ISSN 1725-2555

Official Journal of the European Union

L 52

English edition

Legislation

Volume 53

3 March 2010

Contents

[1] Text with EEA relevance

(Continued overleaf)

Price: EUR 4

EN

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

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

EN

([1]) Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 175/2010

of 2 March 2010

implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species *Crassostrea gigas* in connection with the detection of Ostreid herpesvirus 1 µvar (OsHV-1 µvar)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals [1], and in particular Articles 41(3) and 61(3) thereof,

Whereas:

(1) Directive 2006/88/EC lays down the animal health requirements to be applied for the placing on the market of aquaculture animals and products thereof. In addition, it lays down minimum preventive measures to be applied in the event of a suspicion of, or an outbreak of certain diseases in aquatic animals.

(2) Article 41 of that Directive provides that Member States are to take appropriate measures to control an emerging disease situation and prevent that disease from spreading. In the case of an emerging disease situation, the Member State concerned is to inform the Commission, the Member States and EFTA Member States without delay, where the findings are of epidemiological significance to another Member State.

(3) Increased mortality in oysters of the species *Crassostrea gigas* (*Crassostrea gigas* oysters) were detected in several areas in France and in Ireland during the late spring and summer of 2008. It was attributed to a combination of adverse environmental factors together with the presence of bacteria of the genus Vibrio and the presence of the Ostreid herpesvirus-1 (OsHV-1) including a newly described genotype of that virus named OsHV-1 µvar.

(4) The French authorities informed the Commission, the Member States and EFTA Member States on the situation and on the measures taken in August 2008, and the matter was brought to the attention of the Standing Committee on the Food Chain and Animal Health in September 2008.

(5) In spring 2009 increased mortality attributed to the same combination of factors was again detected in France, Ireland and the Channel Islands. While the causes of the mortalities still remain uncertain, the epidemiological investigations undertaken in Ireland and the United Kingdom in 2009 suggest that OsHV-1 µvar play a major role in the mortalities.

(6) The competent authority of those Member States and of the Channel Islands informed the Commission of the situation and the measures taken and the matter was brought to the attention of the Standing Committee on the Food Chain and Animal Health several times.

(7) The containment measures taken by the competent authority in those Member States and of the Channel Islands to control the emerging disease situation were mainly based on the restriction of movements of *Crassostrea gigas* oysters out of the areas affected by increased mortalities.

(8) In view of the reoccurrence of the emerging disease situation in 2009 and its possible repetition and risk for further spread in spring and summer 2010, and on the basis of the experience gained, it is appropriate and necessary to extend the measures already taken by the affected Member States.

(9) To ensure uniform conditions for the implementation of the requirements of Directive 2006/88/EC regarding emerging diseases, and to ensure that the measures taken provide sufficient protection against further spread whilst not imposing unnecessary restrictions on movements of *Crassostrea gigas* oysters, it is needed to coordinate the measures as regards this emerging disease situation at a European Union level.

[1] OJ L 328, 24.11.2006, p. 14.

(10) When the competent authorities are informed that increased mortality in the *Crassostrea gigas* oysters has been detected, sampling and testing should be carried out to detect or rule out the presence of OsHV-1 µvar.

(11) When the presence of virus genotype OsHV-1 µvar has been confirmed, disease control measures should be implemented by the Member States including the establishment of a containment area. When defining the containment area certain factors set out in this Regulation should be taken into account. Those disease control measures should last until inspections have shown that the increased mortalities have ceased.

(12) Restriction to the movements out of the containment areas of *Crassostrea gigas* oysters should be laid down to limit the risk of spread of the disease. However, certain derogations should be provided for where the risk of spreading the disease is reduced. These derogations affects movements of certain *Crassostrea gigas* oysters intended for farming or relaying areas in another containment area or intended for human consumption. To ensure traceability of consignments of *Crassostrea gigas* oysters intended for farming or relaying areas, they should be accompanied by an animal health certificate. When completing the certificate the explanatory notes set out in Annex V to 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 [1] should be taken into account.

(13) With the aim to gain further knowledge on the status of this emerging disease situation in the Union and in particular in Member States and compartments not yet affected, and to ensure an early detection of any occurrence of OsHV-1 µvar, Member States may wish to establish programmes with targeted sampling and testing for the early detection of OsHV-1 µvar. *Crassostrea gigas* oysters originating from areas which have been subject to containment measures in 2009 in accordance with national measures or in 2010 in accordance with this Regulation should be subject to additional animal health requirements if introduced for farming or relaying purposes into Member States or compartments covered by such a programme, as long as OsHV-1 µvar is not detected in that Member State or compartment.

(14) To ensure that data collected in different Member States in the context of programmes with targeted sampling and testing for the early detection of OsHV-1 µvar are comparable, certain requirements on the content of such programmes should be laid down.

(15) The availability of accurate and timely information on the situation as regards the detection of OsHV-1 µvar in the Member States is a key element to ensure a proper control of the emerging disease situation. For that purpose, Member States should inform the Commission and the other Member States of the first confirmed presence of the OsHV-1 µvar virus on their territories in 2010 without undue delay.

(16) In addition, advantage should be taken of the internet-based information pages drawn up in accordance with Article 10 of Commission Decision 2009/177/EC of 31 October 2008 implementing Council Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of Member States, zones and compartments [2].

(17) To ensure transparency and timely access to the relevant information on the emerging disease situation, Member States should make available to the European Commission and to other Member States information concerning the containment areas, areas previously subjected to containment measures, but where the absence of OsHV-1 µvar has been demonstrated and programmes established for the early detection of the OsHV-1 µvar.

(18) As there are still great uncertainties as regards the emerging disease situation, the measures provided for in this Regulation should apply until the end of December 2010.

(19) 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

Definition

For the purposes of this Regulation, OsHV-1 µvar means a genotype of the virus Ostreid herpesvirus-1 (OsHV-1) which is defined on the basis of partial sequence data exhibiting a systematic deletion of 12 base pairs in ORF 4 of the genome in comparison with OsHV-1 (GenBank # AY509253).

Article 2

Sampling, testing and establishment of containment areas

1. When increased mortality in oysters of the species *Crassostrea gigas* (*Crassostrea gigas* oysters) is detected, the competent authority shall:

(a) take samples in accordance with Part A of Annex I;

(b) test for the presence of OsHV-1 µvar in accordance with the diagnostic methods set out in Part B of Annex I.

[1] OJ L 337, 16.12.2008, p. 41.

[2] OJ L 63, 7.3.2009, p. 15.

2. When the results of the tests referred to in paragraph 1(b) reveal the presence of OsHV-1 µvar, the competent authority shall establish a containment area. That area shall be defined on the basis of a case-by-case analysis taking into account the factors influencing the risk for the spread of the disease set out in Part C of Annex I.

3. Member States shall inform the Commission and other Member States without undue delay of the first containment area established on their territory in 2010.

Article 3

Placing on the market requirements for *Crassostrea gigas* oysters originating from a containment area referred to in Article 2

1. *Crassostrea gigas* oysters originating from containment areas established in accordance with Article 2(2), shall not be moved out of that area.

2. By way of derogation from paragraph 1, consignments of *Crassostrea gigas* oysters may be moved out of the containment area where:

(a) they are intended for another containment area established in accordance with Article 2(2);

(b) they are originating from a part of the containment area, including hatcheries, not affected by the increased mortalities and the consignment has been subject to:

(i) sampling in accordance with Part A of Annex I; and

(ii) testing for the presence of OsHV-1 µvar in accordance with the diagnostic methods set out in Part B of Annex I, with all results being negative;

(c) they are intended for further processing, purification centres, dispatch centres or processing establishments before human consumption which are equipped with an effluent treatment system validated by the competent authority that:

(i) inactivates enveloped viruses; or

(ii) reduces the risk of transmitting diseases to the natural waters to an acceptable level;

(d) they are intended for human consumption and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council [1], and are:

(i) no longer able to survive as living animals if returned to the environment from which they originate; or

(ii) intended for further processing without temporary storage at the place of processing;

(e) the consignments or products thereof are intended for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004.

3. The consignments referred to in paragraph 2(a) and (b) and intended for farming or relaying areas shall be accompanied by an animal health certificate completed in accordance with the model set out in Annex II to this Regulation and the explanatory notes set out in Annex V to Regulation (EC) No 1251/2008.

Article 4

Lifting of measures provided for in Articles 2 and 3

The competent authority may lift the control measures as regards the containment areas established in accordance with Article 2(2) and the placing on the market restrictions provided for in Article 3 after it has carried out two consecutive inspections 15 days apart that show that the increased mortality has ceased.

Article 5

Placing on the market requirements for *Crassostrea gigas* oysters originating from a compartment previously subjected to control measures due to increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar

1. *Crassostrea gigas* oysters that are placed on the market and originating from a compartment which has been subject to containment measures either in 2009 or 2010 due to increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar shall:

(a) be accompanied by an animal health certificate completed in accordance with the model set out in Annex II to this Regulation and the explanatory notes set out in Annex V to Regulation (EC) No 1251/2008, if the animals:

(i) are intended for Member States or compartments which have established a programme for the early detection of OsHV-1 µvar, and in which OsHV-1 µvar is not detected; and

(ii) are intended for farming or relaying areas;

(b) originate from a compartment where the absence of OsHV-1 µVar is demonstrated by sampling and testing carried out in accordance with Part A of Annex I; and

(c) comply with the animal health requirements set out in the model certificate, referred to in point (a).

2. A programme for the early detection of OsHV-1 µvar referred to in paragraph 1(a)(i) shall comply with the following requirements:

(a) the programme must be declared to the Standing Committee on the Food Chain and Animal Health;

[1] OJ L 139, 30.4.2004, p. 55.

(b) such declaration must be in conformity with point 1, points 5.1, 5.2, 5.3, 5.5, and 5.9, and points 6 and 7 of the model form set out in Annex II to Decision 2009/177/EC;

(c) the programme must include:

(i) sampling in accordance with Part A of Annex I;

(ii) testing for the presence of OsHV-1 µvar in accordance with the diagnostic methods set out in Part B of Annex I.

3. Paragraph 1 shall apply one week from the date of the meeting of the Standing Committee on the Food Chain and Animal Health at which the programme referred to in paragraph 1(a)(i) was declared.

Article 6

Internet-based information page

1. Member States shall make available to the Commission and the other Member States:

(a) a list of containment areas and the factors that have been taken into account to define such areas, including a description of the geographical boundaries of the relevant area, established in accordance with Article 2(2);

(b) a list of compartments including a description of the geographical boundaries of the relevant area:

(i) which have been subject to containment measures in 2009 due to increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar;

(ii) where the absence of OsHV-1 µvar has been demonstrated by a testing carried out in accordance with Parts A and B of Annex I in samples taken in the containment area;

(c) declarations of programmes referred to in Article 5(2), including a description of the geographical boundaries of the relevant area.

2. The information provided for in paragraph 1 shall be kept up-to-date and made available through the internet-based information pages established in accordance with Article 10 of Decision 2009/177/EC.

Article 7

Reporting

By 1 October 2010 at the latest, Member States shall submit a report to the Commission on programmes declared in accordance with Article 5(2).

The report shall be in conformity with the model form set out in Annex VI to Decision 2009/177/EC.

Article 8

Entry into force and application

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

It shall apply from 15 March 2010 to 31 December 2010.

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

Done at Brussels, 2 March 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

PART A

Sampling

1. *Sampling for the purposes of Article 2*

Samples as provided for in Article 2 shall consist of at least 12 individuals of *Crassostrea gigas* oysters. When selecting those animals weak, gaping or freshly dead (not decomposed) individuals shall be sampled and they shall be collected from the compartment where the mortality is observed.

2. *Sampling for the purposes of Article 3(2)(b), 5(1)(b) and 5(2)*

(a) Sampling for the purposes of Article 3(2)(b) shall consist of:

(i) in the case of larvae, five pools of at least 50 mg of whole animals collected between 4 and 8 days after fecundation including shell per consignment;

(ii) in the case of spat smaller than 6 mm, 30 pools of 300 mg of whole animals including shell per consignment;

(iii) in the case of oysters bigger than 6 mm, 150 individuals per consignment.

When selecting those animals, all parts of the consignment must be proportionally represented in the sample. If weak, gaping or freshly dead (not decomposed) animals are present, primarily such animals shall be selected.

(b) Sampling for the purposes of Article 5(2) shall consist of at least 150 individuals of *Crassostrea gigas* per sampling points. All farms or mollusc farming areas in the Member State or compartment covered by the programme shall be sampled.

Sampling for the purposes of Article 5(1)(b) shall consist of at least 150 individuals of *Crassostrea gigas* oysters per compartment.

When selecting those animals, the following criteria shall be taken into account:

— If weak, gaping or freshly dead (not decomposed) animals are present, primarily such animals shall be selected. If such animals are not present, the animals selected shall include healthy molluscs less than 12 months old.

— When sampling in farms in which more than one water source is utilised for production, animals representing all water sources must be included for sampling in such a way that all parts of the farm are proportionally represented in the sample.

— When sampling in mollusc farming areas, animals from a sufficient number of sampling points, at least three sampling points, shall be included in the sample in such a way that all parts of the mollusc farming area are proportionally represented in the sample, including natural beds present in the mollusc farming area. The main factors to be considered for the selection of these sampling points are: previous detection of OsHV-1 µvar in the area, stocking density, water flows, bathymetry and management practices.

(c) The sampling provided for in Article 5(2) shall be carried out in the period of the year when prevalence of OsHV-1 µvar in the Member State or compartment is known to be maximal. When such data is not available, sampling shall be carried out just after the period when the water temperature exceeds 16 °C or at the time of the year when the temperature normally reaches its yearly maximum.

(d) The sampling provided for in Article 5(1)(b) shall preferably be carried out in the period of the year described in point c. If samples are collected outside that period of the year, the sampled oysters must be maintained under conditions equivalent to those described in point c for a period suitable for the detection of OsHV-1 µvar, before being tested.

PART B

Diagnostic methods of detecting OsHV-1 µvar

1. *Scope*

This procedure explains a standard diagnostic method to be used for OsHV-1 µvar detection and identification by Polymerase Chain Reaction (hereinafter PCR). It allows distinguishing between OsHV-1 and OsHV-1 µvar.

When appropriate, in order to optimise the reaction conditions and to suit the equipment and conditions in their own laboratory, the laboratories may apply modifications to the methods described in this Annex, provided that an equal sensitivity and specificity can be demonstrated.

2. *Definition*

OsHV-1 µvar is defined in Article 1 of this Regulation.

3. *Equipment and environmental conditions*

The diagnostic test used for OsHV-1 µvar detection and identification by PCR requires the equipment and environmental conditions classically used for PCR assays as follows:

— A closed hood equipped with an UV producing system to eliminate potential contaminations when preparing PCR mix.

— Two complete sets of pipettes (2 µl; 20 µl; 200 µl and 1 000 µl), the first one for DNA extraction, and the second one for PCR mix preparation.

— Three different pipettes: one pipette (2 µl) to dispense samples in PCR mix, one pipette (20 µl) for EB sampling and another pipette (20 µl) to load PCR products in agarose gels.

— Filter pipette tips (2 µl; 20 µl; 200 µl and 1 000 µl) for DNA extraction, PCR mix preparation and sample dispensing.

— Pipette tips (20 µl) to collect EB and to load amplification products in agarose gel.

— A thermal cycler to perform amplifications.

— A horizontal electrophoresis system for PCR products electrophoresis.

— An UV table to observe PCR products after agarose gel electrophoresis.

— A system to acquire pictures of the gels.

The manipulator must wear a lab coat and some gloves during all the different steps described bellow. Lab coat and gloves must be changed preferably after each main step: DNA extraction, preparation of PCR mix, sample dispensing, amplification and gel loading.

It is recommended to perform these different steps in different rooms. More particularly, amplification and gel loading/electrophoresis should take place in a room separate from DNA extraction, PCR mix preparation and DNA dispensing.

4. *Procedure*

4.1. Sample preparation

Live or freshly dead (not decomposed) oysters, which can be previously frozen, are processed for DNA extraction.

Samples are processed differently according to their size:

(a) For larvae, pools of 50 mg of the whole animals (including the shell) completed with 200 µl of distilled water are crushed and centrifuged at 1 000 g for 1 minute.

(b) For spat smaller than or of 6 mm, pools of 300 mg of the whole animals (including the shell) completed with 1 200 µl of distilled water are crushed and centrifuged at 1 000 g for 1 minute.

(c) For spat between 6 and 15 mm in size, all the soft tissues of each animal are crushed individually.

(d) For animals bigger than 15 mm, pieces of gills and mantle are isolated.

DNA extraction is performed using the QIAamp® DNA Mini Kit (QIAGEN) and following the instructions for Tissue Test Protocol.

The further sample preparation is performed in the following order:

1. Place 100 µl of supernatant for samples referred to in (a) and (b) or 10 to 50 mg of tissues for samples referred to point (c) and (d) in a 1,5 ml microcentrifuge tube and add 180 µl of Buffer ATL.

2. Add 20 µl Proteinase K, mix by vortexing and incubate at 56 °C until the tissue is completely lysed (overnight). Vortex occasionally during incubation to disperse sample. Briefly centrifuge the 1,5 ml microcentrifuge tube to remove drops from the lid.

3. Add 200 µl Buffer AL to the sample, mix by pulse-vortexing for 15 s and incubate at 70 °C for 10 minutes. Briefly centrifuge the 1,5 ml microcentrifuge tube to remove drops from the lid.

4. Add 200 µl ethanol (96-100 %) to the sample, and mix by pulse-vortexing for 15 s. Briefly centrifuge the 1,5 ml microcentrifuge tube to remove drops from the lid.

5. Carefully apply the mixture from step 4 to the QIAamp Spin Column (in a 2 ml collection tube) without wetting the rim. Close the cap and centrifuge at 10 000 rpm for 1 min. Place the QIAamp Spin Column in a clean 2 ml collection tube (provided in the kit) and discard the tube containing the filtrate.

6. Carefully open the QIAamp Spin Column and add 500 µl Buffer AW1 without wetting the rim. Close the cap and centrifuge at 10 000 rpm for 1 min. Place the QIAamp Spin Column in a clean 2 ml collection tube (provided in the kit) and discard the collection tube containing the filtrate.

7. Carefully open the QIAamp Spin Column and add 500 µl Buffer AW2 without wetting the rim. Close the cap and centrifuge at full speed (14 000 rpm) for 3 min.

8. (Optional) Place the QIAamp Spin Column in a new 2ml collection tube (not provided in the kit) and discard the collection tube containing the filtrate. Centrifuge at full speed (14 000 rpm) for 1 min.

9. Place the QIAamp Spin Column in a clean 1,5 ml microcentrifuge tube (not provided in the kit) and discard the collection tube containing the filtrate. Carefully open the QIAamp Spin Column and add 100 µl of distilled water. Incubate 5 minutes at room temperature and centrifuge at 10 000 rpm for 1 min.

10. Control the quality and efficacy of the extraction (for example by measuring OD (260 nm) under spectrophotometer or after electrophoresis in agarose gel).

11. Prepare dilution of your samples in order to have a final DNA concentration of 50-100 ng/µl.

12. DNA solutions are kept at 4 °C until PCR analyses are performed.

Other commercial kits may be used for the DNA extractions provided they have been demonstrated to give similar results.

4.2. *Polymerase Chain Reaction (PCR)*

4.2.1. Reactives

— 10 X Buffer (furnished with the Taq DNA polymerase)

— $MgCl_2$ (furnished with the DNA polymerase) (25 mM)

— Taq DNA Polymerase (Goldstar, Eurogentec) 5 U/µl

— dNTP (dATP, dCTP, dGTP, dTTT) Master Mix (20mM) must be diluted 10 fold (at 2 mM) before use

— d H_2O (distilled H_2O free of DNA and RNA)

4.2.2. Primers

The following primers [1] must be used:

CF (10 µM)

CR (10 µM)

4.2.3. PCR mix

PCR mix for each tube is:

	Volume per tube	Final concentration
Buffer (10 X)	5 µl	1 X
$MgCl_2$ (25 mM)	5 µl	2,5 mM
dNTP (2 mM)	5 µl	0,2 mM
CF (10 µM)	1 µl	0,2 µM
CR (10 µM)	1 µl	0,2 µM
Taq polymérase (5U/µl)	0,5 µl	2,5 U
dH_2O	31,5 µl	

— 49 µl of this PCR mix is dispensed in each PCR tube

— 1 µl of extracted DNA (50-100 ng/µl) is added to each tube

4.2.4. Controls

Two types of control are used:

— Negative controls consist of dH_2O (1 µl for 49 µl of PCR mix). They aim at detecting potential reactive contamination or working environment. One negative control should be included every 10 samples or after each batch of samples.

[1] These primers or descriptions thereof may be obtained from the Community Reference Laboratory for Mollusc Diseases (LGP-Ifremer, av de Mus de Loup, 17390 La Tremblade, France).

— Positive controls consist of plasmidic DNA containing the OsHV-1 target genome region CF-CR. They aim at checking the efficacy of the PCR reaction. One positive control should be included for each PCR analysis. Positive controls are available from the Community Reference Laboratory.

4.2.5. Amplification

Amplification cycles are performed in a thermal cycle apparatus.

— Initial denaturation: 2 min at 94 °C

— Amplification: 35 cycles (1 min at 94 °C, 1 min at 50 °C and 1 min at 72 °C)

— Final elongation: 5 min at 72 °C

4.3. *Electrophoresis*

4.3.1. Reactives

— 50 X TAE (can be bought directly ready for use):

Tris base (40 mM) 242 g

Acetic glacial acid (40 mM) 57,1 ml

$Na_2EDTA.2H_2O$ (1 mM) 18,61 g

dH_2O for 1 liter

Ajust at pH 8

— Agarose gel 2,5 % in 1 X TAE

Ethidium bromide (0,5 µg/ml) added after cooling the gel.

— Loading blue dye:

Bromophenol blue 0,25 %

Cyanol xylene FF 0,25 %

Sucrose 40 %

Keep at 4 °C.

Use diluted 6 times (2 µl of loading blue buffer for 10µl of PCR products).

— Molecular weight marker:

SmartLadder SF (Eurogentec): a ready-to-use molecular weight marker including 9 regularly spaced bands from 100 to 1 000 bp.

4.3.2. Agarose gel preparation

1. Weight 2,5 g of agarose, add 100 ml of 1 X TAE and heat until the mix is melted.

2. After cooling the solution, ethidium bromide is added (5 µl for 100 ml of agarose gel) and the solution is disposed in a specific mould equipped with combs (to form slots).

3. When gel is polymerised, combs are removed and gel is placed in a horizontal electrophoresis system containing enough 1 X TAE to the cover agarose gel.

4. 10 µl of PCR products are mixed with 2 µl of blue dye (6 X) and disposed in the slots.

5. One whole is dedicated to the molecular weight marker (5 µl).

6. A voltage of 50 to 150 volts is applied during 30 min to 1 hour depending on the gel size and thickness.

7. Gel is observed under UV.

4.4. *Interpretation*

The presence of OsHV-1 µvar in a sample is indicated by the presence of a band of the appropriate size (157 bp instead of 173 bp for OsHV-1) on a 2,5 % agarose gel with all negative controls negative and all positive controls positive.

PART C

Definition of the containment area

The following factors influencing the risks for the spread of the disease shall be taken into account when defining the containment area in accordance with Article 2(2):

(a) the number, rate and distribution of molluscs on the farm or mollusc farming area infected;

(b) distance and density of neighbouring farms or mollusc farming areas;

(c) proximity to processing establishments, contact farms or contact mollusc farming areas;

(d) species present at the farms or mollusc farming areas;

(e) farming practices applied in the affected and the neighbouring farms or mollusc farming areas; and

(f) hydrodynamic conditions and other factors of epizootiological significance identified.

ANNEX II

Model animal health certificate for the placing on the market of *Crassostrea gigas* oysters intended for farming and relaying areas

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor
Name
Address
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
Name
Address
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
Approved aquaculture holding ☐
Other ☐
Name Approval number
Address
Postal code

I.13. Place of destination
Approved aquaculture holding ☐
Other ☐
Name Approval number
Address
Postal code

I.14. Place of loading
Postal code

I.15. Date and time of departure

I.16. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:

I.17. Transporter
Name Approval number
Address
Postal code Member State

I.18. Animal species/product

I.19. Commodity code (CN code)
03.07

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
Breeding ☐ Relaying ☐

I.26. Transit through third country ☐
Third country ISO code
Exit point Code
Entry point BIP unit no.:

I.27. Transit through Member States ☐
Member State ISO code
Member State ISO code
Member State ISO code

I.28. Export ☐
Third country ISO code
Exit point Code

I.29.

I.30.

I.31. Identification of the animals

Species (Scientific name) Quantity

EUROPEAN UNION

For the placing on the market of *Crassostrea gigas* oysters intended for farming and relaying areas

Part II: Certification

II. **Health information**	II.a. Certificate reference number	II.b.

([1])([2])[II.1 **Requirements for Crassostrea gigas oysters originating from a containment area established in accordance with Article 2 of Regulation (EU) No 175/2010**

I, the undersigned official inspector, hereby certify that the *Crassostrea gigas* oysters referred to in Part I of this certificate:

II.1.1 originate from an area subject to disease control measures regarding increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar;.

([1])[II.1.2 are allowed to be placed on the market according to Article 3(2)(a) of Regulation (EU) No 175/2010;]

([1])[II.1.2 are originating from a part of the containment area not affected by the increased mortalities and the consignment has been subject to sampling and testing in accordance with Annex I to Regulation (EU) No 175/2010 in *Crassostrea gigas* oysters with negative result;]]

([1])([3])[II.2 **Requirements for *Crassostrea gigas* oysters originating from a Member State or compartment previously subjected to containment measures as regards increased mortalities in *Crassostrea gigas* oysters in connection with OsHV-1 µvar and intended for Member States or compartments subject to a programme for the early detection of OsHV-1 µvar**

I, the undersigned official inspector, hereby certify that the *Crassostrea gigas* oysters referred to in Part I of this certificate:

II.2.1 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 increased mortalities;

II.2.2 originate from a compartment, where the absence of OsHV-1 µvar is demonstrated by a sampling and testing carried out in accordance with Annex I to Regulation (EU) No 175/2010 in *Crassostrea gigas* oysters.]

II.3 **Transport and labelling requirements**

I, the undersigned official inspector, hereby certify that:

II.3.1 the *Crassostrea gigas* oysters referred to in Part I of this certificate are placed under conditions, including with a water quality, that do not alter their health status;

II.3.2 the transport container prior to loading is clean and disinfected or previously unused;

II.3.3 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:

either ([1])['*Crassostrea gigas* oysters intended for farming/relaying in an area subject to a programme for the early detection of OsHV-1 µvar']

or (1)['*Crassostrea gigas* oysters intended for farming/relaying in an area subject to disease control measures and originating from an area subject to disease control measures'].

Notes

Part I:

— Box I.12: If appropriate, use the authorisation number for the farm or mollusc farming area in question.

— Box I.13: If appropriate, use the authorisation number for the farm or mollusc farming area in question.

— Box I.20 and I.31: As regards quantity, give the total number.

— Box I.25: Use the option 'Breeding' if intended for farming, 'Relaying' if intended for relaying.

EUROPEAN UNION

For the placing on the market of *Crassostrea gigas* oysters intended for farming and relaying areas

II. **Health information**	II.a. Certificate reference number	II.b.

Part II:

([1]) Keep as appropriate.

([2]) Part II.1 of this certificate applies to consignments of *Crassostrea gigas* oysters originating from a containment area established in accordance with Article 2(2) of Regulation (EU) No 175/2010 and which according to Article 3(2)(a) or (b) of that Regulation is allowed to leave that area.

([3]) Part II.2 of this certificate applies to consignments of *Crassostrea gigas* oysters referred to in Article 5(1) of Regulation (EU) No 175/2010, intended for Member States or compartments subject to a programme for the early detection of OsHV-1 µvar and which originate from an area which previously were subject to containment measures regarding increased mortalities in *Crassostrea gigas* oysters.

Official inspector

Name (in capital letters):

Qualification and title:

Local Veterinary Unit:

No of the related LVU:

Date:

Signature:

Stamp

COMMISSION REGULATION (EU) No 176/2010

of 2 March 2010

amending Annex D to Council Directive 92/65/EEC as regards semen collection and storage centres, embryo collection and production teams, and conditions for donor animals of the equine, ovine and caprine species and for handling semen, ova and embryos of those species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC [1], and in particular the first subparagraph of Article 22 thereof,

Whereas:

(1) Directive 92/65/EEC lays down the animal health requirements governing trade in and imports into the European Union of animals, semen, ova and embryos not subject to the animal health requirements laid down in the specific acts of the European Union referred to in that Directive.

(2) It lays down the conditions governing the approval and supervision of centres for the collection of semen of animals of the equine, ovine and caprine species (semen collection centres).

(3) Certain semen collection centres only carry out storage operations of semen collected from those species. Therefore, it is appropriate to lay down separate conditions for the official approval and supervision of such centres.

(4) Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species [2] contains a definition of semen storage centres. In the interest of consistency of Union law the centres for storage of semen of animals concerned by this Regulation should be referred to as 'semen storage centres' in line with that definition.

(5) In addition, Directive 88/407/EEC lays down conditions for the approval and supervision of semen storage centres for the bovine species. Those conditions should be used as a guideline for the conditions for approval and supervision of semen storage centres for the equine, ovine and caprine species provided for in this Regulation. Chapter I, Sections I and II of Annex D to Directive 92/65/EEC should be amended accordingly.

(6) Directive 92/65/EEC, as amended by Directive 2008/73/EC [3], provides that ova and embryos of the ovine, caprine, equine and porcine species are to be removed by a collection team or produced by a production team approved by the competent authority of a Member State.

(7) It is therefore necessary to set out in Annex D to Directive 92/65/EEC the conditions for the approval of those teams. The Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 18th edition, 2009 (the Terrestrial Code) contains the current technology and international standards as regards the collection and processing of embryos. Chapters 4.7, 4.8 and 4.9 of that Code contain recommendations concerning collection and processing of *in vivo* derived embryos, collection and processing of *in vitro* produced embryos and collection and processing of micromanipulated embryos. Those recommendations should be taken into account for the purpose of Chapter III of Annex D to Directive 92/65/EEC. Those sections should therefore be amended accordingly.

(8) The International Embryo Transfer Society (IETS) is an international organisation and a professional forum which, inter alia, further the science of embryo production and coordinates standardisation of embryo handling and record procedures internationally. IETS has worked for several years to formulate practical and scientifically based protocols in order to avoid risks of disease transmission by embryo transfer from donors to recipients. Those protocols are largely based on the sanitary methods of embryo handling set out in the third edition of the IETS Manual and further reflected in the Terrestrial Code. The methods of handling embryos recommended by the IETS can for some diseases substitute traditional preventative measures, such as diagnostic testing of donors whereas for other measures the recommended methods should be used only to strengthen and complement such traditional measures.

(9) Directive 92/65/EEC also provides that semen of donor animals of the equine, ovine and caprine species must have been collected from animals meeting the conditions laid down in Chapter II of Annex D to that Directive. Those conditions should be reviewed as regards donor stallions, rams and bucks taking into account international standards laid down in Chapter 4.5 of the Terrestrial Code. Chapter II, Sections A and B of Annex D should be amended accordingly.

[1] OJ L 268, 14.9.1992, p. 54.
[2] OJ L 194, 22.7.1988, p. 10.
[3] OJ L 219, 14.8.2008, p. 40.

(10) In application of this Regulation, as regards donor animals of ovine and caprine species, account should be taken of the provisions of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [1], Commission Regulation (EC) No 546/2006 of 31 March 2006 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards national scrapie control programmes and additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation (EC) No 1874/2003 [2], and Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue [3].

(11) In application of this Regulation, as regards the use of antibiotics in the semen or in media used in the collection, freezing and storage of embryo account should be taken of the provisions of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [4].

(12) In application of this Regulation, as regards donor females of porcine species, account should be taken of the provisions of Commission Decision 2008/185/EC of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and criteria to provide information on this disease [5].

(13) Directive 92/65/EEC provides that only semen, ova and embryos meeting certain conditions laid down in that Directive, may be the subject of trade. In particular, it provides that stallions in order to be used for the collection of semen are to be subjected to certain tests, including tests for equine infectious anaemia and contagious equine metritis. Similarly, Directive 92/65/EEC provides that donor females in order to be used for the collection of ova and embryos are to comply with certain conditions. However, there is currently no requirement to subject donor females to testing for equine infectious anaemia and contagious equine metritis. As there is no scientific evidence to suggest that treatment of embryos could eliminate the risks arising from transfer of an embryo collected from an infected donor female, the animal health conditions for trade in ova and embryos of the equine species should be extended to include the tests for equine infectious anaemia and contagious equine metritis of donor females. Chapter II, Section C of Annex D should therefore be amended accordingly.

(14) Annex D to Directive 92/65/EEC should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex D to Directive 92/65/EEC is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 September 2010.

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

Done at Brussels, 2 March 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 147, 31.5.2001, p. 1.
[2] OJ L 94, 1.4.2006, p. 28.
[3] OJ L 283, 27.10.2007, p. 37.
[4] OJ L 311, 28.11.2001, p. 1.
[5] OJ L 59, 4.3.2008, p. 19.

ANNEX

Annex D to Directive 92/65/EEC is replaced by the following:

'*ANNEX D*

CHAPTER I

Conditions applicable to semen collection centres, semen storage centres, embryo collection teams and embryo production teams

I. *Conditions for the approval of semen collection and storage centres*

1. In order to be given approval and the veterinary registration number referred to in Article 11(4) each semen collection centre shall:

1.1. be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;

1.2. have at least:

(a) lockable animal accommodation and if required for equidae an exercise area which is physically separated from the collection facilities, the processing and storage rooms;

(b) isolation facilities which have no direct communication with the normal animal accommodation;

(c) semen collection facilities, that may be open air protected from adverse weather effects, with slip-proof flooring which protects from dramatic injury in case of fall, at and around the place of semen collection, without prejudice to the requirements in point 1.4;

(d) a separate room for the cleansing and disinfection or sterilisation of equipment;

(e) a semen processing room separated from the collection facilities and the room for cleansing equipment referred to in point (d) which need not necessarily be on the same site;

(f) a semen storage room which need not necessarily be on the same site;

1.3. be so constructed or isolated that contact with outside livestock is prevented;

1.4. be so constructed that the entire semen collection centre except the office rooms and, in the case of equidae the exercise area, can be readily cleansed and disinfected.

2. In order to be given approval each semen storage centre shall:

(a) in the case the storage is not limited to semen of a single species collected at semen collection centres approved in accordance with this Directive, or embryos are stored at the centre in compliance with this Directive, be given distinct veterinary registration numbers referred to in Article 11(4) for each of the species the semen of which is stored at the centre;

(b) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;

(c) have a semen storage room furnished with the necessary installation to store the semen and/or the embryos, which is so constructed that it protects those products and the installation from adverse weather and environment effects;

(d) be so constructed that contact with outside livestock or other animals is prevented;

(e) be so constructed that the entire centre except the office rooms and, in the case of equidae the exercise area, can be readily cleansed and disinfected;

(f) be so constructed that unauthorised access of people is effectively prevented.

II. *Conditions for the supervision of semen collection and storage centres*

1. Semen collection centres shall:

1.1. be supervised to ensure that:

(a) they contain only animals of the species whose semen is to be collected;

Other domestic animals may none the less also be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they comply with the conditions laid down by the centre veterinarian.

If in the case of equidae the semen collection centre shares a site with an artificial insemination or service centre, then female equidae (mares) and uncastrated male equidae (stallions) for teasing or natural service shall be admitted provided that they meet the requirements of points 1.1, 1.2, 1.3 and 1.4 of Section I of Chapter II;

(b) the entry of unauthorised persons is prevented and that authorised visitors are required to comply with the conditions laid down by the centre veterinarian;

(c) only competent staff is employed who have received adequate training on disinfection and hygiene techniques to prevent the spread of disease;

1.2. be monitored to ensure that:

(a) records are kept which show:

(i) the species, breed, date of birth and identification of each animal present in the centre;

(ii) any movement of animals entering or leaving the centre;

(iii) the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on animals kept;

(iv) the date of collecting and processing semen;

(v) the destination of semen;

(vi) the storage of semen;

(b) none of the animals kept in the centre is used for natural breeding at least 30 days prior to the date of the first semen collection and during the collection period;

(c) the collection, processing and storage of semen is carried out only in premises set aside for these purposes;

(d) all instruments which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use, except for instruments which are new, disposable and discarded after use (single-use instruments);

Where, in the case of equidae, the collection centre shares a site with an artificial insemination centre or a service centre, there shall be a strict separation between the semen and instruments and equipment for artificial insemination or natural service and instruments and equipment coming into contact with donor animals or other animals kept in the collection centre;

(e) products of animal origin used in the processing of semen, including diluents, additives or extenders, are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(f) cryogenic agents used for the preservation or storage of semen have not been previously used for other products of animal origin;

(g) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for containers which are new, disposable and discarded after use (single-use containers);

(h) each individual dose of semen or each ejaculate of fresh semen intended for further processing is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal and the approval number of the semen collection centre can be readily established;

1.3. be inspected by an official veterinarian during the breeding season at least once every calendar year in the case of animals with seasonal breeding and twice every calendar year in the case of a non-seasonal reproduction in order to consider and verify, where necessary on the base of records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.

2. Semen storage centres shall:

2.1. be supervised to ensure that:

(a) the status of the donor animals whose semen is stored at the centre complies with the requirements of this Directive;

(b) the requirements laid down in points 1.1(b) and (c) are complied with;

(c) records are kept of all movement of semen entering and leaving the storage centre;

2.2. be monitored that:

(a) only semen collected in and coming from approved semen collection or storage centres and transported in conditions offering every possible health guarantee, having had no contact with semen not complying with this Directive, is brought into an approved semen storage centre;

(b) storage of semen takes place only on the premises set aside for the purpose and under strict conditions of hygiene;

(c) all instruments which come into contact with the semen are properly disinfected or sterilised prior to use, except for single-use instruments;

(d) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;

(e) cryogenic agents used for preservation or storage of semen have not been previously used for other products of animal origin;

(f) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal, the approval number of the semen collection centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;

2.3. by way of derogation from point 2.2(a), the storage of embryos in the approved semen storage centre is authorised provided they meet the requirements of this Directive and are stored in separate storage containers;

2.4. be inspected by an official veterinarian at least twice every calendar year in order to consider and verify, where necessary based on records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.

III. *Conditions for the approval and the supervision of embryo collection teams and embryo production teams*

1. In order to be given approval each embryo collection team shall comply with the following requirements:

1.1. the collection, processing and storage of embryos shall be carried out either by a team veterinarian or under his responsibility by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene and in techniques and principles of disease control;

1.2. the team veterinarian shall be responsible for all team operations, including amongst others:

(a) verification of the identity and health status of the donor animal;

(b) sanitary handling and surgery of donor animals;

(c) disinfection and hygienic procedures;

(d) keeping records which shows:

(i) the species, breed, date of birth and identification of each donor animal;

(ii) the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on donor animals;

(iii) the place and date of collecting, processing and storing of oocytes, ova and embryos;

(iv) the identification of embryos and details of their destination if known;

1.3. the team shall be placed under the general supervision of the official veterinarian, who shall inspect it at least once every calendar year to ensure, where necessary based on records, standard operating procedures and internal audits, compliance with the sanitary conditions regarding collection, processing and storage of embryos and to verify all matters relating to the conditions of approval and supervision;

1.4. the team shall have at its disposal a permanently sited laboratory or a mobile laboratory where embryos can be examined, processed and packed, consisting of at least a work surface, an optical or stereo microscope and cryogenic equipment where necessary;

1.5. in the case of a permanently sited laboratory, it shall have:

(a) a room where embryos can be processed which is physically separate from the area used to handle the donor animals during collection;

(b) a room or area for cleansing and sterilising instruments, except when using only single-use equipment;

(c) a room for storing embryos;

1.6. in the case of a mobile laboratory, it shall:

(a) have a specially equipped part of the vehicle consisting of two separate sections:

(i) one for the examination and processing of embryos which shall be a clean section; and

(ii) the other for accommodating equipment and materials used in contact with the donor animals;

(b) use only single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of embryos can be ensured by the contact with a permanently sited laboratory;

1.7. the design and layout of buildings and laboratories shall be laid out and team operations carried out so as to ensure that cross-contaminations of embryos are prevented;

1.8. the team shall have at its disposal storage premises which shall:

(a) comprise at least one lockable room for the storage of ova and embryos;

(b) be easy to cleanse and disinfect;

(c) have permanent records of all incoming and outgoing ova or embryos;

(d) have storage containers for ova and embryos which are stored in a place which is under the control of the team veterinarian and which is subject to regular inspections by an official veterinarian;

1.9. the competent authority may authorise storage of semen in storage premises referred to in point 1.8 provided that the semen:

(a) meets the requirements of this Directive for either ovine and caprine species or equine species, or of Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species [1] for porcine species;

(b) is stored for the operation of the team in separate storage containers in the premises for storing approved embryos.

2. In order to be given approval each embryo production team shall also comply with the following additional requirements:

2.1. the team members have received adequate training on disease control and laboratory techniques, particularly in procedures for working in sterile conditions;

[1] OJ L 224, 18.8.1990, p. 62.

2.2. the team shall have at its disposal a permanently sited laboratory which shall:

(a) have adequate equipment and facilities, including separate rooms for:

— recovering oocytes from ovaries,

— processing oocytes, ova and embryos,

— storing embryos;

(b) have a laminar-flow or other suitable facilities where all technical operations associated with specific sterile conditions (processing of ova, embryos and semen) are conducted.

However, the centrifugation of semen may be carried out outside the laminar-flow facility or other facility, as long as full hygienic precautions are taken;

2.3. where ova and other tissues are to be collected in a slaughterhouse, it shall have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner.

CHAPTER II

Conditions applicable to donor animals

I. *Conditions applicable to donor stallions*

1. In order to be used for the collection of semen, the donor stallion shall, to the satisfaction of the centre veterinarian, meet the following requirements:

1.1. it shall not show any clinical sign of an infectious or contagious disease at the time of admission and on the day the semen is collected;

1.2. it shall come from the territory or, in the case of regionalisation, from the part of the territory of a Member State or a third country and from a holding under veterinary supervision each of which satisfy the requirements of Directive 90/426/EEC;

1.3. it shall be kept for 30 days prior to the date of semen collection in holdings where no equine has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period;

1.4. it shall not be used for natural mating during the 30 days prior to the first semen collection and during the collection period;

1.5. it shall be subjected to the following tests, carried out and certified in a laboratory recognised by the competent authority, according to the program provided for in point 1.6:

(a) an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia with negative result;

(b) a virus isolation test for equine viral arteritis carried out with negative results on an aliquot of the entire semen of the donor stallion, unless a negative result at a serum dilution of 1 in 4 is achieved in a serum neutralisation test for equine viral arteritis;

(c) a test for contagious equine metritis carried out on two occasions on samples collected from the donor stallion with an interval of seven days by isolation of *Taylorella equigenitalis* from pre-ejaculatory fluid or a semen sample and from genital swabs taken at least from the penile sheath, urethra and urethral fossa with negative result in each case;

1.6. it shall be subjected to one of the following testing programmes:

(a) if the donor stallion is continuously resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, and no equidae on the semen collection centre come into direct contact with equidae of lower health status than the donor stallion, the tests required in point 1.5 shall be carried out on samples collected from the donor stallion prior to the first semen collection and at least 14 days following the date of the commencement of the residence period of at least 30 days;

(b) if the donor stallion is resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, but may leave the centre occasionally under the responsibility of the centre veterinarian for a continuous period of less than 14 days, and/or other equidae on the collection centre come into direct contact with equidae of lower health status, the tests required in point 1.5 shall be carried out on samples collected from the donor stallion as follows:

(i) at least once a year at the beginning of the breeding season or prior to the first semen collection and at least 14 days following the date of the commencement of the residence period of at least 30 days; and

(ii) during the period of semen collection as follows:

— for the test required in point 1.5(a) at least every 90 days,

— for the test required in point 1.5(b) at least every 30 days, unless the non-shedder state of a seropositive stallion for equine viral arteritis is confirmed by a biannual virus isolation test, and

— for the test required in point 1.5(c) at least every 60 days;

(c) if the donor stallion does not meet the conditions in points (a) and (b) and/or the semen is collected for trade in frozen semen, the tests required in point 1.5 shall be carried out on samples collected from the donor stallion as follows:

(i) at least once a year at the beginning of the breeding season;

(ii) during the storage period provided for in point 1.3(b) of Section I of Chapter III and before the semen is removed from the centre or used, on samples taken not earlier than 14 days and not later than 90 days following the date of collection of the semen;

By way of derogation from point (ii), post-collection sampling and testing for equine viral arteritis as described in 1.5(b) is not required in case the non-shedder state of a seropositive stallion for equine viral arteritis is confirmed by a biannual virus isolation test;

1.7. if any of the tests provided for in point 1.5 is positive, the donor stallion shall be isolated, and the semen collected from it since the date of the last negative test shall not be subject for trade with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with negative result.

Semen collected from all other stallions at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests provided for in point 1.5. shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 1.5;

1.8. semen collected from stallions at a semen collection centre subject to a prohibition order in accordance with Article 4 or 5 of Directive 90/426/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored by the official veterinarian in accordance with Directive 90/426/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex A to Directive 90/426/EEC.

II. *Conditions applicable to male ovine and caprine donor animals*

1. For all ovine and caprine animals admitted to a semen collection centre the following requirements shall apply:

1.1. they have been kept in quarantine for a period of at least 28 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status are present (quarantine accommodation);

1.2. prior to their stay in the quarantine accommodation, they have belonged to an officially brucellosis-free ovine or caprine holding pursuant to Article 2 of Directive 91/68/EEC and they shall not be previously kept in a holding of a lower health status as regards brucellosis;

1.3. they come from a holding where during the 60 days prior to their stay in the quarantine accommodation they have undergone a serological test for contagious epididymitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC or any other test with an equivalent documented sensitivity and specificity;

1.4. they have undergone the following tests carried out on a blood sample collected within the 28 days preceding the commencement of the period of quarantine specified in point 1.1, with negative results in each case, except for the test for Border disease referred to in point (c)(ii):

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(c) for Border disease:

(i) a virus isolation test or a test for virus antigen; and

(ii) a serological test to determine the presence or absence of antibodies (antibody test).

The competent authority may authorise that the tests referred to in this point are carried out on samples collected in the quarantine accommodation. If such authorisation is granted, the period of quarantine referred to in point 1.1 shall not commence before the date of sampling. However, if any of the tests referred to in this point prove positive, the animal concerned shall be immediately removed from the quarantine accommodation. In the event of group isolation, the quarantine period referred to in point 1.1 shall not commence for the remaining animals until the animal which tested positive has been removed;

1.5. they have undergone the following tests carried out on samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation, with negative results:

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

1.6. they have undergone the tests for Border disease referred in points 1.4(c)(i) and (ii) carried out on the blood samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation.

Any animal (seronegative or seropositive) shall only be allowed entry to the semen collection centre if no sero-conversion occurs in animals which tested seronegative before the day of entry into the quarantine accommodation.

If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks from the day the sero-conversion occurred.

Serologically positive animals shall be allowed entry into the semen collection centre subject to a negative result in a test referred in point 1.4(c)(i).

2. Animals shall only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements into and out of the semen collection centre shall be recorded.

3. No animals admitted to the semen collection centre shall show any clinical sign of disease on the date of admission.

All animals shall, without prejudice to point 4, have come from quarantine accommodation, which on the day of dispatch of the animals to the semen collection centre complies with the following conditions:

(a) it is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius;

(b) it has for the past three months been free from foot-and-mouth disease and brucellosis;

(c) it has for the past 30 days been free from compulsory notifiable diseases as defined in Article 2(b)(6) of Directive 91/68/EEC.

4. Provided, that the conditions set out in point 3 are complied with and the routine tests referred to in point 5 have been carried out during 12 months prior to the movement of the animals, animals may be moved from one approved semen collection centre to another of equal health status, without isolation or testing if the transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used shall be disinfected before use. If an animal is moved from one semen collection centre to a semen collection centre in another Member State that movement shall be carried out in accordance with Directive 91/68/EEC.

5. All ovine and caprine animals kept at an approved semen collection centre shall be subjected at least once every calendar year to the following tests, with negative results:

   (a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

   (b) for contagious epidydimitis (*B. ovis*) a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

   (c) for Border disease, the antibody test referred to in point 1.4(c)(ii) which is applied only to seronegative animals.

6. All tests referred to in this section shall be carried out by an approved laboratory.

7. If any of the tests described in point 5 is positive, the animal shall be isolated and the semen collected from it since the date of the last negative test shall not be subject for trade.

   The animal referred to in the first paragraph shall be removed from the centre, except in the case of Border disease, in which case the animal shall be subjected with negative result to a test referred in point 1.4(c)(i).

   Semen collected from all other animals at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests described in point 5 shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 5.

8. Semen shall be obtained from animals which:

   (a) show no clinical signs of disease on the date the semen was collected;

   (b) during the 12 months prior to the date of the collection of the semen:

      (i) either have not been vaccinated against foot-and-mouth disease; or

      (ii) have been vaccinated against foot-and-mouth disease at least 30 days prior to the collection, in which case 5 % (with a minimum of five straws) of each semen collection shall be submitted to a virus isolation test for foot-and-mouth disease with negative results;

   (c) have been kept at an approved semen collection centre for a continuous period of at least 30 days prior to the date of collection of the semen, in the case of collection of fresh semen;

   (d) meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC;

   (e) if kept on holdings referred to in the first indent of Article 11(2), had undergone with negative results during the 30 days prior to the date of collection of the semen:

      (i) a serological test for brucellosis (*B. melitensis*) carried out in accordance with Annex C to Directive 91/68/EEC;

      (ii) a serological test for contagious epididymitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

      (iii) a test for the Border disease virus;

   (f) shall not be used for natural breeding during at least 30 days prior to the date of first semen collection and between the date of the first sample referred to in points 1.5 and 1.6 or in point (e) and until the end of the collection period.

9. Semen collected from male ovine and caprine donor animals at a semen collection centre or holding referred to in first indent of Article 11(2) subject to a prohibition on animal health grounds in accordance with Article 4 of Directive 91/68/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre or the holding has been restored by the official veterinarian in accordance with Directive 91/68/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex B(I) to Directive 91/68/EEC.

CHAPTER III

Requirements applicable to semen, ova and embryos

I. *Conditions for the collection, processing, preservation, storage and transport of semen*

1.1. Where, without prejudice to Directive 2001/82/EC of the European Parliament and of the Council [1], antibiotics or a mixture of antibiotics are added with a bactericidal activity at least equivalent to that of the following mixtures in each ml of semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg), the names of the antibiotics added and their concentration shall be stated in the health certificate referred to in the fourth indent of Article 11(2).

1.2. All instruments used for the collection, processing, preservation or freezing of semen shall be either disinfected or sterilised as appropriate before use, except for single-use instruments.

1.3. Frozen semen shall:

(a) be placed and stored in storage containers:

(i) which have been cleansed and disinfected or sterilised before use, or are single-use containers;

(ii) with a cryogenic agent; which shall not be previously used for other products of animal origin;

(b) prior to dispatch or use, be stored in approved conditions for a minimum period of 30 days from the date of collection.

1.4. Semen to be subject for trade shall:

(a) be transported to the Member State of destination in transport containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved semen collection or storage centres;

(b) be marked in such a way that the number on the straws or other packages coincides with the number on the health certificate referred to in the fourth indent of Article 11(2) and with the container in which they are stored and transported.

II. *Conditions for ova and embryos*

1. Collection and processing of *in vivo* derived embryos

In vivo derived embryos shall be conceived as a result of artificial insemination with semen meeting the requirements of this Directive and shall be collected, processed and preserved in accordance with the following:

1.1. Embryos shall be collected and processed by an approved embryo collection team, without coming into contact with any other batch of embryos not complying with the requirements of this Directive.

1.2. Embryos shall be collected in a place, which is separated from other parts of the premises or holding where the embryo is collected and which shall be in good repair and constructed with materials which permit its effective and easy cleansing and disinfection.

1.3. Embryos shall be processed (examined, washed, treated and placed in identified and sterile straws, ampoules or other packages) in either a permanently sited laboratory or a mobile laboratory, which, as regards susceptible species, is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.

1.4. All equipment used to collect, handle, wash, freeze and store embryos shall either be sterilised or properly cleansed and disinfected prior to use according to the IETS Manual [2], or be single-use equipment.

[1] OJ L 311, 28.11.2001, p. 1.

[2] Manual of the International Embryo Transfer Society — A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Transfer Society, 1111 North Dunlap Avenue, Savoy, Illinois 61874 USA (http://www.iets.org/).

1.5. Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos shall be free of pathogenic micro-organisms. Media and solutions used in the collection, freezing and storage of embryos shall be sterilised by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics might be added, when appropriate, to collection, processing, washing and storage media according to the IETS Manual.

1.6. The cryogenic agents used for preservation or storage of embryos shall not be previously used for other products of animal origin.

1.7. Each embryo straw, ampoule or other package shall be clearly identified by labels according to the standardised system according to the IETS Manual.

1.8. The embryos shall be washed according to the IETS Manual and have an intact *zona pellucida* before and immediately after washing. The standard washing procedure shall be modified to include additional washes with the enzyme trypsin, according to the IETS Manual, when inactivation or removal of certain viruses is required.

1.9. Embryos from different donor animals shall not be washed together.

1.10. The *zona pellucida* of each embryo shall be examined over its entire surface area at not less than 40 × magnification and certified to be intact and free of adherent material.

1.11. Embryos of a batch that has successfully undergone the examination set out in point 1.10 shall be placed in a sterile straw, ampoule or other package marked in accordance with point 1.7 which shall be sealed immediately.

1.12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian.

1.13. Each embryo collection team shall submit for official examination for bacterial and viral contamination routine samples of non-viable embryos or ova, flushing fluids or washing fluids resulting from its activities according to the IETS Manual.

1.14. Each embryo collection team shall keep a record of its activities in respect of embryo collection for a period of two years after the embryos have been the subject of trade or import, including:

(a) the breed, age and individual identification of the donor animals concerned;

(b) the place of collection, processing and storage of embryos collected by the team;

(c) the identification of the embryos together with details of the consignee of the shipment.

2. Collection and processing of ova, ovaries and other tissues, with the aim of producing *in vitro* derived embryos

The conditions set out in points 1.1 to 1.14 shall apply *mutatis mutandis* to the collection and processing of ova, ovaries and other tissues for use in *in vitro* fertilisation and/or *in vitro* culture. In addition, the following shall apply:

2.1. The competent authority shall have knowledge of, and authority over, the holding(s) of origin of the donor animals.

2.2. When ovaries and other tissues are collected at a slaughterhouse, either from individual animals or from batches of donors (batch collection), the slaughterhouse shall be officially approved in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [1] and under the supervision of a veterinarian whose responsibility it is to ensure that *ante-mortem* and *post-mortem* inspections of potential donor animals are carried out and to certify them to be free of signs of the relevant contagious diseases transmissible to animals. The slaughterhouse shall, as regards susceptible species, be situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.

2.3. Batches of ovaries shall not be brought into the processing laboratory until *post-mortem* inspection of donor animals is completed.

2.4. Equipment for removal and transport of ovaries and other tissues shall be cleansed and disinfected or sterilised before use and exclusively used for these purposes.

[1] OJ L 139, 30.4.2004, p. 206.

3. Processing of *in vitro* derived embryos

The conditions laid down in points 1.1 to 1.14 shall apply *mutatis mutandis* to the processing of *in vitro* derived embryos. In addition, the following shall apply:

3.1. *In vitro* derived embryos shall be conceived as a result of *in vitro* fertilisation with semen meeting the requirements of this Directive.

3.2. After the *in vitro* culture period is completed but prior to freezing, storage and transport of the embryos, they shall be washed and undergo the treatments referred to in points 1.8, 1.10 and 1.11.

3.3. Embryos from different donor animals, in the case of individual animal recovery, or from different batch collections shall not be washed together.

3.4. Embryos from different donor animals, in the case of individual animal recovery, or from different batch collections shall not be stored in the same straw, ampoule or other package.

4. Processing of micromanipulated embryos

Prior to any micromanipulation which compromises the integrity of the *zona pellucida*, all embryos or ova shall be collected and processed according to the sanitary conditions set out in points 1, 2 and 3. In addition, the following conditions shall apply:

4.1. Where micromanipulation of the embryo which involves penetration of the *zona pellucida* is carried out, this shall be done in suitable laboratory facilities under supervision of an approved team veterinarian.

4.2. Each embryo collection team shall keep records of its activities according to point 1.14, including details of micromanipulation techniques which involve penetration of the *zona pellucida* and which have been performed on the embryos. In the case of embryos derived by *in vitro* fertilisation, the identification of the embryos may be done on the basis of a batch, but shall contain details of the date and place of collection of ovaries and/or ova. It shall also be possible to identify the holding of origin of the donor animals.

5. Storage of embryos

5.1. Each embryo collection and production teams shall ensure that the embryos are stored at suitable temperatures in storage premises referred to in point 1.8 of Section III of Chapter I.

5.2. Frozen embryos shall, prior to dispatch, be stored in approved conditions for a minimum period of 30 days from the date of their collection or production.

6. Transport of embryos

6.1. Embryos to be subject for trade shall be transported to the Member State of destination in containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved storage premises.

6.2. The straws, ampoules or other packages shall be marked in such a way that the number on the straws, ampoules or other packages coincides with the number on the health certificate referred to in the third indent of Article 11(3) and with the container in which they are stored and transported.

CHAPTER IV

Requirements applicable to donor females

1. Donor females shall only be used for the collection of embryos or ova if they and the holdings from which they originate meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Union trade in live animals for breeding and production for the species concerned.

2. In addition to the requirements laid down in Directive 64/432/EEC, donor females of porcine species shall, except *in vivo* derived embryos subject to a trypsin treatment, comply with the requirements for Aujeszky's disease laid down in accordance with Article 9 or 10 of that Directive.

3. The provisions of Directive 91/68/EEC shall apply to donor females of ovine and caprine species.

4. In addition to the requirements laid down in Directive 90/426/EEC, donor mares shall:

4.1. not be used for natural breeding during at least 30 days prior to the date of collection of ova or embryos and between date of the first sample referred to in 4.2 and 4.3 and the date of the collection of ova and embryos;

4.2. be subjected with negative result to an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia carried out on a blood samples taken initially during the past 30 days prior to the date of the first collection of ova or embryos and then every 90 days during the collection period;

4.3. be subjected to a test for contagious equine metritis by isolation of *Taylorella equigenitalis* carried out on samples collected from mucosal surfaces of the clitoral fossa and clitoral sinuses on two consecutives oestrus periods, and during one of oestrus periods an additional culture specimen taken from the endometrial cervix, all with negative results after a cultivation of 7 to 14 days.'

COMMISSION REGULATION (EU) No 177/2010

of 2 March 2010

amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [1], and in particular Article 247 thereof,

Whereas:

(1) In the interest of clarity, it is appropriate to modify the structure of Article 313 of Commission Regulation (EEC) No 2454/93 [2] setting out the cases where goods are deemed to be of Community status.

(2) In order to establish the European Maritime Transport Space without Barriers referred to in the Communication and action plan from the Commission with a view to establishing a European maritime transport space without barriers [3], it is appropriate to simplify the tasks of both economic operators and of customs administrations with regard to goods carried by sea between ports located in the customs territory of the Community.

(3) In particular, it is appropriate to provide for a procedure for the authorisation of regular shipping services and for the registration of ships that makes use of the electronic information and communication system for the issuing of AEO certificates as provided in Article 14x of Regulation (EEC) No 2454/93.

(4) In order to reduce the use of paper documents, the presentation of a printout of a data exchange manifest as referred to in Article 324e of Regulation (EEC) No 2454/93 should not be required when customs authorities have access to the electronic information and communication system containing the data exchange manifest.

(5) It is appropriate to amend Article 324c(1) in order to include the correct reference to the security measures to be taken relating to stamps. It is necessary to amend the erroneous references to Annex 37c to Regulation (EEC) No 2454/93 made in the particulars on the data of the transit declaration set out in Annex 37a to that Regulation as amended by Regulation (EC) No 1192/2008 [4].

(6) Regulation (EEC) No 2454/93 should therefore be amended accordingly.

(7) In order to safeguard the legitimate expectations of economic operators, authorisations establishing a regular shipping service prior to the date of application of this Regulation should be deemed to be authorisations granted in accordance with this Regulation. In order to ensure that all authorisations are available in the same electronic system, prior authorisations should be stored in the electronic information and communication system for the issuing of the AEO certificate.

(8) It is appropriate to provide Member States and customs authorities with sufficient time to establish a fully functional electronic information and communication system.

(9) Given that the provisions on the particulars on the data of the transit declaration set out in Annex 37a to Regulation (EEC) No 2454/93 as amended by Regulation (EC) No 1192/2008 apply from 1 July 2008, it is appropriate to provide that the amendments to those provisions also apply from that date.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 2454/93 is amended as follows:

1. Article 313 is replaced by the following:

'*Article 313*

1. Subject to Article 180 of the Code and the exceptions listed in paragraph 2 of this Article, all goods in the customs territory of the Community shall be deemed to be Community goods unless it is established that they do not have Community status.

2. The following shall not be deemed to be Community goods unless it is established in accordance with Articles 314 to 323 of this Regulation that they do have Community status:

(a) goods brought into the customs territory of the Community in accordance with Article 37 of the Code;

[1] OJ L 302, 19.10.1992, p. 1.
[2] OJ L 253, 11.10.1993, p. 1.
[3] COM(2009) 10 final.
[4] OJ L 329, 6.12.2008, p. 1.

(b) goods in temporary storage or in a free zone of control type I within the meaning of Article 799 of this Regulation or in a free warehouse;

(c) goods placed under a suspensive procedure or in a free zone of control type II within the meaning of Article 799 of this Regulation.

3. By way of derogation from paragraph 2(a), goods brought into the customs territory of the Community shall be deemed to be Community goods unless it is established that they do not have Community status:

(a) where, if carried by air, the goods have been loaded or transhipped at an airport in the customs territory of the Community, for consignment to another airport in the Community customs territory, provided that they are carried under cover of a single transport document drawn up in a Member State; or

(b) where, if carried by sea, the goods have been shipped between ports in the customs territory of the Community by a regular shipping service authorised in accordance with Article 313b.';

2. Articles 313a and 313b are replaced by the following:

'Article 313a

A regular shipping service' means a service which carries goods in vessels that ply only between ports situated in the customs territory of the Community and may not come from, go to or call at any points outside that territory or in a free zone of control type I within the meaning of Article 799 of a port in that territory.

Article 313b

1. A shipping company may be authorised to establish regular shipping services following an application to the customs authorities of the Member State in whose territory that company is established or, failing this, in whose territory it has a regional office, provided that the conditions of this Article and of Article 313c are fulfilled.

2. An authorisation shall be issued only to shipping companies which:

(a) are established in the customs territory of the Community or have a regional office there and whose records will be available to the competent customs authorities;

(b) fulfil the conditions laid down in Article 14h;

(c) determine the vessel(s) to be used for the regular shipping service and specify the ports of call once the authorisation is issued;

(d) undertake that on the routes of regular shipping services, no calls will be made at any port in a territory outside the customs territory of the Community or at any free zone of control type I in a port in the customs territory of the Community, and that no transhipments of goods will be made at sea;

(e) undertake to register the names of the vessels assigned to regular shipping services and the ports of call with the authorising customs authority.

3. The application for an authorisation for a regular shipping service shall specify the Member States concerned by that service. The customs authorities of the Member State to whom the application has been made (the authorising customs authority) shall notify the customs authorities of the other Member States concerned by the shipping service (the corresponding customs authorities) through the electronic information and communication system referred to in Article 14x.

Without prejudice to paragraph 4, within 45 days of receipt of such notification, the corresponding customs authorities may refuse the application on the basis that the condition of paragraph 2(b) is not met and communicate the refusal through the electronic information and communication system referred to in Article 14x. The corresponding customs authority shall indicate the grounds for the refusal and the legal provisions relating to the offences committed. In that case, the authorising customs authority shall not issue the authorisation and shall notify the refusal to the applicant stating the reasons for the refusal.

Where no reply or refusal is received from the corresponding customs authorities, the authorising customs authority, having examined whether the conditions for the authorisation are met, shall issue an authorisation which shall be accepted by the other Member States concerned by the shipping service. The electronic information and communication system referred to in Article 14x shall be used to store the authorisation and to notify the corresponding customs authorities that the authorisation was issued.

4. Where the shipping company holds an AEO certificate referred to in point (a) or (c) of Article 14a(1), the requirements set out in points (a) and (b) of paragraph 2 of this Article, and as referred to in paragraph 3 of this Article, shall be deemed to be met.';

3. the following Articles 313c to 313f are inserted:

'Article 313c

1. Once a regular shipping service has been authorised in accordance with Article 313b, the shipping company concerned shall be required to use the authorisation for the vessels registered for that purpose.

2. The shipping company shall inform the authorising customs authority of any circumstances arising after the authorisation is granted which may influence its continuation or content.

Where an authorisation is revoked by the authorising customs authority or at the request of the shipping company, the authorising customs authority shall notify the revocation to the corresponding customs authorities using the electronic information and communication system referred to in Article 14x.

3. The procedure provided for in Article 313b(3) shall apply if the authorisation is to be amended to cover Member States that were not included in the original authorisation or a previous authorisation. The provisions of Article 313b(4) shall apply *mutatis mutandis*.

Article 313d

1. The shipping company authorised to establish regular shipping services shall communicate to the authorising customs authority the following:

(a) the names of the vessels assigned to the regular shipping service;

(b) the first port where the vessel starts its operation as a regular shipping service;

(c) the ports of call;

(d) any amendments to the information referred to in points (a), (b) and (c);

(e) the date and time when the amendments referred to in point (d) take effect.

2. The information communicated in accordance with paragraph 1 shall be registered by the authorising customs authority in the electronic information and communication system referred to in Article 14x within one working day from the day of its communication. It shall be accessible to the customs authorities operating in ports located in the customs territory of the Community.

The registration shall take effect on the first working day following that of the registration.

Article 313e

When a vessel registered to a regular shipping service is forced by circumstances beyond its control to tranship goods at sea or temporarily put into a port that is not part of the regular shipping service, including ports outside the customs territory of the Community or a free zone of control type I of a port in the customs territory of the Community, the shipping company shall immediately inform the customs authorities of the subsequent Community ports of call, including those along the vessel's scheduled route. Goods loaded or unloaded in those ports shall not be deemed to be Community goods.

Article 313f

1. The customs authorities may require proof from the shipping company that the provisions of Articles 313b to 313e have been observed.

2. Where the customs authorities establish that the provisions referred to in paragraph 1 have not been observed by the shipping company, they shall immediately inform all the customs authorities concerned by the shipping service, using the electronic information and communication system referred to in Article 14x, so that those authorities can take the required measures.';

4. in Article 324c(1), the second subparagraph is replaced by the following:

'Section 27 of Annex 37d shall apply *mutatis mutandis*.';

5. in Article 324e(4), points (c) and (d) are replaced by the following:

'(c) the manifest transmitted by electronic data exchange (data exchange manifest) shall be presented to the customs authorities at the port of departure at the latest on the working day following the departure of the vessel and in any case before it arrives at the port of destination. The customs authorities may require a printout of the data exchange manifest to be presented when they do not have access to an information system as approved by the customs authorities containing the data exchange manifest;

(d) the data exchange manifest shall be presented to the customs authorities at the port of destination. The customs authorities may require a printout of the data exchange manifest to be presented when they do not have access to an information system as approved by the customs authorities containing the data exchange manifest.';

6. in Annex 37a, Title II, Point B 'Particulars on the data of the transit declaration', the Data group 'PACKAGES' is amended as follows:

(a) the text of the attribute 'Marks and number of packages' is replaced by the following:

'**Marks and numbers of packages** **(box 31)**

Type/Length: an ..42

The attribute shall be used if the attribute "**Kind of packages**" contains other codes presented in Annex 38 than those for bulk (VQ, VG, VL, VY, VR or VO) or for "Unpacked" (NE, NF, NG). It is optional if the attribute "**Kind of packages**" contains one of the previously mentioned codes.';

(b) the text of the attribute 'Number of packages' is replaced by the following:

'**Number of packages** **(box 31)**

Type/Length: an ..5

The attribute shall be used if the attribute "**Kind of packages**" contains other codes shown in Annex 38 than those for bulk (VQ, VG, VL, VY, VR or VO) or for "unpacked" (NE, NF, NG). It may not be used if the attribute "**Kind of packages**" contains one of the previously mentioned codes.'

Article 2

Authorisations establishing a regular shipping service prior to the date of application referred to in the second paragraph of Article 3 of this Regulation shall be deemed to be authorisations issued in accordance with Regulation (EEC) No 2454/93 as amended by this Regulation.

The authorising customs authority shall store these authorisations in the electronic information and communication system referred to in Article 14x of Regulation (EEC) No 2454/93 within one month from the date of application referred to in the second paragraph of Article 3 of this Regulation.

Article 3

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

Points 2 and 3 of Article 1 shall apply from 1 January 2012.

Points 4 and 6 of Article 1 shall apply from 1 July 2008.

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

Done at Brussels, 2 March 2010.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 178/2010

of 2 March 2010

amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1], in particular Article 11(4),

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs [2] provides for maximum limits for certain mycotoxins in certain foodstuffs.

(2) Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are very heterogeneously distributed in a lot. It is therefore necessary to fix general criteria which the sampling method should comply with.

(3) Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs [3] establishes the criteria for the sampling for the control of the levels of mycotoxins.

(4) It is necessary to amend certain provisions for sampling aflatoxins in certain foodstuffs to take into account developments in Codex Alimentarius and to take into account recently established maximum levels of mycotoxins for new categories of foodstuffs.

(5) Codex Alimentarius established a new sampling plan for groundnuts (peanuts), almonds, hazelnuts and pistachios intended for further processing and a new sampling plan for almonds, hazelnuts and pistachios 'ready-to-eat' [4].

(6) To facilitate the enforcement of the maximum levels of aflatoxins, it is appropriate to apply the sampling provisions as provided for by Codex Alimentarius for peanuts, almonds, hazelnuts and pistachios intended for further processing as well to other tree nuts which are intended for further processing and the sampling provisions as provided for by Codex for almonds, hazelnuts and pistachios 'ready-to-eat' to other tree nuts and groundnuts (peanuts) 'ready-to-eat'. The sampling procedure for tree nuts should also be applied to apricot kernels. Part D of the Annex I to Regulation (EC) No 401/2006 should therefore be amended accordingly to provide only for the sampling procedure for dried figs which should remain unchanged and the new sampling procedure for groundnuts (peanuts), other oilseeds, apricot kernels, tree nuts should be provided in a separate Part of the Annex.

(7) Maximum levels have been established for aflatoxins in oilseeds other than groundnuts (peanuts) [5] and for ochratoxin A in spices, liquorice root and liquorice extract [6]. It is appropriate to provide for specific sampling provisions for these new categories of foodstuffs and to refer to existing provisions where applicable.

(8) The sampling of vegetable oils for the control of mycotoxins has specific characteristics and it is therefore appropriate to provide for specific sampling rules.

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

[1] OJ L 165, 30.4.2004, p. 1.
[2] OJ L 364, 20.12.2006, p. 5.
[3] OJ L 70, 9.3.2006, p. 12.
[4] Codex General Standard for Contaminants and Toxins in Foods (CODEX STAN 193-1995) http://www.codexalimentarius.net/download/standards/17/CXS_193e.pdf
[5] Commission Regulation (EU) No 165/2010 of 26 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins (OJ L 50, 27.2.2010, p. 8).
[6] Commission Regulation (EU) No 105/2010 of 5 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A (OJ L 35, 6.2.2010, p. 7).

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 401/2006 is amended as follows:

1. Part D is replaced by the text set out in Annex I to this Regulation.

2. In Part E, the first sentence is replaced by the following:

'This method of sampling is of application for the official control of the maximum levels established for ochratoxin A, aflatoxin B1 and total aflatoxins in spices.'

3. Part G is replaced by the text set out in Annex II to this Regulation.

4. A Part K, as set out in Annex III to this Regulation, is added.

Article 2

This Regulation shall enter into force on the 10th day following its publication in the *Official Journal of the European Union*.

It shall apply from the date of entry into force.

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

Done at Brussels, 2 March 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

'D.1. **Method of sampling for dried figs**

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in dried figs.

D.1.1. *Weight of the incremental sample*

The weight of the incremental sample shall be about 300 grams, unless otherwise defined in part D.1 of Annex I.

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of more than 300 grams, this will result in aggregate samples weighing more than 30 kg. If the weight of a single retail pack is much more than 300 grams, then 300 grams shall be taken from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail packs of 500 grams or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1, 2 and 3, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1, 2 and 3.

Where the retail pack is less than 300 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 30 kg. If the weight of the retail pack is much less than 300 grams, one incremental sample shall consist of two or more retail packs, whereby the 300 grams are approximated as closely as possible.

D.1.2. *General survey of the method of sampling for dried figs*

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
Dried figs	≥ 15	15-30 tonnes	100	30
	< 15	—	10-100 (*)	≤ 30

(*) Depending on the lot weight — see table 2 of this part D.1 of this Annex.

D.1.3. *Method of sampling for dried figs (lots ≥ 15 tonnes)*

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following table 1. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately,

— Number of incremental samples: 100,

— Weight of the aggregate sample = 30 kg which shall be mixed and to be divided into three equal laboratory samples of 10 kg before grinding (this division into three laboratory samples is not necessary in case of dried figs subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 30 kg sample).

— Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II,

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

D.1.4. *Method of sampling for dried figs (lots < 15 tonnes)*

The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100.

The figures in the following table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2

Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	No of incremental samples	Aggregate sample Weight (kg) (in case of retail packings, weight of aggregate sample can diverge — see point D.1.1)	No of laboratory samples from aggregate sample
≤ 0,1	10	3	1 (no division)
> 0,1 – ≤ 0,2	15	4,5	1 (no division)
> 0,2 – ≤ 0,5	20	6	1 (no division)
> 0,5 – ≤ 1,0	30	9 (- < 12 kg)	1 (no division)
> 1,0 – ≤ 2,0	40	12	2
> 2,0 – ≤ 5,0	60	18 (- < 24 kg)	2
> 5,0 – ≤ 10,0	80	24	3
> 10,0 – ≤ 15,0	100	30	3

— Weight of the aggregate sample ≤ 30 kg which shall be mixed and divided into two or three equal laboratory samples of ≤ 10 kg before grinding (this division into two or three laboratory samples is not necessary in case of dried figs, subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise up to 30 kg samples).

In cases where the aggregate sample weights are less than 30 kg, the aggregate sample shall be divided into laboratory samples according to following guidance:

— < 12 kg: no division into laboratory samples;

— ≥ 12 – < 24 kg: division into two laboratory samples;

— ≥ 24 kg: division into three laboratory samples.

— Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II,

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

D.1.5. *Method of sampling for derived products and compound foods*

D.1.5.1. Derived products with very small particle weight (homogeneous distribution of aflatoxin contamination)

— Number of incremental samples: 100; for lots of under 50 tons the number of incremental samples shall be 10 to 100, depending on the lot weight (see table 3),

Table 3

Number of incremental samples to be taken depending on the weight of the lot

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 1	10	1
> 1 – ≤ 3	20	2
> 3 – ≤ 10	40	4
> 10 – ≤ 20	60	6
> 20 – ≤ 50	100	10

— The weight of the incremental sample shall be about 100 grams. In the case of lots in retail packing, the weight of the incremental sample depends on the weight of the retail packing,

— Weight of aggregate sample = 1-10 kg sufficiently mixed,

D.1.5.2. Other derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)

Method of sampling and acceptance as for dried figs (D.1.3 and D.1.4).

D.1.6. *Sampling at retail stage*

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the provisions set out in this part of Annex I.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg (*).

D.1.7. *Specific method of sampling of dried figs and derived products traded in vacuum packs*

D.1.7.1. Dried figs

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 30 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

D.1.7.2. Products derived from dried figs with small particle size

For lots equal to or more than 50 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in table 3 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 3).

D.1.8. *Acceptance of a lot or sublot*

For dried figs subjected to a sorting or other physical treatment:

— acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty,

For dried figs intended for direct human consumption:

— acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if one or more of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty,

In cases where the aggregate sample is 12 kg or less:

— acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty,

D.2. **Method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts**

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts.

D.2.1. *Weight of the incremental sample*

The weight of the incremental sample shall be about 200 grams, unless otherwise defined in part D.2 of Annex I.

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of more than 200 grams, this will result in aggregate samples weighing more than 20 kg. If the weight of a single retail pack is much more than 200 grams, then 200 grams shall be taken from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail packs of 500 grams or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1, 2 and 3, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1, 2 and 3.

Where the retail pack is less than 200 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 20 kg. If the weight of the retail pack is much less than 200 grams, one incremental sample shall consist of two or more retail packs, whereby the 200 grams are approximated as closely as possible.

D.2.2. *General survey of the method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts*

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
Groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts	≥ 500	100 tonnes	100	20
	> 125 and < 500	5 sublots	100	20
	≥ 15 and ≤ 125	25 tonnes	100	20
	< 15	—	10-100 (*)	≤ 20

(*) Depending on the lot weight — see table 2 of this part D.2 of this Annex.

D.2.3. *Method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (lots ≥ 15 tonnes)*

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following table 1. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately,

— Number of incremental samples: 100,

— Weight of the aggregate sample = 20 kg which shall be mixed and to be divided into two equal laboratory samples of 10 kg before grinding (this division into two laboratory samples is not necessary in case of groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 20 kg sample).

— Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II,

— If it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

D.2.4. *Method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (lots < 15 tonnes)*

The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100.

The figures in the following table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2

Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	No of incremental samples	Aggregate sample Weight (kg) (in case of retail packings, weight of aggregate sample can diverge — see point D.2.1)	No of laboratory samples from aggregate sample
≤ 0,1	10	2	1 (no division)
> 0,1 – ≤ 0,2	15	3	1 (no division)
> 0,2 – ≤ 0,5	20	4	1 (no division)
> 0,5 – ≤ 1,0	30	6	1 (no division)
> 1,0 – ≤ 2,0	40	8 (- < 12 kg)	1 (no division)
> 2,0 – ≤ 5,0	60	12	2
> 5,0 – ≤ 10,0	80	16	2
> 10,0 – ≤ 15,0	100	20	2

— Weight of the aggregate sample ≤ 20 kg which shall be mixed and if necessary divided into two equal laboratory samples of ≤ 10 kg before grinding (this division into two laboratory samples is not necessary in case of, groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise up to 20 kg samples).

In cases where the aggregate sample weights are less than 20 kg, the aggregate sample shall be divided into laboratory samples according to following guidance:

— < 12 kg: no division into laboratory samples;

— ≥ 12 kg division into two laboratory samples.

— Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II,

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

D.2.5. *Method of sampling for derived products, with the exception of vegetable oil, and compound foods*

D.2.5.1. Derived products (other than vegetable oil) with small particle size, i.e. flour, peanut butter (homogeneous distribution of aflatoxin contamination)

— Number of incremental samples: 100; for lots of under 50 tons the number of incremental samples shall be 10 to 100, depending on the lot weight (see table 3),

Table 3

Number of incremental samples to be taken depending on the weight of the lot

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 1	10	1
> 1 – ≤ 3	20	2
> 3 – ≤ 10	40	4
> 10 – ≤ 20	60	6
> 20 – ≤ 50	100	10

— The weight of the incremental sample shall be about 100 grams. In the case of lots in retail packing, the weight of the incremental sample depends on the weight of the retail packing,

— Weight of aggregate sample = 1-10 kg sufficiently mixed,

D.2.5.2. Derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)

Method of sampling and acceptance as for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (D.2.3 and D.2.4).

D.2.6. *Sampling at retail stage*

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the provisions set out in this part of Annex I.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg (*).

D.2.7. *Specific method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels, tree nuts and derived products traded in vacuum packs*

D.2.7.1. Pistachios, groundnuts (peanuts), Brazil nuts

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

D.2.7.2. Apricot kernels, tree nuts other than pistachios and Brazil nuts, other oilseeds

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

D.2.7.3. Products derived from tree nuts, apricot kernels and groundnuts (peanuts) with small particle size

For lots equal to or more than 50 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in table 3 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 3).

D.2.8. *Acceptance of a lot or sublot*

For groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to a sorting or other physical treatment:

— acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty,

For groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts intended for direct human consumption:

— acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if one or both of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty,

In cases where the aggregate sample is 12 kg or less:

— acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty;.

(*) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.'

ANNEX II

'G. METHOD OF SAMPLING FOR COFFEE, COFFEE PRODUCTS, LIQUORICE ROOT AND LIQUORICE EXTRACT

This method of sampling is of application for the official control of the maximum levels established for ochratoxin A in roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract.

G.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 100 grams, unless otherwise defined in this part G of Annex I.

In the case of lots in retail packings, the weight of the incremental sample shall depend on the weight of the retail packing.

In the case of retail packs of more than 100 grams, this will result in aggregate samples weighing more than 10 kg. If the weight of a single retail pack is much more than 100 grams, then 100 grams shall be taken from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail packs of 500 grams or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1 and 2, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1 and 2.

Where the retail pack is less than 100 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 10 kg. If the weight of the retail pack is much less than 100 grams, one incremental sample shall consist of two or more retail packs, whereby the 100 grams are approximated as closely as possible.

G.2. **General survey of the method of sampling for roasted coffee, ground roasted coffee, soluble coffee, liquorice root and liquorice extract**

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	No incremental samples	Aggregate sample Weight (kg)
Roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract	≥ 15	15-30 tonnes	100	10
	< 15	—	10-100 (*)	1-10

(*) Depending on the lot weight — see table 2 of this part of this Annex.

G.3. **Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee liquorice root and liquorice extract (lots ≥ 15 tonnes)**

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following table 1. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may vary from the mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately,

— Number of incremental samples: 100,

— Weight of the aggregate sample = 10 kg,

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

G.4. **Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee liquorice root and liquorice extract (lots < 15 tonnes)**

For roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract under 15 tonnes the sampling plan shall be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg.

The figures in the following table can be used to determine the number of incremental samples to be taken.

Table 2

Number of incremental samples to be taken depending on the weight of the lot of roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 0,1	10	1
> 0,1 – ≤ 0,2	15	1,5
> 0,2 – ≤ 0,5	20	2
> 0,5 – ≤ 1,0	30	3
> 1,0 – ≤ 2,0	40	4
> 2,0 – ≤ 5,0	60	6
> 5,0 – ≤ 10,0	80	8
> 10,0 – ≤ 15,0	100	10

G.5. **Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract traded in vacuum packs**

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

G.6. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part of Annex I.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg (*).

G.7. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

(*) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.'

ANNEX III

'K. METHOD OF SAMPLING FOR VEGETABLE OILS

This method of sampling is of application for the official control of the maximum levels established for mycotoxins, in particular aflatoxin B1, aflatoxin total and zearalenone, in vegetable oils.

K.1. **Method of sampling for vegetable oils**

— The weight of the incremental sample shall be at least about 100 grams (ml) (depending of the nature of the consignment e.g. vegetable oil in bulk, at least 3 incremental samples of about 350 ml have to be taken), resulting in an aggregate sample of at least 1 kg (litre),

— The minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The lot shall be thoroughly mixed insofar possible by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of aflatoxin can be assumed within a given lot, it is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

Table 1

Minimum number of incremental samples to be taken from the lot

Form of commercialisation	Weight of lot (in kg) Volume of lot (in litres)	Minimum number of incremental samples to be taken
Bulk (*)	—	3
packages	≤ 50	3
packages	> 50 to 500	5
packages	> 500	10

(*) On condition that the sublot can be separated physically, large bulk consignments/lots of vegetable oils shall be subdivided into sublots as foreseen in table 2 of this part.

Table 2

Subdivision of lots into sublots depending on lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	Minimum N° incremental samples	Minimum aggregate sample weight (kg)
Vegetable oils	≥ 1 500	500 tonnes	3	1
	> 300 and < 1 500	3 sublots	3	1
	≥ 50 and ≤ 300	100 tonnes	3	1
	< 50	—	3	1

K.2. **Method of sampling for vegetable oils at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the provisions set out in this part of Annex I.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg (*).

K.3. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

(*) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.'

COMMISSION REGULATION (EU) No 179/2010

of 2 March 2010

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

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 3 March 2010.

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

Done at Brussels, 2 March 2010.

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

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	JO	67,6
	MA	113,6
	TN	130,0
	TR	116,9
	ZZ	107,0
0707 00 05	EG	211,5
	JO	145,3
	MK	147,9
	TR	148,5
	ZZ	163,3
0709 90 70	MA	132,4
	TR	89,4
	ZZ	110,9
0709 90 80	EG	43,6
	ZZ	43,6
0805 10 20	CL	52,4
	EG	45,1
	IL	56,5
	MA	46,5
	TN	46,6
	TR	58,8
	ZZ	51,0
0805 50 10	EG	76,3
	IL	76,3
	MA	68,6
	TR	70,3
	ZZ	72,9
0808 10 80	CA	76,4
	CN	70,6
	MK	24,7
	US	99,2
	ZZ	67,7
0808 20 50	AR	78,5
	CL	200,0
	CN	54,8
	US	92,4
	ZA	91,9
	ZZ	103,5

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

COMMISSION REGULATION (EU) No 180/2010

of 2 March 2010

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EC) No 877/2009 for the 2009/10 marketing year

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2009/10 marketing year are fixed by Commission Regulation (EC) No 877/2009 ([3]). These prices and duties have been last amended by Commission Regulation (EU) No 160/2010 ([4]).

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

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EC) No 877/2009 for the 2009/10, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 3 March 2010.

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

Done at Brussels, 2 March 2010.

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

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 178, 1.7.2006, p. 24.
([3]) OJ L 253, 25.9.2009, p. 3.
([4]) OJ L 49, 26.2.2010, p. 18.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 3 March 2010

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 (1)	40,51	0,00
1701 11 90 (1)	40,51	2,75
1701 12 10 (1)	40,51	0,00
1701 12 90 (1)	40,51	2,45
1701 91 00 (2)	47,12	3,33
1701 99 10 (2)	47,12	0,20
1701 99 90 (2)	47,12	0,20
1702 90 95 (3)	0,47	0,23

(1) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.
(2) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.
(3) Per 1 % sucrose content.

COMMISSION REGULATION (EU) No 181/2010

of 2 March 2010

on the issue of licences for the import of garlic in the subperiod from 1 June 2010 to 31 August 2010

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 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 [2], and in particular Article 7(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 341/2007 [3] opens and provides for the administration of tariff quotas and introduces a system of import licences and certificates of origin for garlic and other agricultural products imported from third countries.

(2) The quantities for which 'A' licence applications have been lodged by traditional importers and by new importers during the first five working days following the 15th day of February 2010, pursuant to Article 10(1) of Regulation (EC) No 341/2007 exceed the quantities available for products originating in China and all third countries other than China.

(3) Therefore, in accordance with Article 7(2) of Regulation (EC) No 1301/2006, it is now necessary to establish the extent to which the 'A' licence applications sent to the Commission by the end of February 2010 can be met in accordance with Article 12 of Regulation (EC) No 341/2007,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for 'A' import licences lodged pursuant to Article 10(1) of Regulation (EC) No 341/2007 during the first five working days following the 15th day of February 2010 and sent to the Commission by the end of February 2010 shall be met at a percentage rate of the quantities applied for as set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 2 March 2010.

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

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 238, 1.9.2006, p. 13.
[3] OJ L 90, 30.3.2007, p. 12.

ANNEX

Origin	Order number	Allocation coefficient
Argentina		
— Traditional importers	09.4104	X
— New importers	09.4099	X
China		
— Traditional importers	09.4105	17,875957 %
— New importers	09.4100	0,387100 %
Other third countries		
— Traditional importers	09.4106	100 %
— New importers	09.4102	31,057336 %

'X: No quota for this origin for the subperiod in question.'

DECISIONS

COUNCIL DECISION

of 25 February 2010

on setting up the Standing Committee on operational cooperation on internal security

(2010/131/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard the Treaty on the Functioning of the European Union, and in particular Article 240(3) thereof,

Whereas:

(1) Article 71 of the Treaty on the Functioning of the European Union provides that a standing committee shall be set up within the Council in order to ensure that operational cooperation on internal security is promoted and strengthened within the Union.

(2) It is therefore appropriate to adopt a Decision on the setting up of such a Committee and to define its tasks,

HAS ADOPTED THIS DECISION:

Article 1

The Standing Committee on operational cooperation on internal security (hereinafter referred to as 'the Standing Committee') foreseen in Article 71 of the Treaty is hereby set up within the Council.

Article 2

The Standing Committee shall facilitate, promote and strengthen coordination of operational actions of the authorities of the Member States competent in the field of internal security.

Article 3

1. Without prejudice to the mandates of the bodies referred to in Article 5, the Standing Committee shall facilitate and ensure effective operational cooperation and coordination under Title V of Part Three of the Treaty, including in areas covered by police and customs cooperation and by authorities responsible for the control and protection of external borders. It shall also cover, where appropriate, judicial cooperation in criminal matters relevant to operational cooperation in the field of internal security.

2. The Standing Committee shall also evaluate the general direction and efficiency of operational cooperation; it shall identify possible shortcomings or failures and adopt appropriate concrete recommendations to address them.

3. The Standing Committee shall assist the Council in accordance with the provisions of Article 222 of the Treaty.

Article 4

1. The Standing Committee shall not be involved in conducting operations, which shall remain the task of the Member States.

2. The Standing Committee shall not be involved in preparing legislative acts.

Article 5

1. When appropriate, representatives from Eurojust, Europol, the European Agency for the Management of Operational Cooperation at the External Borders of the EU Member States (Frontex) and other relevant bodies shall be invited to attend, as observers, the meetings of the Standing Committee.

2. The Standing Committee will help ensure consistency of action by those bodies.

Article 6

1. The Standing Committee shall regularly submit a report to the Council on its activities.

2. The Council shall keep informed the European Parliament and the national Parliaments of the proceedings of the Standing Committee.

Article 7

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

It shall be published in the *Official Journal of the European Union*.

Done at Brussels, 25 February 2010.

For the Council
The President
A. PÉREZ RUBALCABA

COMMISSION DECISION

of 2 March 2010

recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of *Trichoderma asperelleum* (strain T34) and isopyrazam in Annex I to Council Directive 91/414/EEC

(notified under document C(2010) 1099)

(Text with EEA relevance)

(2010/132/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection products on the market [1], and in particular Article 6(3) thereof,

Whereas:

(1) Directive 91/414/EEC provides for the development of a Community list of active substances authorised for incorporation in plant protection products.

(2) A dossier for the active substance *Trichoderma asperellum* (strain T34) was submitted by Biocontrol Technologies S.L. to the authorities of the United Kingdom on 22 April 2009 with an application to obtain its inclusion in Annex I to Directive 91/414/EEC. For isopyrazam, a dossier was submitted by Syngenta Crop Protection AG to the authorities of the United Kingdom on 25 November 2008 with an application to obtain its inclusion in Annex I to Directive 91/414/EEC.

(3) The United Kingdoms authorities have indicated to the Commission that, on preliminary examination, the dossiers for the active substances concerned appear to satisfy the data and information requirements set out in Annex II to Directive 91/414/EEC. The dossiers submitted appear also to satisfy the data and information requirements set out in Annex III to Directive 91/414/EEC in respect of one plant protection product containing the active substance concerned. In accordance with Article 6(2) of Directive 91/414/EEC, the dossiers were subsequently forwarded by the respective applicants to the Commission and other Member States, and were referred to the Standing Committee on the Food Chain and Animal Health.

(4) By this Decision it should be formally confirmed at European Union level that the dossiers are considered as satisfying in principle the data and information requirements set out in Annex II and, for at least one plant protection product containing the active substance concerned, the requirements set out in Annex III to Directive 91/414/EEC.

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

HAS ADOPTED THIS DECISION:

Article 1

The dossiers concerning the active substances identified in the Annex to this Decision, which were submitted to the Commission and the Member States with a view to obtaining the inclusion of those substances in Annex I to Directive 91/414/EEC, satisfy in principle the data and information requirements set out in Annex II to that Directive.

The dossiers also satisfy the data and information requirements set out in Annex III to that Directive in respect of one plant protection product containing the active substance, taking into account the uses proposed.

Article 2

The rapporteur Member State shall pursue the detailed examination for the dossiers referred to in Article 1 and shall communicate to the Commission the conclusions of its examinations accompanied by any recommendations on the inclusion or non-inclusion in Annex I to Directive 91/414/EEC of the active substances referred to in article 1 and any conditions for those inclusions as soon as possible and at the latest within a period of one year from the date of publication of this Decision in the *Official Journal of the European Union*.

[1] OJ L 230, 19.8.1991, p. 1.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 2 March 2010.

For the Commission
John DALLI
Member of the Commission

ANNEX

ACTIVE SUBSTANCES CONCERNED BY THIS DECISION

No	Common Name, CIPAC Identification Number	Applicant	Date of application	Rapporteur Member State
1	*Trichoderma asperellum* (strain T34) CIPAC-No: not relevant	Biocontrol Technologies S.L.	22.4.2009	UK
2	Isopyrazam CIPAC-No: Syn-isomer: 683777-13-1 Anti-isomer: 683777-14-2	Syngenta Crop Protection AG	25.11.2008	UK

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 2 March 2010

on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate levels in these beverages

(Text with EEA relevance)

(2010/133/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof

Whereas,

(1) The Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted on 20 September 2007 a scientific opinion on ethyl carbamate and hydrocyanic acid in food and beverages [1]. In this opinion the Panel derived margins of exposure (MOE) for ethyl carbamate for different scenarios of food and beverage consumption. Based on these MOE the Panel concluded that ethyl carbamate in alcoholic beverages indicates a health concern, particularly with respect to stone fruit brandies, and recommended taking mitigation measures to reduce the levels of ethyl carbamate in these beverages. As hydrocyanic acid is an important precursor of ethyl carbamate formation in stone fruit spirits and stone fruit marc spirits, the Panel concluded that such measures should include focus on hydrocyanic acid and other precursors of ethyl carbamate, to prevent the formation of ethyl carbamate during the shelf-life of these products.

(2) Maximum contents of hydrocyanic acid in stone fruit spirits and stone fruit marc spirits have been laid down in Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 [2]. This Regulation stipulates that the maximum hydrocyanic acid content in stone fruit spirits and stone fruit marc spirits shall be 7 grams per hectolitre of 100 % vol. alcohol (70 mg/l).

(3) A Code of Practice for the prevention and reduction of ethyl carbamate levels in stone fruit spirits and stone fruit marc spirits is considered a suitable tool to address the EFSA recommendations. This Code recommends Good Manufacturing Practices (GMP) for which there is evidence that lower ethyl carbamate levels can be achieved when they are applied. An ethyl carbamate target level of 1 mg/l in the ready-to-drink spirit is realistic and achievable when applying good practices.

(4) The levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits should be monitored during a time period of three years and the results be used to assess the effects of this Code of Practice after three years of implementation. Furthermore, the possibility of setting a maximum level should be assessed.

HAS ADOPTED THIS RECOMMENDATION:

It is recommended that the Member States:

1. take the necessary measures to ensure that the Code of Practice on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits as described in the Annex to this Recommendation, is implemented by all operators involved in the production, packaging, transport, holding and storage of stone fruit spirits and stone fruit marc spirits.

2. ensure that all the appropriate measures are taken to achieve levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits as low as possible with the aim to achieve the level of 1 mg/l as a target.

[1] Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on ethyl carbamate and hydrocyanic acid in food and beverages, *The EFSA Journal* (2007) Journal number, 551, p. 1. http://www.efsa.europa.eu/en/scdocs/doc/Contam_ej551_ethyl_carbamate_en_rev.1,3.pdf

[2] OJ L 39, 13.2.2008, p. 16.

3. monitor levels of ethyl carbamate in stone fruit spirits and stone fruit marc spirits during the years 2010, 2011 and 2012 in order to assess the effects of the Code of Practice set out in the Annex to this Recommendation.

4. report the monitoring data of the previous year to EFSA by 1 June each year with the information and in the format set out by EFSA.

5. follow the sampling procedures for the purpose of the monitoring programme as laid down in part B of the Annex to Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs [1].

6. carry out the analysis of ethyl carbamate in accordance with the criteria laid down in points 1 and 2 of Annex III to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [2].

Done at Brussels, 2 March 2010.

For the Commission
John DALLI
Member of the Commission

[1] OJ L 88, 29.3.2007, p. 29.

[2] OJ L 165, 3.4.2004, p. 1.

ANNEX

Code of Practice for the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits

INTRODUCTION

1. Ethyl carbamate is a compound that occurs naturally in fermented foods and alcoholic beverages such as bread, yoghurt, soy sauce, wine, beer, and particularly in stone fruit spirits and stone fruit marc spirits, mainly those made from cherries, plums, mirabelles and apricots.

2. Ethyl carbamate can be formed from various substances inherent in food and beverages, including hydrogen cyanide (or hydrocyanic acid), urea, citrulline, and other N-carbamyl compounds. Cyanate is probably the ultimate precursor in most cases, reacting with ethanol to form ethyl carbamate.

3. In stone fruit distillates (stone fruit spirits and stone fruit marc spirits) ethyl carbamate can be formed from cyanogenic glycosides that are natural constituents of the stones. When mashing the fruit, the stones may be broken and cyanogenic glycosides from the stones may come into contact with enzymes in the fruit mash. Cyanogenic glycosides are then degraded to hydrocyanic acid/cyanides. Hydrocyanic acid may also be released from intact stones during a longer storage of the fermented mash. During the distillation process hydrocyanic acid may be enriched in all fractions. Under influence of light cyanide is oxidised to cyanate reacting with ethanol to form ethyl carbamate. Once the reaction has been triggered, it cannot be stopped.

4. A major reduction in the concentration of ethyl carbamate could be achieved using two different approaches: first, by reducing the concentration of the main precursor substances; second, by reducing the tendency of these substances to react to form cyanate. The main influencing factors are the concentration of precursors (e.g. hydrocyanic acid and cyanides) and storage conditions, such as light exposure and temperature.

5. Although no strong correlation between the level of hydrocyanic acid and ethyl carbamate has been established so far, it is evident that under certain conditions high concentrations of hydrocyanic acid lead to higher levels of ethyl carbamate. A potential increase in ethyl carbamate formation has been associated with levels at or above 1 mg/l hydrocyanic acid in the final distillate ([1]) ([2]).

6. Part I gives details of the production process. Part II contains specific recommendations based on Good Manufacturing Practices (GMP).

I. DESCRIPTION OF THE PRODUCTION PROCESS

7. The production process for fruit spirits and fruit marc spirits involves mashing and fermentation of the whole fruit, followed by distillation. The process typically follows the steps listed below:

— crushing the whole ripe fruit;

— fermenting the mash in stainless steel tanks or other suitable fermentation vessels;

— transferring the fermented mash into the distillation device, often a copper pot;

— heating the fermented mash by a suitable heating method in order to slowly boil off the alcohol;

([1]) Christoph, N., Bauer-Christoph C., *Maßnahmen zur Reduzierung des Ethylcarbamatgehaltes bei der Herstellung von Steinobstbränden (I)*, Kleinbrennerei 1998; 11: 9-13.

([2]) Christoph, N., Bauer-Christoph C., *Maßnahmen zur Reduzierung des Ethylcarbamatgehaltes bei der Herstellung von Steinobstbränden (II)*, Kleinbrennerei 1999; 1: 5-13.

— cooling the alcohol vapour in an appropriate (e.g. stainless steel) column where it condenses and is collected;

— separation of three different fractions of alcohol: 'heads', 'hearts' and 'tails';

8. During distillation, the heads boil off first. They can usually be recognised by their solvent or lacquer aromas. This fraction is generally unsuitable for consumption and should be discarded.

9. During the middle distillation run (the 'hearts'), the principal alcohol in all spirits, ethyl alcohol (ethanol), is distilled. This part of the distilling run, where the content of volatiles other than ethanol is lowest and the purest fruit aromas are found, is always collected.

10. The 'tails' of the distillation include acetic acid and fusel oils, which are often identified by unpleasant vinegary and vegetal aromas. They are also discarded, but they may be re-distilled because some ethanol is invariably included with the tails.

II. RECOMMENDED PRACTICES BASED ON GOOD MANUFACTURING PRACTICES (GMP)

Raw materials and preparation of fruit mash

11. The raw materials and preparation of the fruit mash should be suitable to avoid the release of hydrocyanic acid.

12. The stone fruits should be of high quality, not mechanically damaged and not microbiologically spoiled.

13. The fruit should preferably be de-stoned.

14. If the fruits are not de-stoned, they should be mashed gently to avoid crushing the stones.

Fermentation

15. Selected yeast strains for alcohol production should be added to the mashed fruits, according to the instructions for users.

16. Mashed fermented fruits should be handled with high standards of hygiene, and exposure to light should be minimised. The fermented fruit mash should be stored as short as possible before distillation since hydrocyanic acid may also be released from intact stones during longer storage of the mash.

Distillation equipment

17. Distillation equipment and the distillation process should be suitable, to ensure that hydrocyanic acid is not transferred into the distillate.

18. The distillation equipment should include automatic rinsing devices and copper catalytic converters. The automatic rinsing devices will keep the stills cleaned while the copper catalytic converters will bind hydrocyanic acid before it passes into the distillate.

19. Automatic rinsing devices are not necessary in the case of discontinuous distillation. The distillation equipment should be cleaned by systematic and thorough cleaning procedures.

20. In certain cases, when no copper catalytic converters or other dedicated cyanide separators are used, copper agents should be added to the fermented fruit mash before distillation. The purpose of the copper agents is to bind hydrocyanic acid. Copper agents are sold at specialised shops and should be used very carefully according to the manufacturer's instructions.

Distillation process

21. Stones settled in the fermented mash should not be pumped into the distillation device.

22. Distillation should be carried out in such a way that alcohol is boiled off slowly (e.g. by using steam instead of a direct flame as the heating source).

23. The first fractions of the distillate, called 'heads', should be separated carefully.

24. The middle fraction, called 'hearts', should then be collected and should be stored in the dark. When the alcohol content reaches 50 % vol. in the receiver, collection should be switched to the 'tails', so that any ethyl carbamate that may have been formed is separated in the tail fraction.

25. The separated tails, possibly containing ethyl carbamate, should be collected and if they are used for re-distilling, they should be re-distilled separately.

Checks on the distillate, re-distillation and storage

Hydrocyanic acid

26. The distillates should be regularly checked for their levels of hydrocyanic acid. The determination should be carried out by appropriate tests, either by kits for rapid testing of the hydrocyanic acid levels, or, alternatively, by a specialist laboratory.

27. If the concentration of hydrocyanic acid in the distillate exceeds a level of 1 mg/l, re-distillation with catalytic converters or copper agents (cf. points 18 and 20) is recommended, where appropriate.

28. Distillates with hydrocyanic acid levels close to 1 mg/l should ideally also be re-distilled or, where this is not possible, be stored in lightproof bottles or covering boxes with storage times as short as possible in order to avoid ethyl carbamate formation during storage.

Ethyl carbamate

29. Testing of ethyl carbamate is recommended for distillates in which the compound may already have been formed (e.g. distillates with unknown history of production, higher levels of cyanide, storage at light). The level of ethyl carbamate can only be tested by a specialist laboratory.

30. If the distillate shows an ethyl carbamate concentration exceeding the target level of 1 mg/l, the distillate should be re-distilled, where appropriate.

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