

It is known for its firm texture and specific aromas with vegetable overtones.

5.3. *Causal link between the geographical area and the quality or characteristics of the product (for PDO) or a specific quality, the reputation or other characteristic of the product (for PGI)*

The early growth of the 'pomme de terre de l'île de Ré' is due both to the nature of the particular climate of the Ile de Ré and a choice of particularly appropriate soil.

The 'pomme de terre de l'île de Ré' grows earlier than on the mainland without a need of cultivation under glass or shelter as the climate of the island and, in particular, its mild temperatures, allow early crops which will then profit from good quantities of sun and mildness to grow rapidly.

The nature of the soil chosen by the producers also helps this early growth. The light and filtering soils heat up very quickly and also evacuate the excess humidity which is harmful to the root development of the potato and to the development of the tuber.

In order to benefit from these favourable conditions, the 'pommes de terre de l'île de Ré' are planted at shallow depths.

Light soil also aids the quality of the tubers which, harvested before they are fully mature, are fragile and therefore sensitive to the slightest blows including those received at the time of harvesting. The parcels chosen are therefore sandy and not stony.

The crops are densely planted and in close rows under a slight furrow in order to resist the sometimes violent winds on the island.

These planting conditions, in particular the density, produce the characteristically small-sized 'pomme de terre de l'île de Ré'.

The organoleptic characteristics of the 'pomme de terre de l'île de Ré' play a role both in the choice of the varieties and in the early character of this potato which, together with the soil on the island, ensure that this potato remains firm after cooking and emits vegetable and spring aromas.

**Reference to the publication of the specification**

<http://www.inao.gouv.fr/repository/editeur/pdf/CDC-AOP/CDCPommeDeTerreDeLlleDeRe.pdf>

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**COMMISSION REGULATION (EU) No 353/2010****of 23 April 2010****approving minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Mirabelles de Lorraine (PGI)]**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs <sup>(1)</sup>, and in particular the second sentence of Article 9(2) thereof,

Whereas:

- (1) In accordance with the first subparagraph of Article 9(1) of Regulation (EC) No 510/2006, the Commission has examined France's application for approval of an amendment to the specification for the protected geographical indication 'Mirabelles de Lorraine', registered under Commission Regulation (EC) No 1107/1996 <sup>(2)</sup>.
- (2) The application is for the specification to be amended by the inclusion of deep-frozen mirabelles. Some other amendments have been made, in particular as regards the proof of origin and the labelling.

- (3) The Commission has examined the amendment in question and decided that it is justified. Since the amendment is minor within the meaning of Article 9 of Regulation (EC) No 510/2006, the Commission may approve it without following the procedure set out in Articles 5, 6 and 7 of the Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specification for the protected geographical indication 'Mirabelles de Lorraine' is hereby amended in accordance with Annex I to this Regulation.

*Article 2*

Annex II to this Regulation contains the Single Document setting out the main points of the specification.

*Article 3*

This Regulation shall enter into force on the 20th 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, 23 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

<sup>(1)</sup> OJ L 93, 31.3.2006, p. 12.

<sup>(2)</sup> OJ L 148, 21.6.1996, p. 1.

## ANNEX I

The specification for the protected geographical indication 'Mirabelles de Lorraine' is amended as follows:

**Description**

- (1) The following paragraph is added: '“Mirabelles de Lorraine” may be packaged and presented as a fresh or a deep-frozen product. The fresh mirabelles are for direct consumption or processing. The deep-frozen mirabelles are for processing or retail sale and come in different forms:
  - (a) whole, with stone in;
  - (b) whole, with stone removed; and
  - (c) in halves, with stone removed.'
- (2) The description of the product is more specific as to the various possible uses of the fruit and the ways in which it may be presented.
- (3) The following paragraph is added: 'The characteristics of each category of the product must comply with the respective rules in force.'
- (4) The following table laying down the physical and chemical characteristics of the product is added:

|                 | 'Mirabelles de Lorraine'                                                                                                                            |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Characteristics | Fruits $\geq 22$ mm in diameter                                                                                                                     |
|                 | Category I fruits for direct consumption                                                                                                            |
|                 | Rules for fruit for processing                                                                                                                      |
|                 | Colour $\geq 4$ (see AREFE colour scale in Annex 5)                                                                                                 |
|                 | Average sugar content $\geq 16^{\circ}$ Brix for fruit for direct consumption and $\geq 15^{\circ}$ Brix for fruit for processing (crushing method) |

**Proof of origin**

- (1) The sentence 'For each consignment, the member companies record in a register the holding where the fruit was produced, the quantity, the type of packaging and the end use' is replaced by 'For each consignment, the member companies put in place upstream and downstream traceability arrangements whereby origin, quantity, type of packaging and end use can be identified.'
- (2) The following points are deleted:
  - (a) 'the declarations of printing and use of aerex crates, banners, labels or vignettes referring to the designation;
  - (b) copy of the members' stock accounts for identifying labels, banners and vignettes.'
- (3) The following paragraphs are added:
  - (a) 'After packaging, each package of fruit for direct consumption or pallet of fruit for processing has a unique code linking to information about previous stages of handling (this code may correspond to the number of the production or pallet record).
  - (b) On consignment, the date of consignment and name of the customer are entered in the production record.'

**Method of production**

- (1) The following is added to make the reference to the types of soil more precise: '45 % of fine elements of less than 20 microns (clay plus fine silt).'
- (2) The following part of paragraph 4.4.2 is deleted: 'the climate probably has an influence on the quality of the product; the link between soil, climate and quality is currently the subject of an AREFE study: 20 orchards have been studied for the past 6 years and the conclusions of the study will be published in three years' time.'

- (3) The references to the provisions of the regional orchard replanting specifications are deleted.
- (4) The reference to the analysis of leaves in the autumn is deleted.
- (5) The reference to minimum planting densities of 150 trees per hectare is deleted.
- (6) The criteria for analysing the degree of ripeness are amended.
- (7) Reference is made to the AREFE scale rather than the Hunter A scale.
- (8) The reference to a sugar to acidity ratio of 4 or more is replaced by the minimum sugar content figure of 15° Brix.
- (9) The following explanations of cumulative temperatures are added: 'Minimum cumulative temperatures at the F2 stage of 1 750 °C (Annex 6: ripeness guide): From the point at which 50 % of the flowers are open, a cumulative count is kept of each day's average temperature. It has been shown that the Mirabelle 1510 variety is ripe at around 1 850 °C. The early strains are ripe at around 1 750 °C.'
- (10) The following paragraph on deep-freezing is added: 'The deep-freezing technique involves creating an intense heat exchange whereby the maximum temperature is reduced very rapidly to – 18 °C; this differentiates it from simple freezing. The more rapid the exchange, the better are the organoleptic properties of the product. This method of conservation preserves the quality and organoleptic characteristics of the mirabelles. Deep-freezing has certain advantages, such as:
  - (a) organoleptic advantages (appearance, consistency, flavour): of all the conservation processes, this cold treatment is the only one that is capable of restoring all the organoleptic qualities of the produce as captured in its fresh state;
  - (b) nutritional advantages: deep-freezing in itself has no impact on the nutritional value. The cold stabilises the state of the product;
  - (c) microbiological advantages: below – 18 °C, micro-organisms no longer develop. Their proliferation is also prevented by the total absence of water (which quickly turns to ice).'
- (11) The sentence 'This area corresponds to the stages in which the fruit is produced, stored before packaging and then packaged' is replaced by 'For the fresh fruit, all operations (production, sorting, sizing, packaging) are carried out in the geographical area. For the deep-frozen fruit, the following stages take place in the geographical area: production, sorting, sizing, stoning, deep-freezing.'

### Labelling

The section on labelling is brought into line with regulatory developments.

### Other

As regards the name and composition of the group:

AIAL is now AMDL.

The name of the president of the association is removed.

The names of the member companies are removed.

Text is added on the purpose and functioning of the association.

More detail is added, on the basis of the association's statute, as regards its functioning and its role in promoting quality.

The class designation is updated in line with Regulation (EC) No 1898/2006.

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## ANNEX II

## SINGLE DOCUMENT

Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin

**'MIRABELLES DE LORRAINE'**

EC No: FR-PGI-0117-0194-10.12.2007

PGI (X)      PDO ( )

**1. Name**

'Mirabelles de Lorraine'

**2. Member state or third country**

France

**3. Description of the agricultural product or foodstuff****3.1. Type of product**

Class 1.6. Fruit and vegetables

**3.2. Description of the product to which the name in (1) applies**

A round fruit, yellow or golden when ripe, with an unattached stone, small (diameter >22 mm), with an average sugar content of 16° Brix for the fruit for direct consumption and 15° Brix for the fruit for processing, colour 4 on the AREFE colour scale, produced from clones of the 'Mirabelles de Nancy' and 'Mirabelles de Metz' varieties registered in 1961 under nos 91 291 and 91 290 (*Rosaceae* family, species *Prunus Insistitia*) in the official catalogue of species.

'Mirabelles de Lorraine' are presented fresh or deep-frozen (whole with stone in, or whole or in halves with stone removed).

**3.3. Raw materials (for processed products only)**

—

**3.4. Feed (for products of animal origin only)**

—

**3.5. Specific steps in production that must take place in the identified geographical area**

For the fresh fruit, all production, sorting, sizing and packaging operations are carried out in the geographical area.

For the deep-frozen fruit, only the production, sorting, sizing, stoning and deep-freezing stages take place in the geographical area.

Specific rules concerning slicing, grating, packaging, etc.

Because of the delicacy of the fruit and the risk of squashing during transport, the fresh fruit is packaged in the geographical area.

Packaging is taken to mean wrapping of individual fruits, placing in pallets and deep-freezing.

**3.6. Specific rules concerning labelling**

'Mirabelles de Lorraine'

Name and address of the certifying group

The term 'PGI' and/or the Community logo

**4. Concise definition of the geographical area**

The geographical area of the 'Mirabelle de Lorraine' includes all municipalities in the Meuse, Meurthe-et-Moselle, Moselle and Vosges *départements*.

The protected geographical indication 'Mirabelles de Lorraine' may be used only for fruit from orchards in this area.

## 5. Link with the geographical area

### 5.1. Specificity of the geographical area

The Lorraine region is ideal for growing mirabelles. It is characterised by clay-limestone (magnesium-potassium) soils. The Lorraine mirabelle orchards are planted on soil with 45 % of fine elements of less than 20 microns (clay plus fine silt).

### 5.2. Specificity of the product

'Mirabelles de Lorraine' are the product of two local varieties, 'Mirabelles de Nancy' and 'Mirabelles de Metz'.

The specificity of 'Mirabelles de Lorraine' is linked to the method of training: for the best possible development of the fruit, the planting density in the orchards may not exceed 400 trees per hectare, the fruit is picked at the best stage of ripeness and within a short period (around six weeks from the beginning of August to mid-September). The aim is to produce a yellow, sweet fruit unlike the green, sour mirabelles found in other regions.

### 5.3. Causal link between the geographical area and the quality or characteristics of the product (for PDO) or a specific quality, the reputation or other characteristic of the product (for PGI)

The link with the geographical origin derives from the product's reputation. This, in turn, is based on the prominence of the 'Mirabelle de Lorraine' in local gastronomy and reflected in literature, in particular through historical references from the 16<sup>th</sup> century.

Also, traditional festivals that are still held today testify to the recognition enjoyed by the product among consumers. Lorraine is responsible for 70 to 80 % of France's production of fresh mirabelles.

The traditional forms of processing, to produce jam, baked goods and canned fruit, account for a significant part of the activity in the sector. The myriad of local recipes calling for mirabelles testifies to their use in these traditional forms, apart from being eaten fresh.

## Reference to publication of the specification

<http://www.inao.gouv.fr/repository/editeur/pdf/CDC-IGP/CDC-mirabelle-de-Lorraine.pdf>

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**COMMISSION REGULATION (EU) No 354/2010****of 23 April 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) <sup>(1)</sup>,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 <sup>(2)</sup>, 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 24 April 2010.

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

Done at Brussels, 23 April 2010.

*For the Commission,  
On behalf of the President,**Jean-Luc DEMARTY  
Director-General for Agriculture and  
Rural Development*<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.<sup>(2)</sup> 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 <sup>(1)</sup> | Standard import value |
|------------|-----------------------------------|-----------------------|
| 0702 00 00 | JO                                | 94,2                  |
|            | MA                                | 85,7                  |
|            | TN                                | 113,3                 |
|            | TR                                | 93,1                  |
|            | ZZ                                | 96,6                  |
| 0707 00 05 | MA                                | 41,9                  |
|            | TR                                | 113,1                 |
|            | ZZ                                | 77,5                  |
| 0709 90 70 | MA                                | 86,8                  |
|            | TR                                | 89,7                  |
|            | ZZ                                | 88,3                  |
| 0805 10 20 | EG                                | 46,5                  |
|            | IL                                | 55,6                  |
|            | MA                                | 51,7                  |
|            | TN                                | 50,4                  |
|            | TR                                | 55,8                  |
|            | ZZ                                | 52,0                  |
| 0805 50 10 | EG                                | 65,6                  |
|            | IL                                | 58,2                  |
|            | TR                                | 61,6                  |
|            | ZA                                | 64,6                  |
|            | ZZ                                | 62,5                  |
| 0808 10 80 | AR                                | 96,8                  |
|            | BR                                | 82,0                  |
|            | CA                                | 113,4                 |
|            | CL                                | 84,3                  |
|            | CN                                | 77,8                  |
|            | MK                                | 26,2                  |
|            | NZ                                | 120,0                 |
|            | US                                | 132,2                 |
|            | UY                                | 78,3                  |
|            | ZA                                | 83,0                  |
|            | ZZ                                | 89,4                  |
| 0808 20 50 | AR                                | 94,2                  |
|            | CL                                | 95,9                  |
|            | CN                                | 76,1                  |
|            | NZ                                | 167,4                 |
|            | ZA                                | 88,0                  |
|            | ZZ                                | 104,3                 |

<sup>(1)</sup> 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'.

**COMMISSION REGULATION (EU) No 355/2010****of 23 April 2010****on the issue of licences for importing rice under the tariff quotas opened for the April 2010 subperiod by Regulation (EC) No 327/98**

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) <sup>(1)</sup>,

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences <sup>(2)</sup>, and in particular Article 7(2) thereof,

Having regard to Commission Regulation (EC) No 327/98 of 10 February 1998 opening and providing for the administration of certain tariff quotas for imports of rice and broken rice <sup>(3)</sup>, and in particular the first paragraph of Article 5 thereof,

Whereas:

- (1) Regulation (EC) No 327/98 opened and provided for the administration of certain import tariff quotas for rice and broken rice, broken down by country of origin and split into several subperiods in accordance with Annex IX to that Regulation.
- (2) April is the second subperiod for the quotas provided for in Article 1(1)(a) of Regulation (EC) No 327/98.
- (3) The notification sent in accordance with Article 8(a) of Regulation (EC) No 327/98 shows that, for the quota with order number 09.4130, the applications lodged in

the first 10 working days of April 2010 under Article 4(1) of that Regulation relate to a quantity greater than that available. The extent to which import licences may be issued should therefore be determined and the allocation coefficient to be applied to the quantities applied for under the quota concerned should be laid down.

- (4) The notification also shows that, for the quotas with order numbers 09.4127 — 09.4128 — 09.4129, the applications lodged in the first 10 working days of April 2010 in accordance with Article 4(1) of the Regulation relate to a quantity less than that available.
- (5) For the quotas with order numbers 09.4127 — 09.4128 — 09.4129 — 09.4130 the total quantities available for the following subperiod should therefore be set, in accordance with the first paragraph of Article 5 of Regulation (EC) No 327/98.
- (6) In order to ensure sound management of the procedure of issuing import licences, the present Regulation should enter into force immediately after its publication,

HAS ADOPTED THIS REGULATION:

*Article 1*

1. For import licence applications for rice under the quotas with order number 09.4130 referred to in Regulation (EC) No 327/98 lodged in the first 10 working days of April 2010, licences shall be issued for the quantities requested, multiplied by the allocation coefficient set out in the Annex to this Regulation.
2. The total quantities available for the following subperiod under the quotas with order numbers 09.4127 — 09.4128 — 09.4129 — 09.4130, referred to in Regulation (EC) No 327/98, are 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*.

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 238, 1.9.2006, p. 13.

<sup>(3)</sup> OJ L 37, 11.2.1998, p. 5.

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

Done at Brussels, 23 April 2010.

*For the Commission,  
On behalf of the President,  
Jean-Luc DEMARTY  
Director-General for Agriculture and  
Rural Development*

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ANNEX

**Quantities to be allocated for the April 2010 subperiod and quantities available for the following subperiod under Regulation (EC) No 327/98**

Quota of wholly milled or semi-milled rice falling within CN code 1006 30 provided for in Article 1(1)(a) of Regulation (EC) No 327/98:

| Origin                   | Order number | Allocation coefficient for the April 2010 subperiod | Total quantities available for the July 2010 (kg) |
|--------------------------|--------------|-----------------------------------------------------|---------------------------------------------------|
| United States of America | 09.4127      | — <sup>(1)</sup>                                    | 16 870 000                                        |
| Thailand                 | 09.4128      | — <sup>(1)</sup>                                    | 8 520 395                                         |
| Australia                | 09.4129      | — <sup>(1)</sup>                                    | 876 000                                           |
| Other origins            | 09.4130      | 1,077721 %                                          | 0                                                 |

<sup>(1)</sup> Applications cover quantities less than or equal to the quantities available; all applications are therefore acceptable.

# DIRECTIVES

## COMMISSION DIRECTIVE 2010/27/EU

of 23 April 2010

amending Council Directive 91/414/EEC to include triflumizole as active substance

(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<sup>(1)</sup>, and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000<sup>(2)</sup> and (EC) No 1490/2002<sup>(3)</sup> 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 triflumizole. By Commission Decision 2008/748/EC<sup>(4)</sup> it was decided not to include triflumizole in Annex I to Directive 91/414/EEC.

(2) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier submitted a new application requesting the application of the accelerated procedure 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<sup>(5)</sup>.

(3) 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 2008/748/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(4) The Netherlands evaluated the new information and data submitted by the notifier and prepared an additional report on 6 March 2009.

(5) The additional report was peer reviewed by the Member States and the EFSA and presented to the Commission on 14 December 2009 in the format of the EFSA Conclusions for triflumizole<sup>(6)</sup>. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 12 March 2010 in the format of the Commission review report for triflumizole.

(6) The new assessment by the rapporteur Member State and the conclusion by the EFSA concentrated on the concerns that led to the non-inclusion. Those concerns were the unacceptable risk assessment for operators and workers.

(7) The new data submitted by the notifier show that the exposure of operators and workers may be considered as acceptable provided that additional protective equipment is worn.

(8) It has appeared from the various examinations made that plant protection products containing triflumizole may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include triflumizole in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 55, 29.2.2000, p. 25.

<sup>(3)</sup> OJ L 224, 21.8.2002, p. 23.

<sup>(4)</sup> OJ L 252, 20.9.2008, p. 37.

<sup>(5)</sup> OJ L 15, 18.1.2008, p. 5.

<sup>(6)</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance triflumizole. *EFSA Journal* 2009; 7(12):1415. [49 pp.]. doi:10.2903/j.efsa.2009.1415. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

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

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

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

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

*Article 2*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 November 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

*Article 3*

This Directive shall enter into force on 1 July 2010.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 23 April 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 <sup>(1)</sup>                                           | Entry into force | Expiration of inclusion | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|------------------|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '311 | Triflumizole<br>CAS No: 99387-89-0<br>CIPAC No: 730 | <i>(E)</i> -4-chloro- $\alpha,\alpha,\alpha$ -trifluoro-N-(1-imidazol-1-yl-2-propoxy-ethylidene)-o-toluidine | $\geq 980$ g/kg<br>Impurities:<br>Toluene: not more than 1 g/kg | 1 July 2010      | 30 June 2020            | PART A<br><br>Only uses as fungicide in greenhouses on artificial substrates may be authorised.<br><br>PART B<br><br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on triflumizole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to:<br><br>— the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment,<br><br>— the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, as appropriate, risk mitigation measures.' |

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

**COMMISSION DIRECTIVE 2010/28/EU**  
**of 23 April 2010**  
**amending Council Directive 91/414/EEC to include metalaxyl as active substance**  
**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

therefore necessary to assess metalaxyl once more taking into account the additional information submitted.

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

(4) An additional assessment report has been submitted by the rapporteur Member State Portugal, which has been peer reviewed by the Member States and the Commission and finalised within the Standing Committee on the Food Chain and Animal Health on 12 March 2010 in the format of the Commission review report for metalaxyl.

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

(5) The review of metalaxyl did not reveal any open questions to be addressed by the European Food Safety Authority which has taken over the role of the Scientific Committee on Plants.

Whereas:

(1) Metalaxyl is one of the substances listed in Annex I to 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 <sup>(2)</sup>.

(6) It has appeared from the various examinations made that plant protection products containing metalaxyl may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include metalaxyl in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing metalaxyl can be granted in accordance with the provisions of that Directive.

(2) As a consequence of the judgment of the Court of Justice of 18 July 2007 in Case C-326/05 P *Industrias Químicas del Vallés v Commission* <sup>(3)</sup>, which annulled Commission Decision 2003/308/EC <sup>(4)</sup> concerning the non-inclusion of metalaxyl in Annex I to Council Directive 91/414/EEC, the Commission adopted Regulation (EC) No 1313/2007 of 8 November 2007 amending Regulations (EC) No 2076/2002 as regards the extension of the time period referred to in Article 8(2) of Council Directive 91/414/EEC with respect to metalaxyl and (EC) No 2024/2006 as regards the deletion of the derogation concerning metalaxyl <sup>(5)</sup> and Regulation (EC) No 416/2008 of 8 May 2008 amending Regulation (EEC) No 3600/92 as regards the assessment of the active substance metalaxyl in the framework of Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market <sup>(6)</sup>.

(7) 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.

(3) Article 266 TFEU requires the institution whose act has been declared void to take the necessary measures to comply with the judgment of the Court of Justice. It is

(8) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of 6 months after inclusion to review existing authorisations of plant protection products containing metalaxyl 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.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 366, 15.12.1992, p. 10.

<sup>(3)</sup> [2007] ECR I-6557.

<sup>(4)</sup> OJ L 113, 7.5.2003, p. 8.

<sup>(5)</sup> OJ L 291, 9.11.2007, p. 11.

<sup>(6)</sup> OJ L 125, 9.5.2008, p. 25.

- (9) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.
- (10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

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

#### *Article 2*

Member States shall adopt and publish by 31 December 2010 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 January 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 3*

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing metalaxyl as an active substance by 31 December 2010.

By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to metalaxyl 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.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing metalaxyl 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 June 2010 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 metalaxyl. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing metalaxyl as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2014 at the latest; or
- (b) in the case of a product containing metalaxyl as one of several active substances, where necessary, amend or withdraw the authorisation by 30 June 2014 or by the date fixed for such an amendment or withdrawal in the respective directive or directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

#### *Article 4*

This Directive shall enter into force on 1 July 2010.

#### *Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 23 April 2010.

*For the Commission*  
*The President*

José Manuel BARROSO

## ANNEX

In Annex I to Directive 91/414/EEC, the following row is added at the end of the table:

| No   | Common Name,<br>Identification Numbers         | IUPAC Name                                          | Purity <sup>(1)</sup>                                                                                                                  | Entry into force | Expiration of inclusion | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------|------------------------------------------------|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '309 | Metalaxyl<br>CAS No 57837-19-1<br>CIPAC No 365 | Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-DL-alaninate | 950 g/kg<br><br>The impurity 2,6-dimethylaniline was considered of toxicological concern and a maximum level of 1 g/kg is established. | 1 July 2010      | 30 June 2020            | PART A<br><br>Only uses as fungicide may be authorised.<br><br>PART B<br><br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metalaxyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account.<br><br>Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate.' |

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

## DECISIONS

## COMMISSION DECISION

of 23 April 2010

**on financing the 2010 work programme on training in the field of food and feed safety, animal health and animal welfare in the framework of the 'Better Training for Safer Food Programme'**

(2010/230/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities <sup>(1)</sup> (hereinafter referred to as the 'Financial Regulation'), and in particular Article 75 thereof,

Having regard to Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities <sup>(2)</sup> (hereinafter referred to as the 'Implementing Rules'), and in particular Article 90 thereof,

Having regard to Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes <sup>(3)</sup>, and in particular Article 12(3) thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <sup>(4)</sup>, and in particular Article 66(1)(b) and (c) thereof,

Whereas:

- (1) Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating or reducing to acceptable levels risks to humans and animals and guaranteeing fair practices in feed and food trade and protecting

consumer interests. Article 51 of that Regulation provides that the Commission may organise training courses for the staff of the competent authorities of Member States responsible for the official controls referred to in that Regulation, which may be opened to participants from third countries, in particular developing countries. Those courses may include in particular training on Union feed and food law and animal health and animal welfare rules.

- (2) The 'Better Training for Safer Food Programme' has been established by the Commission in order to achieve the aims set out in Regulation (EC) No 882/2004. The Commission Communication COM(2006) 519 final <sup>(5)</sup> explores options for future organisation of training.
- (3) The 2010 work programme for the implementation of 'Better Training for Safer Food Programme' should therefore be adopted.
- (4) Commission Decision 2004/858/EC of 15 December 2004 setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the management of Community action in the field of public health — pursuant to Council Regulation (EC) No 58/2003 <sup>(6)</sup> has established the Executive Agency for Health and Consumers ('the Agency').
- (5) In addition, Commission Decision C(2008) 4943 of 9 September 2008 delegated to the Agency certain management and programme implementation tasks pertaining to the food safety training measures performed pursuant to Regulation (EC) No 882/2004. An operating subsidy should therefore be granted to the Agency for 2010 for financing activities related to the 'Better Training for Safer Food Programme'.
- (6) The 2010 work programme being a sufficiently detailed framework, the present Decision constitutes a financing decision within the meaning of Article 90 of the Implementing Rules.

<sup>(1)</sup> OJ L 248, 16.9.2002, p. 1.

<sup>(2)</sup> OJ L 357, 31.12.2002, p. 1.

<sup>(3)</sup> OJ L 11, 16.1.2003, p. 1.

<sup>(4)</sup> OJ L 165, 30.4.2004, p. 1.

<sup>(5)</sup> SEC(2006) 1163 and SEC(2006) 1164, 20.9.2006.

<sup>(6)</sup> OJ L 369, 16.12.2004, p. 73.

- (7) For the application of this Decision, it is appropriate to define the term 'substantial change', within the meaning of Article 90(4) of the Implementing Rules.
- (8) Pursuant to Article 83 of Regulation (EC, Euratom) No 1605/2002, the validation, authorisation and payment of expenditure must be completed within the time limits laid down in the Implementing Rules. Those rules are also to specify the circumstances in which creditors paid late are entitled to receive default interest charged to the line from which the principal was paid.
- (9) This Decision should therefore provide rules on the payment of default interest due for late payments related to actions included in the 2010 work programme,

HAS ADOPTED THIS DECISION:

#### *Article 1*

The work programme for the implementation in 2010 of the 'Better Training for Safer Food Programme' as set out in the Annex is hereby adopted. It constitutes a financing decision in the meaning of Article 75 of the Financial Regulation.

#### *Article 2*

1. The total amount of the financial contribution from the Commission for the implementation of the work programme shall be EUR 15 370 000, to be financed from the following budget lines of the General Budget of the European Union for 2010:

- (a) budget line no 17 04 07 01: EUR 14 000 000;

- (b) budget line no 17 01 04 05: EUR 260 000;

- (c) budget line no 17 01 04 31: EUR 1 110 000.

2. The amount provided for in paragraph 1(c) shall be paid to the Agency and shall constitute an operating subsidy.

3. Default interest due for late payment may also be paid from the same budget lines, in accordance with Article 83 of Regulation (EC, Euratom) No 1605/2002.

#### *Article 3*

Cumulated changes of the allocations to the specific actions covered by the work programme not exceeding 20 % of the maximum financial contribution provided for in Article 2(1) shall not be considered to be substantial within the meaning of Article 90(4) of Regulation (EC, Euratom) No 2342/2002, provided that they do not significantly affect the nature and objective of the work programme.

The authorising officer may adopt such changes in accordance with the principles of sound financial management and of proportionality.

Done at Brussels, 23 April 2010.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

**2010 work programme on training in the field of food and feed safety, animal health and animal welfare in the framework of the 'Better Training for Safer Food Programme'****1.1. Introduction**

This work programme contains three implementing measures for 2010. On the basis of the objectives laid down in Regulation (EC) No 882/2004, the distribution of budget and the main actions are the following:

**1.2. Procurement (implemented in direct centralised management):**

|                                                                                                                     |                       |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|
| 1.2.1. Training: external contracts for the execution of the training programme                                     | EUR 14 000 000        |
| 1.2.2. Training: annual report, IT equipment and tools, promotional material, information and communication support | EUR 260 000           |
| 1.3. Other actions: operating subsidy for the Agency                                                                | EUR 1 110 000         |
| <b>TOTAL</b>                                                                                                        | <b>EUR 15 370 000</b> |

**1.2. Procurement**

The global budgetary envelope reserved in 2010 for the procurement contracts amounts to EUR 14 000 000.

**1.2.1. Training: External contract for the execution of the training programme****LEGAL BASIS**

Regulation (EC) No 882/2004, Article 51 and Article 66(1)(b).

**BUDGETARY LINE**

Budget line: 17 04 07 01

**INDICATIVE NUMBER AND TYPE OF CONTRACTS ENVISAGED**

For each of the technical issues referred to below, one or more specific service contracts will be signed. It is estimated that around 17 service contracts will be signed. External contractors are mainly involved in the organisational and logistical aspects of the training activities.

**SUBJECT OF THE CONTRACTS ENVISAGED (IF POSSIBLE)**

For 2010, the training action will concern the following subjects:

- veterinary and food and feed safety control checks in Border Inspection Posts (airports, seaports and roads/rail),
- zoonoses and microbiological criteria in foodstuffs,
- Animal Welfare,
- Plant Protection Products,
- feed law: focus on feed hygiene rules,
- prevention, control and eradication of Transmissible Spongiform Encephalopathies,
- controls on products of non-animal origin at import,
- EU quality schemes (organic farming and geographical indications),
- internal auditing of official control systems,
- support for Union controls in Member States and third countries,
- RASFF/TRACES in third countries,
- GMO analysis,
- EU food rules and food import requirements,

- diagnosis and control of Highly Pathogenic Avian Influenza and other animal diseases,
- other animal health and welfare, feed and food safety issues, cooperation with other International Organisations on food safety training and studies, conferences and assessments.

#### IMPLEMENTATION

EUR 13 320 000 (financing of food safety measures under Regulation (EC) No 882/2004) will be managed and implemented by the Agency (Commission Decision 2008/544/EC <sup>(1)</sup>). The remaining EUR 680 000 will be used by the Commission to cover the programme on GMO and studies, conferences and assessments.

#### INDICATIVE TIMEFRAME FOR LAUNCHING THE PROCUREMENT PROCEDURE

Approximately between April and June in order to have the contracts signed during 2010.

#### INDICATIVE AMOUNT OF THE CALL FOR TENDERS

EUR 14 000 000.

#### 1.2.2. *Training: annual report, IT equipment and tools, promotional material, information and communication support*

##### LEGAL BASIS

Regulation (EC) No 882/2004, Article 66(1)(c).

##### BUDGETARY LINE

Budget line: 17 01 04 05

##### INDICATIVE NUMBER AND TYPE OF CONTRACTS ENVISAGED

It is estimated that around 3 service contracts will be signed.

##### SUBJECT OF THE CONTRACTS ENVISAGED (IF POSSIBLE)

The actions to be financed under this budget are aimed at arranging the training programmes, IT and e-learning equipment and tools, as well as promotional material, information and communication supports.

#### IMPLEMENTATION

This action will be implemented directly by DG SANCO.

#### INDICATIVE TIMEFRAME FOR LAUNCHING THE PROCUREMENT PROCEDURE

Approximately between April and September.

#### INDICATIVE AMOUNT OF THE CALL FOR TENDERS

EUR 260 000.

#### 1.3. **Other actions: operating subsidy for the Agency**

##### LEGAL BASIS

Regulation (EC) No 58/2003, in particular Article 12(3).

##### BUDGETARY LINE

Budget line: 17 01 04 31

##### AMOUNT

EUR 1 110 000.

##### DESCRIPTION AND OBJECTIVE OF THE IMPLEMENTING MEASURE

This budget finances the Agency's operating subsidy for 2010 related to the programmes under 'FP Heading 2'. Budget line 17 01 04 31 finances the Agency's 2010 operating subsidy for the part related to the 'Better Training for Safer Food Programme'. According to Article 12(3) of Regulation (EC) No 58/2003 the operating subsidy is to be drawn from the financial allocation to the Union programmes managed by the Agency. Two separate budget lines have been created in the 2010 budget for the subsidy to be paid to the Agency, one for programmes under heading 2 and another for programmes under heading 3b of the Financial Perspectives.

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<sup>(1)</sup> OJ L 173, 3.7.2008, p. 27.





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