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Contents

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[1] Text with EEA relevance

EN

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

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

DECISIONS

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 14/2011

of 10 January 2011

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Limone di Sorrento (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1], and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

(1) In accordance with the first subparagraph of Article 9(1) of Regulation (EC) No 510/2006, the Commission has examined Italy's application for the approval of amendments to the specification for the protected geographical indication 'Limone di Sorrento' registered in accordance with Commission Regulation (EC) No 2400/96 [2], as amended by Regulation (EC) No 2446/2000 [3].

(2) Since the amendments in question are not minor within the meaning of Article 9 of Regulation (EC) No 510/2006, the Commission published the amendment application in the *Official Journal of the European Union* [4], as required by the first subparagraph of Article 6(2) of that Regulation. As no statement of objection within the meaning of Article 7 of Regulation (EC) No 510/2006 has been notified to the Commission, the amendments should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name contained in the Annex to this Regulation are hereby approved.

Article 2

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

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

Done at Brussels, 10 January 2011.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 93, 31.3.2006, p. 12.
[2] OJ L 327, 18.12.1996, p. 11.
[3] OJ L 281, 7.11.2000, p. 12.
[4] OJ C 105, 24.4.2010, p. 12.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

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

ITALY

Limone di Sorrento (PGI)

COMMISSION REGULATION (EU) No 15/2011

of 10 January 2011

amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs

(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 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [1], and in particular Article 11(4) thereof,

Having regard to 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 [2], and in particular Article 18(13)(a) thereof,

Whereas:

(1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin and Regulation (EC) No 853/2004 lays down specific requirements concerning hygiene rules for food of animal origin. Implementing measures for those Regulations as regards recognised testing methods for marine biotoxins are set out in Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 [3]. It is necessary to modify those implementing measures in the light of new scientific evidence.

(2) In July 2006 the Commission requested the European Food Safety Authority (EFSA) to provide a scientific opinion to assess the current limits and methods of analysis with regard to human health for various marine biotoxins as established in the Community legislation, including new emerging toxins. The last of a series of opinions was published on 24 July 2009.

(3) The mouse bioassay (MBA) and the rat bioassay (RBA) are the official methods for the detection of lipophilic biotoxins. The Panel on Contaminants in the Food Chain of EFSA noted that these bioassays have shortcomings and are not considered an appropriate tool for control purposes because of the high variability in results, the insufficient detection capability and the limited specificity.

(4) Recently developed alternatives to the biological methods for the determination of the marine biotoxins with lower limits of detection (LOD) have successfully been tested in prevalidation studies.

(5) A liquid chromatography-mass spectrometry (LC-MS/MS) method was validated under the coordination of the European Union Reference Laboratory on marine biotoxins (EU-RL) in an inter-laboratory validation study carried out by the Member States. This method is publicly available for consultation in the web page of the EU-RL (http://www.aesan.msps.es/en/CRLMB/web/home.shtml). This validated technique of liquid chromatography (LC) mass spectrometry (MS) should be applied as the reference method for the detection of lipophilic toxins and used as matter of routine, both for the purposes of official controls at any stage of the food chain and own-checks by food business operators.

(6) Any other recognised method, different from the liquid chromatography (LC) mass spectrometry (MS), could be applied for the detection of lipophilic toxins provided that they fulfil the method performance criteria stipulated by the EU-RL. Such methods should be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. If the results are challenged, the reference method shall be the EU-RL LC-MS/MS method.

(7) To allow Member States to adapt their methods to the chemical method, the biological methods should continue to be used for a limited period of time. After this period, the biological methods should be used not as a matter of routine and only during the periodic monitoring of production areas for detecting new or unknown marine toxins.

(8) Therefore, Regulation (EC) No 2074/2005 should be amended accordingly.

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

[1] OJ L 139, 30.4.2004, p. 55.
[2] OJ L 139, 30.4.2004, p. 206.
[3] OJ L 338, 22.12.2005, p. 27.

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 2074/2005 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 July 2011.

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

Done at Brussels, 10 January 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex III to Regulation (EC) No 2074/2005, Chapter III is replaced by the following:

'CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. **Chemical methodology**

(1) The EU-RL LC-MS/MS method shall be the reference method for the detection of marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. This method shall determine at least the following compounds:

— okadaic acid group toxins: OA, DTX1, DTX2, DTX3 including their esters,

— pectenotoxins group toxins: PTX1 and PTX2,

— yessotoxins group toxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,

— azaspiracids group toxins: AZA1, AZA2 and AZA3.

(2) Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.

(3) If new analogues of public health significance are discovered, they should be included in the analysis. Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.

(4) Other methods, such as liquid chromatography (LC) mass spectrometry (MS) method, high-performance liquid chromatography (HPLC) with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, can be used as alternatives or supplementary to the EU-RL LC-MS/MS method, provided that:

(a) either alone or combined they can detect at least the analogues as identified in point A(1) of this Chapter; more appropriate criteria shall be defined when necessary;

(b) they fulfil the method performance criteria stipulated by the EU-RL. Such methods should be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The EU-RL shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation;

(c) their implementation provides an equivalent level of public health protection.

B. **Biological methods**

(1) To allow Member States to adapt their methods to the LC-MS/MS method as defined in point A(1) of this Chapter, a series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be still used until 31 December 2014 for detecting marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

(2) Sensitivity and selectivity depend on the choice of solvents used for extraction and purification and this should be taken into account when a decision is made on the method to be used in order to cover the full range of toxins.

(3) A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, azaspiracids, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences.

(4) Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of one or more toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004 at levels above those laid down.

(5) A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids but it cannot be used to detect yessotoxins as losses of these toxins may take place during the partition step. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

(6) A rat bioassay may be used to detect okadaic acid, dinophysistoxins and azaspiracids. Three rats shall be used for each test. A diarrhetic response in any of the three rats shall be considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

C. After the period established in point B(1) of this Chapter, the mouse bioassay shall be used only during the periodic monitoring of production areas and relaying areas for detecting new or unknown marine toxins on the basis of the national control programmes elaborated by the Member States.'

COMMISSION REGULATION (EU) No 16/2011

of 10 January 2011

laying down implementing measures for the Rapid alert system for food and feed

(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 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1], and in particular Article 51 thereof,

Whereas:

(1) Regulation (EC) No 178/2002 establishes a Rapid alert system for food and feed (hereinafter — 'RASFF'), managed by the Commission and involving the Member States, the Commission and the European Food Safety Authority, to provide the control authorities with an effective tool for the notification of risks to human health deriving from food or feed. Article 50 of that Regulation sets out the scope and requirements for the RASFF to operate.

(2) Article 51 of Regulation (EC) No 178/2002 requires the Commission to establish implementing measures for Article 50 of that Regulation, in particular as regards the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

(3) Member States are primarily responsible for the enforcement of the EU legislation. They perform official controls, the rules for which are laid down in 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 [2]. The RASFF supports the Member States' actions by allowing the rapid exchange of information on risks posed by food or feed and on measures taken or to be taken to counter such risks.

(4) Article 29 of Regulation EC No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene [3] extends the scope of the RASFF to serious risks to animal health and to the environment. Therefore, the term 'risk' used in this Regulation is to be understood as a direct or indirect risk to human health in connection with food, food contact material or feed in accordance with Regulation (EC) No 178/2002 or as a serious risk to human health, animal health or the environment in connection with feed in accordance with Regulation (EC) No 183/2005.

(5) Rules should be established to allow the RASFF to operate correctly both in relation to cases where a serious risk within the meaning of Article 50(2) of Regulation (EC) No 178/2002 is identified and in relation to other cases where, even though a risk of lesser gravity or urgency is identified, an efficient exchange of information is necessary between and among the members of the RASFF network. Notifications are classified into alert, information and border rejection notifications to allow for a more efficient handling by members of the network.

(6) For the RASFF to operate efficiently, requirements should be formulated for the procedure for transmission of the different types of notifications. Alert notifications should be transmitted and treated with priority. Border rejection notifications are particularly relevant to controls carried out at border inspection posts and designated points of entry along the European Economic Area border. Templates and data dictionaries enhance the legibility and understanding of the notifications. Flagging members of the network for certain notifications draws their attention to particular notifications ensuring thereby that they are handled quickly.

(7) In accordance with Regulation (EC) No 178/2002, the Commission, the Member States and EFSA have designated contact points, which represent the members of the network in order to benefit from a correct and fast communication. In application of Article 50 of that Regulation and in order to avoid possible mistakes in the transmission of the notifications, only one designated contact point should exist for each member of the network. This contact point should facilitate the rapid transmission to a competent authority inside a member country.

(8) In order to ensure the correct and efficient functioning of the network between its members, common rules for duties of the contact points should be established. Provisions concerning the coordinating role of the Commission should also be set out, including the verification of the notifications. In this respect, the Commission should also assist members of the network in taking appropriate measures by identifying recurrent hazards and operators reported in the notifications.

[1] OJ L 31, 1.2.2002, p. 1.
[2] OJ L 165, 30.4.2004, p. 1.
[3] OJ L 35, 8.2.2005, p. 1.

(9) In case that, notwithstanding the checks carried out by the notifying member and by the Commission, a transmitted notification turns out to be erroneous or unfounded, then a procedure providing for either its amendment or its withdrawal from the system should be laid down.

(10) According to paragraphs 3 and 4 of Article 50 of Regulation (EC) No 178/2002 the Commission is required to inform third countries of certain RASFF notifications. Therefore, without prejudice to specific provisions in agreements concluded pursuant to Article 50.6 of Regulation (EC) No 178/2002, the Commission should ensure direct contact with food safety authorities in third countries in order to send out notifications to these third countries and at the same time ensure the exchange of relevant information with regard to these notifications and any direct or indirect risk to human health deriving from food or feed.

(11) Article 10 of Regulation (EC) No 178/2002 requires the public authorities to inform the public of risks to human health inter alia. The Commission should provide summary information about the RASFF notifications transmitted and annual reports highlighting the trends in food safety issues notified through RASFF and the evolution of the network itself to inform members, stakeholders and the general public.

(12) This Regulation has been discussed with the European Food Safety Authority.

(13) 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

Definitions

For the purposes of this Regulation the following definitions shall apply in addition to those set out in Regulations (EC) No 178/2002 and (EC) No 882/2004:

1. 'network' means the rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed, as established by Article 50 of Regulation (EC) No 178/2002;

2. 'member of the network' means a Member State, the Commission, the European Food Safety Authority and any applicant country, third country or international organisation having concluded an agreement with the European Union in accordance with Article 50(6) of Regulation (EC) No 178/2002;

3. 'contact point' means the designated contact point that represents the member of the network;

4. 'alert notification' means a notification of a risk that requires or might require rapid action in another member country;

5. 'information notification' means a notification of a risk that does not require rapid action in another member country;

   (a) 'information notification for follow-up' means an information notification related to a product that is or may be placed on the market in another member country;

   (b) 'information notification for attention' means an information notification related to a product that:

      (i) is present only in the notifying member country; or

      (ii) has not been placed on the market; or

      (iii) is no longer on the market;

6. 'border rejection notification' means a notification of a rejection of a batch, container or cargo of food or feed as referred to in Article 50(3)(c) of Regulation (EC) No 178/2002;

7. 'original notification' means an alert notification, an information notification or a border rejection notification;

8. 'follow-up notification' means a notification that contains additional information in relation to an original notification;

9. 'professional operators' means food business operators and feed business operators as defined in Regulation (EC) No 178/2002 or business operators as defined in Regulation (EC) No 1935/2004 of the European Parliament and of the Council [1].

Article 2

Duties of members of the network

1. Members of the network shall ensure the efficient functioning of the network within their jurisdiction.

2. Members of the network shall each designate one contact point and communicate that designation to the Commission contact point, as well as detailed information regarding the persons operating it and their contact details. For that purpose they shall use the contact point information template to be provided by the Commission contact point.

3. The Commission contact point shall maintain and update the list of contact points and make it available to all members of the network. Members of the network shall inform the Commission contact point immediately of any changes in their contact points and contact details.

4. The Commission contact point shall provide members of the network with templates to be used for notification purposes.

5. Members of the network shall ensure effective communication between their contact points and competent authorities within their jurisdiction on the one hand and between their contact points and the Commission contact point on the other hand for the purposes of the network. In particular they shall:

(a) set up an effective communication network between their contact points and all relevant competent authorities within

[1] OJ L 338, 13.11.2004, p. 4.

their jurisdiction allowing immediate transmission of a notification to the competent authorities for appropriate action, and maintain it in permanent good order;

(b) define the roles and responsibilities of their contact points and those of the relevant competent authorities within their jurisdiction, as regards the preparation and transmission of notifications sent to the Commission contact point, as well as the assessment and distribution of notifications received from the Commission contact point.

6. All contact points shall ensure the availability of an on-duty officer reachable outside office hours for emergency communications on a 24-hour/7-day-a-week basis.

Article 3

Alert notifications

1. Members of the network shall send alert notifications to the Commission contact point without undue delay and in any event within 48 hours from the moment the risk was reported to them. Alert notifications shall include all information available regarding, in particular, the risk and the product from which the risk derives. However, the fact that not all relevant information has been collected shall not unduly delay transmission of alert notifications.

2. The Commission contact point shall transmit alert notifications to all members of the network within 24 hours after reception, upon verification as referred to in Article 8.

3. Outside office hours, members of the network shall announce the transmission of an alert notification or follow-up to an alert notification by a telephone call to the emergency phone number of the Commission contact point. The Commission contact point shall inform the members of the network flagged for follow-up by a telephone call to their emergency phone numbers.

Article 4

Information notifications

1. Members of the network shall send information notifications to the Commission contact point without undue delay. The notification shall include all information available regarding, in particular, the risk and the product from which the risk derives.

2. The Commission contact point shall transmit information notifications to all members of the network without undue delay upon verification as referred to in Article 8.

Article 5

Border rejection notifications

1. Members of the network shall send border rejection notifications to the Commission contact point without undue delay. The notification shall include all information available regarding, in particular, the risk and the product from which the risk derives.

2. The Commission contact point shall transmit border rejection notifications to border inspection posts as defined in Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries [1] and to designated points of entry as referred to in Regulation (EC) No 882/2004.

Article 6

Follow-up notifications

1. Whenever a member of the network has any additional information relating to the risk or product referred to in an original notification, it shall immediately transmit a follow-up notification through its contact point to the Commission contact point.

2. When follow up information relating to an original notification has been requested by a member of the network, such information shall be provided to the extent possible and without undue delay.

3. When action is taken upon receipt of an original notification as referred to in Article 50(5) of Regulation (EC) No 178/2002, the member which took the action shall immediately transmit detailed information thereof to the Commission contact point by way of a follow-up notification.

4. If the action referred to in paragraph 3 consists of a product being detained and returned to a dispatcher residing in another member country:

(a) the member taking the action shall provide relevant information about the returned product by way of a follow-up notification unless that information was already included in full in the original notification;

(b) the member country to which the products were returned shall inform on the action taken on the returned products, by way of a follow-up notification.

5. The Commission contact point shall transmit follow-up notifications to all members of the network without undue delay and within 24 hours for follow-up notifications to alerts.

Article 7

Notification submission

1. Notifications shall be submitted using the templates provided by the Commission contact point.

2. All relevant fields of the templates shall be completed to enable clear identification of the product(s) and risk(s) involved and to provide the traceability information. Data dictionaries provided by the Commission contact point shall be used to the maximum extent possible.

3. Notifications shall be classified according to the definitions provided in Article 1 in one of the following categories:

(a) original notification

(i) alert notification;

(ii) information notification for follow-up;

[1] OJ L 24, 30.1.1998, p. 9.

(iii) information notification for attention;

(iv) border rejection notifications;

(b) follow-up notification

4. Notifications shall identify members of the network that are asked to provide follow-up to the notification.

5. All relevant documents shall be added to the notification and sent to the Commission contact point without undue delay.

Article 8

Verification of the notification

Before transmitting a notification to all members of the network, the Commission contact point shall:

(a) verify the completeness and legibility of the notification, including whether the appropriate data from the dictionaries referred to in Article 7(2) were selected;

(b) verify the correctness of the legal basis given for the cases of non-compliance found; however an incorrect legal basis shall not prevent transmission of the notification if a risk was identified;

(c) verify that the subject of the notification falls within the scope of the network as laid down in Article 50 of Regulation (EC) No 178/2002;

(d) ensure that the essential information in the notification is provided in a language easily understandable by all members of the network;

(e) verify compliance with the requirements laid down in this Regulation;

(f) identify recurrences of the same professional operator and/or hazard and/or country of origin in notifications.

In order to respect the delay for transmission, the Commission can make small changes to the notification provided that they are agreed with the notifying member prior to transmission.

Article 9

Notification withdrawal and amendments

1. Any member of the network may request that a notification transmitted through the network be withdrawn by the Commission contact point upon agreement from the notifying member if the information upon which the action to be taken is based appears to be unfounded or if the notification was transmitted erroneously.

2. Any member of the network may request amendments to a notification upon agreement from the notifying member. A follow-up notification shall not be considered an amendment to a notification and may therefore be transmitted without the agreement of any other member of the network.

Article 10

Exchange of information with third countries

1. If the notified product originates from or is distributed to a third country, the Commission shall inform the third country without undue delay.

2. Without prejudice to specific provisions in agreements concluded pursuant to Article 50(6) of Regulation (EC) No 178/2002, the Commission contact point shall establish contact with a designated single contact point in the third country, if any, with a view to reinforce communication, including through the use of information technology. The Commission contact point shall send notifications to that contact point in the third country for attention or for follow-up based on the seriousness of the risk.

Article 11

Publications

The Commission may publish:

(a) a summary of all alert, information and border rejection notifications, providing information on the classification and the status of the notification, the products and risks identified, the country of origin, the countries where the products were distributed, the notifying member of the network, the basis for the notification and the measures taken;

(b) an annual report on the notifications transmitted through the network.

Article 12

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

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

Done at Brussels, 10 January 2011.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 17/2011

of 10 January 2011

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

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission 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 11 January 2011.

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

Done at Brussels, 10 January 2011.

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

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 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	EC	65,1
	MA	60,1
	TR	100,6
	ZZ	75,3
0707 00 05	EG	174,9
	JO	96,7
	TR	141,9
	ZZ	137,8
0709 90 70	MA	43,2
	TR	123,8
	ZZ	83,5
0709 90 80	EG	222,3
	ZZ	222,3
0805 10 20	AR	41,5
	BR	41,5
	IL	67,1
	MA	58,0
	TR	71,6
	UY	46,7
	ZA	41,3
	ZZ	52,5
0805 20 10	MA	68,6
	TR	79,6
	ZZ	74,1
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	129,3
	HR	46,1
	IL	84,6
	JM	94,4
	MA	112,4
	TR	74,7
	ZZ	90,3
0805 50 10	AR	49,2
	TR	60,2
	UY	49,2
	ZZ	52,9
0808 10 80	AR	78,5
	CA	99,7
	CN	103,0
	EC	79,3
	US	137,8
	ZA	124,2
	ZZ	103,8
0808 20 50	CN	53,7
	US	112,9
	ZZ	83,3

(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 18/2011

of 10 January 2011

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 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 2010/11 marketing year are fixed by Commission Regulation (EU) No 867/2010 [3]. These prices and duties have been last amended by Commission Regulation (EU) No 13/2011 [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 (EU) No 867/2010 for the 2010/11, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 January 2011.

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

Done at Brussels, 10 January 2011.

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

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 178, 1.7.2006, p. 24.
[3] OJ L 259, 1.10.2010, p. 3.
[4] OJ L 5, 8.1.2011, p. 5.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 11 January 2011

(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)	62,47	0,00
1701 11 90 (1)	62,47	0,00
1701 12 10 (1)	62,47	0,00
1701 12 90 (1)	62,47	0,00
1701 91 00 (2)	59,08	0,00
1701 99 10 (2)	59,08	0,00
1701 99 90 (2)	59,08	0,00
1702 90 95 (3)	0,59	0,17

(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.

DECISIONS

COMMISSION DECISION

of 6 January 2011

concerning certain interim protection measures against foot-and-mouth disease in Bulgaria

(notified under document C(2011) 70)

(Text with EEA relevance)

(2011/8/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [1], and in particular Article 9(3) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market [2], and in particular Article 10(3) thereof,

Whereas:

(1) A case of foot-and-mouth disease ('FMD') has been detected in a wild boar in Burgas region in the South-East of Bulgaria within a zone of reinforced surveillance along the border with Turkey.

(2) The FMD situation in Bulgaria is liable to endanger the herds of other Member States in view of trade in live biungulate animals and the placing on the market of certain of their products.

(3) Bulgaria has taken measures in the framework of Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease [3] ('the Directive'), in particular the measures provide for in Article 85(4) of that Directive and detailed in Annex XVIII thereto.

(4) The whole territory of Bulgaria is subject to the restrictions of Articles 2, 4, 5, 6, 8b and 11 of Commission Decision 2008/855/EC of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States [4]. However, being listed in Part II of Annex I to that Decision allows Bulgaria to dispatch under certain health conditions fresh pig meat and meat preparations and products produced from such meat.

(5) The disease situation in Bulgaria makes it necessary to reinforce the control measures for FMD taken by the competent authorities in Bulgaria.

(6) It is appropriate to define as a permanent measure the high and low risk areas in the affected Member State and to provide for a prohibition on the dispatch of susceptible animals from the high and low risk areas and on the dispatch of products derived from susceptible animals from the high risk area. The Decision should also provide for the rules applicable to the dispatch from those areas of safe products that either had been produced before the restrictions, from raw material sourced from outside the restricted areas or that had undergone a treatment proven effective in inactivating possible foot-and-mouth disease virus.

(7) The size of the defined risk areas is a direct function of the outcome of tracing of possible contacts to the infected holding and takes into account the possibility to implement sufficient controls on the movement of animals and products. At this point of time and based on information provided by Bulgaria, the whole of Burgas region should currently remain a high risk area.

(8) The prohibition of dispatch should only cover products derived from animals of susceptible species coming from or obtained from animals originating in the high risk areas listed in Annex I and should not affect transit through these areas of such products coming from or obtained from animals originating in other areas.

(9) Council Directive 64/432/EEC [5] concerns animal health problems affecting intra-Community trade in bovine animals and swine.

[1] OJ L 395, 30.12.1989, p. 13.
[2] OJ L 224, 18.8.1990, p. 29.
[3] OJ L 306, 22.11.2003, p. 1.
[4] OJ L 302, 13.11.2008, p. 19.
[5] OJ 121, 29.7.1964, p. 1977/64.

(10) Council Directive 91/68/EEC [1] concerns animal health conditions governing intra-Community trade in ovine and caprine animals.

(11) 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 [2] concerns, amongst others, trade in other biungulates and in semen, ova and embryos of sheep and goats, and in embryos of porcine animals.

(12) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [3] concerns, amongst others, the health conditions for the production and marketing of fresh meat, minced meat, mechanically separated meat, meat preparations, farmed game meat, meat products, including treated stomachs, bladders and intestines, and dairy products.

(13) 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 [4] concerns, amongst others, the health marking of food of animal origin.

(14) Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption [5] provides for specific treatment of meat products that ensure inactivation of the FMD virus in products of animal origin.

(15) Commission Decision 2001/304/EC of 11 April 2001 on marking and use of certain animal products in relation to Decision 2001/172/EC concerning certain protection measures with regard to foot-and-mouth disease in the United Kingdom [6] concerns a specific health mark to be applied to certain products of animal origin that shall be restricted to the national market. It is appropriate to lay down in a separate Annex a similar marking in the case of FMD in Bulgaria.

(16) Council Directive 92/118/EEC [7] lays down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

(17) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption [8] provides for a range of treatments of animal by-products suitable to inactivate the FMD virus.

(18) Council Directive 88/407/EEC [9] lays down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species.

(19) Council Directive 89/556/EEC [10] concerns the animal health conditions governing intra-Community trade in and imports from third countries of embryos of domestic animals of the bovine species.

(20) Council Directive 90/429/EEC [11] lays down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species.

(21) The model health certificates for trade within the Union in semen, ova and embryos of animals of the ovine and caprine species and in ova and embryos of animals of the porcine species are laid down in Commission Decision 2010/470/EU of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species [12].

(22) Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field [13] provides for a mechanism to compensate affected holdings for losses incurred as a result of disease control measures.

[1] OJ L 46, 19.2.1991, p. 19.
[2] OJ L 268, 14.9.1992, p. 54.
[3] OJ L 139, 30.4.2004, p. 55.
[4] OJ L 139, 30.4.2004, p. 206.
[5] OJ L 18, 23.1.2003, p. 11.
[6] OJ L 104, 13.4.2001, p. 6.
[7] OJ L 62, 15.3.1993, p. 49.
[8] OJ L 273, 10.10.2002, p. 1.
[9] OJ L 194, 22.7.1988, p. 10.
[10] OJ L 302, 19.10.1989, p. 1.
[11] OJ L 224, 18.8.1990, p. 62.
[12] OJ L 228, 31.8.2010, p. 15.
[13] OJ L 155, 18.6.2009, p. 30.

(23) In so far as medicinal products defined in 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 [1], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2], and Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [3] no longer fall under the scope of Regulation (EC) No 1774/2002 they should be excluded from animal health related restrictions set up by this Decision.

(24) Article 6 of Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC [4] provides for a derogation from the veterinary checks for certain products containing animal products. It is appropriate to allow dispatch from the high risk areas of such products under a simplified certification regime.

(25) Member States other than Bulgaria should support the disease control measures carried out in the affected areas by ensuring that live susceptible animals are not consigned to those areas.

(26) To better understand the epidemiological situation and to facilitate the detection of possible infection, it is necessary to enforce a prolonged standstill for livestock in the Member State concerned while granting the possibility for slaughter and the transport of equidae under controlled conditions.

(27) Pending the meeting of the Standing Committee on the Food Chain and Animal Health and in collaboration with the Member State concerned the Commission should take interim protection measures relating to FMD in Bulgaria.

(28) The situation shall be reviewed at the meeting of the Standing Committee on the Food Chain and Animal Health scheduled for 11-12 January 2011, and the measures adapted where necessary,

HAS ADOPTED THIS DECISION:

Article 1

Live animals

1. Without prejudice to the measures taken by Bulgaria within the framework of

(a) Directive 2003/85/EC, and in particular those provided for in Article 85(4) of that Directive and detailed in Annex XVIII thereto; and

(b) Articles 2 and 4 of Decision 2008/855/EC;

Bulgaria shall ensure that the conditions set out in paragraphs 2 to 7 of this Article are met.

2. No live animals of the bovine, ovine, caprine and porcine species and other biungulates shall move between the areas listed in Annex I and Annex II.

3. No live animals of the bovine, ovine, caprine and porcine species and other biungulates shall be dispatched from or moved through the areas listed in Annex I and Annex II.

4. By way of derogation from paragraph 3, the competent authorities of Bulgaria may authorise the direct and uninterrupted transit of biungulate animals through the areas listed in Annex I and Annex II on main roads and railway lines.

5. The health certificates, as provided for in Directive 64/432/EEC for live bovine animals and, without prejudice to Articles 8b and 9 of Decision 2008/855/EC, for porcine animals and in Directive 91/68/EEC for live ovine and caprine animals, accompanying animals consigned from parts of the territory of Bulgaria not listed in Annex I and Annex II to other Member States shall bear the following words:

'Animals conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

[1] OJ L 311, 28.11.2001, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.
[3] OJ L 121, 1.5.2001, p. 34.
[4] OJ L 116, 4.5.2007, p. 9.

(*) OJ L 6, 11.1.2011, p. 15.'

6. The health certificates accompanying biungulates other than those covered by the certificates referred to in paragraph 5, consigned from parts of the territory of Bulgaria not listed in Annex I and Annex II to other Member States shall bear the following words:

'Live biungulates conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

7. Animals accompanied by an animal health certificate as referred to in paragraphs 5 and 6 may be moved to other Member States only if the local veterinary authority in Bulgaria has, three days before the move, notified the central and local veterinary authorities in the Member State of destination.

8. By way of derogation from paragraph 2 the competent authorities of Bulgaria may authorise the transport of animals of species susceptible to foot-and-mouth disease from holding situated in areas listed in Annex II to a slaughterhouse situated in the areas listed in Annex I.

Article 2

Meats

1. For the purposes of this Article, 'meats' means 'fresh meat', 'minced meat', 'mechanically separated meat' and 'meat preparations' as defined in points 1.10, 1.13, 1.14 and 1.15 of Annex I to Regulation (EC) No 853/2004.

2. Bulgaria shall not dispatch meats of the bovine, ovine, caprine and porcine species and other biungulates coming from or obtained from animals originating in the areas listed in Annex I.

3. Meats not eligible for dispatch from Bulgaria in accordance with this Decision shall be marked in accordance with the second subparagraph of Article 4(1) of Directive 2002/99/EC or in accordance with Annex IV.

4. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 2 shall not apply to meats bearing the health mark in accordance with Chapter III of Section I of Annex I to Regulation (EC) No 854/2004, provided that:

(a) the meat is clearly identified, and has been transported and stored since the date of production separately from meat which is not eligible, in accordance with this Decision, for dispatch outside the areas listed in Annex I;

(b) the meat complies with one of the following conditions:

(i) it was obtained before the date of application of this Decision; or

(ii) it is derived from animals that have been reared for at least 90 days, or since birth if less than 90 days of age, prior to the date of slaughter and which have been slaughtered, or in the case of meat obtained from wild game of species susceptible to foot-and-mouth disease ('wild game') killed, outside the areas listed in Annexes I and II; or

(iii) it complies with the conditions set out in points (c), (d) and (e);

(c) the meat was obtained from domestic ungulates or from farmed game of species susceptible to foot-and-mouth disease ('farmed game'), as specified for the respective category of meat in one of the appropriate columns 4 to 7 in Annex III, and complies with the following conditions:

(i) the animals have been reared for at least 90 days prior to the date of slaughter, or since birth if less than 90 days of age, on holdings situated within the areas specified in columns 1, 2 and 3 of Annex III, where there has been no outbreak of foot-and-mouth disease during at least 90 days prior to the date of slaughter;

(ii) during the 21 days prior to the date of transport to the slaughterhouse, or in the case of farmed game prior to the date of on-farm slaughtering, the animals have remained under the supervision of the competent veterinary authorities on a single holding which is situated in the centre of a circle around the holding of at least 10 km radius, where there has been no outbreak of foot-and-mouth disease during at least 30 days prior to the date of loading;

(iii) no animals of species susceptible to foot-and-mouth disease have been introduced into the holding referred to in point (ii) during the 21 days prior to the date of loading, or in the case of farmed game prior to the date of on-farm slaughtering, except in the case of pigs coming from a supplying holding which complies with the conditions laid down in point (ii), in which case the period of 21 days may be reduced to 7 days;

However, the competent authority may authorise the introduction into the holding referred to in point (ii) of animals of species susceptible to foot-and-mouth disease which comply with the conditions set out in points (i) and (ii) and which

— come from a holding where no animals of species susceptible to foot-and-mouth disease have been introduced during the 21 days prior to the date of transport to the holding referred to in point (ii),except in the case of pigs coming from a supplying holding in which case the period of 21 days may be reduced to 7 days, or

— were subjected with negative results to a test for antibodies against the foot-and-mouth disease virus carried out on a blood sample taken within 10 days prior to the date of transport to the holding referred to in point (ii), or

— come from a holding that was subjected with negative results to a serological survey pursuant to a sampling protocol suitable to detect 5 % prevalence of foot-and-mouth disease with at least a 95 % level of confidence;

(iv) the animals or, in the case of farmed game slaughtered on the farm, the carcases have been transported under official control in means of transport that have been cleansed and disinfected before loading from the holding referred to in point (ii) to the designated slaughterhouse;

(v) the animals have been slaughtered less than 24 hours following the time of arrival at the slaughterhouse and separately from animals the meat of which is not eligible for dispatch from the area listed in Annex I;

(d) the meat, if positively marked in column 8 of Annex III, was obtained from wild game, that was killed in areas where there has been no outbreak of foot-and-mouth disease for at least a period of 90 days before the date of killing and at a distance of at least 20 km from areas not specified in columns 1, 2 and 3 of Annex III;

(e) Meat referred to in points (c) and (d) must in addition comply with the following conditions:

(i) the dispatch of such meat is only to be authorised by the competent veterinary authority of Bulgaria, if

— the animals referred to in point (c)(iv) have been transported to the establishment without contact to holdings situated in areas not specified in columns 1, 2 and 3 of Annex III, and

— the establishment is not situated in a protection zone;

(ii) the meat is at all times clearly identified, handled, stored and transported separately from meat which is not eligible for dispatch from the area listed in Annex I;

(iii) during post-mortem inspection by the official veterinarian in the establishment of dispatch, or in the case of on-farm slaughtering of farmed game on the holding referred to in point (c)(ii), or in the case of wild game at the game-handling establishment, no clinical signs or post-mortem evidence of foot-and-mouth disease were established;

(iv) the meat has remained in the establishments or holdings referred to in point (e)(iii) for at least 24 hours following the post-mortem inspection of the animals referred to in points (c) and (d);

(v) any further preparation of meat for dispatch outside the area listed in Annex I shall be suspended:

— in the case where foot-and-mouth disease has been diagnosed in the establishments or holdings referred to in point (e)(iii), until the slaughter of all animals present and the removal of all meat and dead animals has been completed, and at least 24 hours have elapsed since the completion of the total cleansing and disinfection of those establishments and holdings under the control of an official veterinarian, and

— in the case of slaughter in the same establishment of animals susceptible to foot-and-mouth disease coming from holdings situated in areas listed in Annex I that do not comply with the conditions set out in point 4(c) or (d), until the slaughter of all such animals and the cleansing and disinfection of those establishments have been completed under the control of an official veterinarian;

(vi) the central veterinary authorities shall communicate to the other Member States and the Commission a list of those establishments and holdings which they have approved for the purposes of application of points (c), (d) and (e).

5. Compliance with the conditions set out in paragraphs 3 and 4 shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

6. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 2 of this Article shall not apply to fresh meat obtained from animals reared outside the areas listed in Annex I and Annex II and transported, by way of derogation from Article 1(2) and (3), directly and under official control without contact to holdings situated in areas listed in Annex I to a slaughterhouse situated in the areas listed in Annex I outside the protection zone for immediate slaughter, provided that such fresh meat is only placed on the market in the areas listed in Annex I and Annex II and complies with the following conditions:

(a) all such fresh meat is marked in accordance with the second subparagraph of Article 4(1) of Directive 2002/99/EC or in accordance with Annex IV to this Decision;

(b) the slaughterhouse

(i) is operated under strict veterinary control;

(ii) suspends any further preparation of meat for dispatch outside the areas listed in Annex I in the case of slaughter in the same slaughterhouse of animals susceptible to foot-and-mouth disease coming from holdings situated in areas listed in Annex I until the slaughter of all such animals and the cleansing and disinfection of the slaughterhouse have been completed under the control of an official veterinarian;

(c) the fresh meat is clearly identified, and transported and stored separately from meat which is eligible for dispatch outside Bulgaria.

(d) Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

(e) The central veterinary authorities shall communicate to the Commission and to the other Member States a list of the establishments which they have approved for the purposes of
application of this paragraph.

7. Without prejudice to Article 6 of Decision 2008/855/EC, the prohibition set out in paragraph 2 shall not apply to fresh meat obtained from cutting plants situated in the areas listed in Annex I under the following conditions:

(a) only fresh meat as described in paragraph 4(b) is processed in that cutting plant, on the same day. Cleaning and disinfection shall be carried out after processing of any meat not meeting this requirement;

(b) all meat bears the health mark in accordance with Chapter III of Section I of Annex I to Regulation (EC) No 854/2004;

(c) the cutting plant is operated under strict veterinary control;

(d) the fresh meat is clearly identified, and transported and stored separately from meat which is not eligible for dispatch outside the areas listed in Annex I.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purpose of application of this paragraph.

8. Meat dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Meat conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

Article 3

Meat products

1. Bulgaria shall not dispatch meat products, including treated stomachs, bladders and intestines, of animals of the bovine, ovine, caprine and porcine species and other biungulates ('meat products') coming from the areas listed in Annex I or prepared using meat obtained from animals originating in those areas.

2. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 1 shall not apply to meat products, including treated stomachs, bladders and intestines, bearing the health mark in accordance with Chapter III of Section I of Annex I to Regulation (EC) No 854/2004, provided that the meat products:

(a) are clearly identified and have been transported and stored since the date of production separately from meat products not eligible, in accordance with this Decision, for dispatch outside the areas listed in Annex I;

(b) comply with one of the following conditions:

(i) they are made from meats described in Article 2(4)(b); or

(ii) they have undergone at least one of the relevant treatments laid down for foot-and-mouth disease in Part 1 of Annex III to Directive 2002/99/EC.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purpose of application of this paragraph.

3. Meat products dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Meat products, including treated stomachs, bladders and intestines, conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

4. By way of derogation from paragraph 3 it shall be sufficient, in the case of meat products which comply with the requirements of paragraph 2 and have been processed in an establishment operating hazard analysis and critical control points (HACCP) and an auditable standard operating procedure which ensures that standards for treatment are met and recorded, that compliance with the conditions required for the treatment laid down in point (b)(ii) of the first subparagraph of paragraph 2 is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

5. By way of derogation from paragraph 3 it shall be sufficient, in the case of meat products heat treated in accordance with point (b)(ii) of the first subparagraph of paragraph 2 in hermetically sealed containers so as to ensure that they are shelf stable, to be accompanied by a commercial document stating the heat treatment applied.

Article 4

Colostrums and milk

1. Bulgaria shall not dispatch colostrums and milk from animals of species susceptible to foot-and-mouth disease intended or not intended for human consumption from the areas listed in Annex I.

2. The prohibition set out in paragraph 1 shall not apply to milk produced from bovine, ovine and caprine animals kept in areas listed in Annex I which has been subjected to a treatment in accordance with:

(a) Part A of Annex IX to Directive 2003/85/EC, if the milk is intended for human consumption; or

(b) Part B of Annex IX to Directive 2003/85/EC, if the milk is not intended for human consumption or is intended for feeding to animals of species susceptible to foot-and-mouth disease.

3. The prohibition set out in paragraph 1 shall not apply to milk from bovine, ovine and caprine animals prepared in establishments situated in the areas listed in Annex I under the following conditions:

(a) all milk used in the establishment must either conform to the conditions set out in paragraph 2 or be obtained from animals reared and milked outside the areas listed in Annex I;

(b) the establishment is operated under strict veterinary control;

(c) the milk must be clearly identified, and transported and stored separately from milk and dairy products which are not eligible for dispatch outside the areas listed in Annex I;

(d) transport of raw milk from holdings situated outside the areas listed in Annex I to the establishments situated in the areas listed in Annex I is carried out in vehicles which were cleaned and disinfected prior to operation and had no subsequent contact with holdings in the areas listed in Annex I keeping animals of species susceptible to foot-and-mouth disease.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purpose of application of this paragraph.

4. Milk dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Milk conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

5. By way of derogation from paragraph 4 it shall be sufficient, in the case of milk which complies with the requirements of paragraph 2 and has been processed in an establishment operating HACCP and an auditable standard operating procedure which ensures that standards for treatment are met and recorded, that compliance with those requirements is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

6. By way of derogation from paragraph 4 it shall be sufficient, in the case of milk which complies with the requirements in paragraph 2(a) or (b) and which has been heat treated in hermetically sealed containers so as to ensure that it is shelf stable, to be accompanied by a commercial document stating the heat treatment applied.

Article 5

Dairy products

1. Bulgaria shall not dispatch dairy products produced from colostrums and milk from animals of species susceptible to foot-and-mouth disease intended or not intended for human consumption from the areas listed in Annex I.

2. The prohibition set out in paragraph 1 shall not apply to dairy products:

(a) produced before the date of application of this Decision; or

(b) prepared from milk complying with the provisions in Article 4(2) or (3); or

(c) for export to a third country where import conditions permit such products to be subject to treatment other than those laid down in Article 4(2) which ensures the inactivation of the foot-and-mouth disease virus.

3. Without prejudice to Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, the prohibition set out in paragraph 1 of this Article shall not apply to the following dairy products intended for human consumption:

(a) dairy products produced from milk of a controlled pH less than 7,0 and subject to a heat treatment at a temperature of at least 72 °C for at least 15 seconds, on the understanding that such treatment was not necessary for finished products, the ingredients of which comply with the respective animal health conditions laid down in Articles 2, 3 and 4 of this Decision;

(b) dairy products produced from raw milk of bovine, ovine or caprine animals which have been resident for at least 30 days on a holding situated, within an area listed in Annex I, in the centre of a circle of at least 10 km radius in which no outbreak of foot-and-mouth disease has occurred during 30 days prior to the date of production of the raw milk, and subject to a maturation or ripening process of at least 90 days during which the pH is lowered below 6,0 throughout the substance, and the rind of which has been treated with 0,2 % citric acid immediately prior to wrapping or packaging.

4. The prohibition set out in paragraph 1 shall not apply to dairy products prepared in establishments situated in the areas listed in Annex I under the following conditions:

(a) all milk used in the establishment either complies with the conditions laid down in Article 4(2) or is obtained from animals outside the areas listed in Annex I;

(b) all dairy products used in the final products either comply with the conditions set out in paragraph 2(a) and (b) or paragraph 3 or are made from milk obtained from animals outside the areas listed in Annex I;

(c) the establishment is operated under strict veterinary control;

(d) the dairy products are clearly identified and transported and stored separately from milk and dairy products which are not eligible for dispatch outside the areas listed in Annex I.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent authority under the responsibility of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purposes of application of this paragraph.

5. The prohibition set out in paragraph 1 shall not apply to dairy products prepared in establishment situated outside the areas listed in Annex I using milk obtained before the date of application of this Decision, provided that the dairy products are clearly identified and transported and stored separately from dairy products which are not eligible for dispatch outside those areas.

6. Dairy products dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Dairy products conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

7. By way of derogation from paragraph 6 it shall be sufficient, in the case of dairy products which comply with the requirements of paragraph 2(a) and (b) and paragraphs 3 and 4 and have been processed in an establishment operating HACCP and an auditable standard operating procedure which ensures that standards for treatment are met and recorded, that compliance with those requirements is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

8. By way of derogation from paragraph 6 it shall be sufficient, in the case of dairy products which comply with the requirements of paragraph 2(a) and (b) and paragraphs 3 and 4 and which have been heat treated in hermetically sealed containers so as to ensure that they are shelf stable, to be accompanied by a commercial document stating the heat treatment applied.

Article 6

Semen, ova and embryos

1. Bulgaria shall not dispatch semen, ova and embryos of the bovine, ovine, caprine and porcine species and other biungulates ('semen, ova and embryos') from the areas listed in Annex I and Annex II.

2. Without prejudice to Article 5 of Decision 2008/855/EC, the prohibitions set out in paragraph 1 shall not apply to:

(a) semen, ova and embryos produced before the date of application of this Decision;

(b) frozen bovine semen and embryos, frozen porcine semen, and frozen ovine and caprine semen and embryos imported into Bulgaria in accordance with the conditions laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC or 92/65/EEC respectively, and which since their introduction into Bulgaria have been stored and transported separately from semen, ova and embryos not eligible for dispatch in accordance with paragraph 1;

(c) frozen semen and embryos obtained from bovine, porcine, ovine and caprine animals kept for at least 90 days prior to the date of and during collection outside the areas listed in Annex I and Annex II and which:

(i) have been be stored in approved conditions for a minimum period of 30 days prior to the date of dispatch; and

(ii) have been collected from donor animals standing in centres or on holdings which have been free from foot-and-mouth disease for at least three months prior to the date of collection of the semen or embryos and 30 days after the date of collection and which are situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days prior to the date of collection.

(d) Before the dispatch of the semen or embryos referred to in points (a), (b) and (c) the central veterinary authorities shall communicate to the other Member States and the Commission a list of centres and teams approved for the purpose of application of this paragraph.

3. The health certificate provided for in Directive 88/407/EEC and accompanying frozen bovine semen dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen bovine semen conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

_____

(*) OJ L 6, 11.1.2011, p. 15.'

4. Without prejudice to Article 9(b) of Decision 2008/855/EC, the health certificate provided for in Directive 90/429/EEC and accompanying frozen porcine semen dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen porcine semen conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

_____

(*) OJ L 6, 11.1.2011, p. 15.'

5. The health certificate provided for in Directive 89/556/EEC and accompanying bovine embryos dispatched from Bulgaria to other Member States shall bear the following words:

'Bovine embryos conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

_____

(*) OJ L 6, 11.1.2011, p. 15.'

6. The health certificate provided for in Directive 92/65/EEC and accompanying frozen ovine or caprine semen dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen ovine/caprine semen conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (*).

_____

(*) OJ L 6, 11.1.2011, p. 15.'

7. The health certificate provided for in Directive 92/65/EEC and accompanying frozen ovine or caprine embryos dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen ovine/caprine embryos conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

_____

(*) OJ L 6, 11.1.2011, p. 15.'

8. Without prejudice to Article 9(c) of Decision 2008/855/EC, the health certificate provided for in Directive 92/65/EEC and accompanying frozen porcine embryos dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen porcine embryos conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

_____

(*) OJ L 6, 11.1.2011, p. 15.'

Article 7

Hides and skins

1. Bulgaria shall not dispatch skins of animals of the porcine species ('skins') from the areas listed in Annex I.

2. The prohibition set out in paragraph 1 shall not apply to skins which:

(a) were produced in Bulgaria before the date of application of this Decision; or

(b) comply with the requirements provided for in point (2)(c) or (d) of Part A of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002; or

(c) were produced outside the areas listed in Annex I in accordance with the conditions laid down in Regulation (EC) No 1774/2002, and have since introduction into Bulgaria been stored and transported separately from skins not eligible for dispatch in accordance with paragraph 1.

Treated pig skins shall be separated from untreated hides and skins of animals of species susceptible to foot-and-mouth disease.

3. Bulgaria shall ensure that skins to be dispatched to other Member States shall be accompanied by an official certificate which bears the following words:

'Skins conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

4. By way of derogation from paragraph 3 it shall be sufficient, in the case of skins which comply with the requirements of points (1)(b) to (e) of Part A of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002, to be accompanied by a commercial document stating compliance with those requirements.

5. By way of derogation from paragraph 3 it shall be sufficient, in the case of skins which comply with the requirements of point (2)(c) or (d) of Part A of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002, that compliance with those requirements is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

Article 8

Other animal products

1. Bulgaria shall not dispatch products of animals of the bovine, ovine, caprine and porcine species and other biungulates not mentioned in Articles 2 to 7 produced after the date of application of this Decision and coming from the areas listed in Annex I, or obtained from animals originating in the areas listed in Annex I.

Bulgaria shall not dispatch dung and manure of the bovine, ovine, caprine and porcine species and other biungulates from the areas listed in Annex I.

2. The prohibition set out in the first subparagraph of paragraph 1 shall not apply to:

(a) animal products which:

(i) have been subjected to a heat treatment

— in a hermetically sealed container with a Fo value of 3,00 or more, or

— in which the centre temperature is raised to at least 70 °C; or

(ii) were produced outside the areas listed in Annex I in accordance with the conditions laid down in Regulation (EC) No 1774/2002, and which since introduction into Bulgaria have been stored and transported separately from animal products not eligible for dispatch in accordance with paragraph 1;

(b) blood and blood products as defined in points 4 and 5 of Annex I to Regulation (EC) No 1774/2002 which have been subjected to at least one of the treatments provided for in point 4(a) of Part A of Chapter IV of Annex VIII to Regulation (EC) No 1774/2002, followed by an effectiveness check, or have been imported in accordance with Part A of Chapter IV of Annex VIII to Regulation (EC) No 1774/2002;

(c) lard and rendered fats which have been subject to the heat treatment prescribed in point 2(d)(iv) of Part B of Chapter IV of Annex VII to Regulation (EC) No 1774/2002;

(d) animal casings complying with the conditions in Part A of Chapter 2 of Annex I to Directive 92/118/EEC and which have been cleaned, scraped and then either salted, bleached or dried, followed by steps to prevent the recontamination of the casings;

(e) sheep wool, ruminant hair and pigs bristles which have undergone factory washing or have been obtained from tanning and unprocessed sheep wool, ruminant hair and pigs bristles which are securely enclosed in packaging and dry;

(f) petfood conforming to the requirements of points 2, 3 and 4 of Part B of Chapter II of Annex VIII to Regulation (EC) No 1774/2002;

(g) composite products which are not subject to further treatment containing products of animal origin, on the understanding that the treatment was not necessary for finished products, the ingredients of which comply with the respective animal health conditions laid down in this Decision;

(h) game trophies in accordance with points 1, 3 or 4 of Part A of Chapter VII of Annex VIII to Regulation (EC) No 1774/2002;

(i) packed animal products intended for use as in-vitro diagnostic, laboratory reagents;

(j) medicinal products as defined in Directive 2001/83/EC, medical devices manufactured utilising animal tissue which is rendered non-viable as referred to in Article 1(5)(g) of Directive 93/42/EEC, veterinary medicinal products as defined in Directive 2001/82/EC, and investigational medicinal products as defined in Directive 2001/20/EC.

3. Bulgaria shall ensure that the animal products referred to in paragraph 2 to be dispatched to other Member States shall be accompanied by an official certificate which bears the following words:

'Animal products conforming to Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria (*).

(*) OJ L 6, 11.1.2011, p. 15.'

4. By way of derogation from paragraph 3, it shall be sufficient, in the case of the products referred to in paragraph 2(a) to (d) and (f) of this Article that compliance with the conditions for the treatment stated in the commercial document required in accordance with the respective Union legislation is endorsed in accordance with Article 9(1).

5. By way of derogation from paragraph 3 it shall be sufficient, in the case of products referred to in paragraph 2(e) to be accompanied by a commercial document stating either the factory washing or origin from tanning or compliance with the conditions laid down in points 1 and 4 of Part A of Chapter VIII of Annex VIII to Regulation (EC) No 1774/2002.

6. By way of derogation from paragraph 3 it shall be sufficient, in the case of products referred to in paragraph 2(g) which have been produced in an establishment operating HACCP and an auditable standard operating procedure which ensures that pre-processed ingredients comply with the respective animal health conditions laid down in this Decision, that this is stated on the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

7. By way of derogation from paragraph 3, it shall be sufficient, in the case of products referred to in paragraph 2(i) and (j), to be accompanied by a commercial document stating that the products are for use as in- vitro diagnostic, laboratory reagents, medical products or medical devices, provided that the products are clearly labelled 'for in-vitro diagnostic use only' or 'for laboratory use only', as 'medicinal products' or as 'medical devices'.

8. Derogating from the provisions in paragraph 3, it shall be sufficient, in the case of composite products that fulfil the conditions set out in Article 6(1) of Decision 2007/275/EC that they are accompanied by a commercial document, which bears the following words:

'These composite products are shelf stable at ambient temperature or have clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw material is de-natured'.

Article 9

Certification

1. Where reference is made to this paragraph, the competent authorities of Bulgaria shall ensure that the commercial document required by Union legislation for trade between Member States is endorsed by the attachment of a copy of an official certificate stating that:

(a) the products concerned have been produced

(i) in a production process that has been audited and found in compliance with the appropriate requirements in Union animal health legislation and suitable to destroy the foot-and-mouth disease virus; or

(ii) from pre-processed materials which had been certified accordingly; and

(b) provisions are in place to avoid possible re-contamination with the foot-and-mouth disease virus after treatment.

Such certification of the production process shall bear a reference to this Decision, shall be valid for 30 days, shall state the expiry date and shall be renewable after inspection of the establishment.

2. In case of products for retail sale to the final consumer, the competent authorities of Bulgaria may authorise consolidated consignments of animal products other than fresh meat, minced meat, mechanically separated meat and meat preparations, each of which is eligible for dispatch in accordance with this Decision, to be accompanied by a commercial document endorsed by the attachment of a copy of an official veterinary certificate confirming that:

(a) the premises of dispatch have in place a system to ensure that goods can only be dispatched if they are traceable to documentary evidence of compliance with this Decision; and

(b) the system referred to in (a) has been audited and found satisfactory.

Such certification of the traceability system shall bear a reference to this Decision, shall be valid for 30 days, shall state the expiry date and shall be renewable only after the establishment had been audited with satisfactory results.

The competent authorities of Bulgaria shall communicate to the other Member States and the Commission the list of establishments which they have approved for the purpose of application of this paragraph.

Article 10

Cleansing and disinfection

Without prejudice to Article 11 of Decision 2008/855/EC, Bulgaria shall ensure that vehicles which have been used for the transport of live animals in the areas listed in Annex I and Annex II are cleansed and disinfected after each operation, and that such cleansing and disinfection is recorded in accordance with Article 12(2)(d) of Directive 64/432/EEC.

Article 11

Certain exempted products

The restrictions laid down in Articles 3, 4, 5 and 8 shall not apply to the dispatch from the areas listed in Annex I of the animal products referred to in those Articles if such products were:

(a) not produced in Bulgaria and remained in their original packaging indicating the country of origin of the products; or

(b) produced in an approved establishment situated in the areas listed in Annex I from pre-processed products not originating from those areas, which:

(i) have, since introduction into the territory of Bulgaria, been transported, stored and processed separately from products which are not eligible for dispatch outside the areas listed in Annex I;

(ii) are accompanied by a commercial document or official certificate as required by this Decision.

Article 12

Cooperation between Member States

Member States shall cooperate in monitoring personal luggage of passengers travelling from the areas listed in Annex I and in information campaigns carried out to prevent introduction of products of animal origin into the territory of Member States other than Bulgaria.

Article 13

Implementation

Member States shall amend the measures which they apply to trade so as to bring them into compliance with this Decision. They shall immediately inform the Commission thereof.

Article 14

This Decision shall apply until 28 February 2011.

Article 15

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 6 January 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX I

The following areas in Bulgaria:

Region of Burgas

ANNEX II

The following areas in Bulgaria:

Regions of Yambol, Sliven, Shumen and Varna

ANNEX III

The following areas in Bulgaria:

1	2	3	4	5	6	7	8
Group	ADNS	Administrative unit	B	S/G	P	FG	WG
Bulgaria	00002	Region of Burgas	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—

ADNS = animal disease notification system code (Decision 2005/176/EC).
B = bovine meat.
S/G = sheep and goat meat.
P = pigmeat.
FG = farmed game of species susceptible to foot-and-mouth disease.
WG = wild game of species susceptible to foot-and-mouth disease.

ANNEX IV

The health mark referred to in Article 2(3):

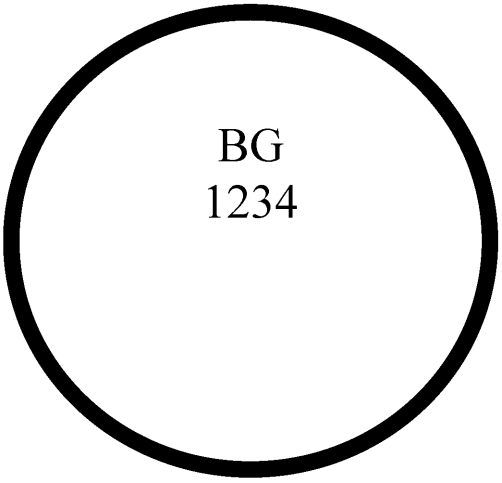
Dimensions:

BG = 7 mm

Establishment No = 10 mm

Circle outer diameter = 50 mm

Line thickness of circle = 3 mm



COMMISSION DECISION

of 10 January 2011

amending Decision 2010/89/EU as regards transitional measures concerning the application to establishments in Romania of certain structural requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council

(notified under document C(2010) 9695)

(Text with EEA relevance)

(2011/9/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [1], and in particular the second paragraph of Article 12 thereof,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [2], and in particular the second paragraph of Article 9 thereof,

Whereas:

(1) Commission Decision 2010/89/EU of 9 February 2010 on transitional measures concerning the application of certain structural requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council to certain establishments for meat, fishery products and egg products and cold stores in Romania [3] limits the application of certain structural requirements laid down in those Regulations to certain establishments and cold stores in that Member State. Those transitional measures apply until 31 December 2010.

(2) Decision 2010/89/EU also provides that products produced or stored in the establishments and stores listed in Annexes I to IV thereto are only to be placed on the domestic market or used for further processing in the establishments

(3) In October 2010, Romania informed the Commission that following an evaluation carried out by their veterinary services, certain establishments listed in that Decision finalised their upgrading programme and have been approved and some establishments have been closed. Accordingly, it is necessary to update the lists set out in the Annexes to Decision 2010/89/EU. The Annexes to that Decision should therefore be amended accordingly.

(4) Romania estimates that of the 117 establishments concerned by the upgrading programmes, 36 of the meat establishments, three of the fishery product establishments and one cold store will not be able to complete their programmes before 31 December 2010, even though they are at an advanced level of compliance.

(5) Romania estimates that the establishments concerned should be in full compliance with the relevant structural requirements laid down in Regulations (EC) No 852/2004 and (EC) No 853/2004 by 31 December 2011. In light of the ongoing structural improvements, it is necessary to prolong the period of application of the transitional measures provided for in Decision 2010/89/EU until that date.

(6) The situation in that Member State should be reviewed before 31 December 2011. Therefore, Romania should submit a report to the Commission by 31 October 2011 regarding progress made in the upgrading of the concerned establishments and cold stores.

(7) Accordingly, the period of application of Decision 2010/89/EU should be prolonged until 31 December 2011.

(8) In addition, in order to ensure the continuity of the transitional measures and prevent any disruption in the industry, this Decision should apply from 1 January 2011.

(9) Decision 2010/89/EU should therefore be amended accordingly.

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

[1] OJ L 139, 30.4.2004, p. 1.
[2] OJ L 139, 30.4.2004, p. 55.
[3] OJ L 40, 13.2.2010, p. 55.

HAS ADOPTED THIS DECISION:

Article 1

Decision 2010/89/EU is amended as follows:

1. in Article 2, the date '31 December 2010' is replaced by '31 December 2011';

2. Article 3 is amended as follows:

   (a) in the introductory phrase, the date '31 December 2010' is replaced by '31 December 2011';

   (b) point (c) is deleted;

3. in Article 4(1), the introductory phrase is replaced by the following:

   '1. Products produced by the establishments listed in Annexes I or II or stored in the establishments listed in Annex IV shall only:';

4. in Article 5(2), the date '31 October 2010' is replaced by '31 October 2011';

5. in Article 6, the date '31 December 2010' is replaced by '31 December 2011';

6. the Annexes are amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 1 January 2011.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 10 January 2011.

For the Commission
John DALLI
Member of the Commission

ANNEX

The Annexes to Decision 2010/89/EU are amended as follows:

1. Annexes I and II are replaced by the following:

'ANNEX I

LIST OF MEAT ESTABLISHMENTS

No	Veterinary No	Name of establishments	Town/street or village/region	Activities			
				SH	CP	PP	MM/ MP
1	AB 2771	SC MONTANA POPA SRL	Blaj, str. Gh. Barițiu, jud. Alba, 515400	X	X	X	X
2	AB 3263	SC TRANSEURO SRL	Ighiu, str. Principală, nr. 205 A, jud. Alba, 517360	X	X	X	X
3	AG 008 IC	SC CARMEN SRL	Bascov, jud. Argeș, 117045	X	X	X	X
4	BC 5196	SC MIRALEX SRL	Bacău, str. Bicaz, nr. 8, jud. Bacău, 600293			X	
5	BH 3001	SC GLOBAL AGRO PRODEXIM SRL	Sârbi, nr. 469, jud. Bihor, 417520		X	X	
6	BH 5185	SC CARMANGERIE TAVI BOGDAN SRL	Mihai Bravu, nr. 169, jud. Bihor, 417237	X			
7	BR 574	SC ELECTIV PROD SRL	Comuna Romanu, jud. Brăila, 817115	X			
8	BR 774	SC ROFISH GROUP (*)	Brăila, str. Fata Portului, nr. 2, jud. Brăila, 810015			X	
9	BT 140	SC RAFFAELLO SRL	Tîngeni, jud. Botoșani, 717120			X	
10	BT 144	SC AGROCARN COMPANY SRL	Botoșani, str. Pod de Piatră, nr. 89, jud. Botoșani, 710350			X	
11	BT 198	SC EMANUEL COM SRL	Răchiți, jud. Botoșani, 717310	X	X	X	
12	BZ 115	SC FERM COM PROD SRL	Căldărăști, jud. Buzău, 125201	X			
13	BZ 110	SC CARMOZIMBRUL SRL	Râmnicu Sărat, str. Lt. Sava Roșescu, nr. 140, jud. Buzău, 125300	X			
14	BZ 112	SC TRI 94 PROD COM SRL	Comuna Berca, sat Valea Nucului, jud. Buzău, 127048		X	X	X
15	CS 40	SC PALALOGA CARNEPREP SRL	Bocșa, str. Binișului, nr. 1, jud. Caraș-Severin, 325300	X	X		
16	CT 19	SC CARNOB SRL	Lumina, str. Lebedelor, nr. 1A, jud. Constanța, 907175	X			
17	DB 3457	SC NEVAL SRL	Pietroșița, jud. Dâmbovița, 137360	X			

No	Veterinary No	Name of establishments	Town/street or village/region	Activities			
				SH	CP	PP	MM/MP
18	GJ 5	SC LEXI STAR SRL	Comuna Dănești, sat Bucureasa, jud. Gorj, 217200	X	X	X	X
19	GL 3330	SC KAROMTEC SRL	Tecuci, str. Mihail Kogălniceanu, nr. 48, jud. Galați, 805300			X	X
20	GL 4121	SC ROMNEF SRL	Munteni, jud. Galați, 807200	X			
21	HR 73	SC ELAN TRIDENT SRL	Odorheiu Secuiesc, str. Rákóczi Ferenc, nr. 90, jud. Harghita, 535600			X	
22	HR 153	SC ARTEIMPEX SRL	Gheorgheni, str. Kossuth Lajos, nr. 211, jud. Harghita, 535500	X			
23	HR 263	SC AVICOOPEX SRL	Cristuru Secuiesc, str. Orban Balays, jud. Harghita, 535400			X	
24	NT 33	SC CORD COMPANY SRL	Roman, str. Bogdan Dragoș, nr. 111, jud. Neamț, 611160	X			
25	PH 3618	SC BRUTUS IMPEX SRL	Mănești, jud. Prahova, 107375	X			
26	SV 5661	SC HARALD PROD SRL	Măzănăiești, jud. Suceava, 727219	X	X	X	X
27	SV 5963	SC DANILEVICI SRL	Gura Humorului, str. Fundătura Ghiocei, nr. 2, jud. Suceava, 725300	X	X	X	X
28	SV 6071	SC ANCAROL SRL	Gura Humorului, bd. Bucovina, FN, jud. Suceava, 725300	X	X	X	X
29	TL 782	SC PROD IMPORT CDC SRL	Frecăței, jud. Tulcea, 827075	X	X		
30	TM 378	SC VEROMEN SRL	Timișoara, jud. Timiș, 300970		X	X	X
31	TM 4187	SC FEMADAR SRL	Giroc, str. Gloria, nr. 4, jud. Timiș, 307220		X	X	X
32	TR 36	SC AVICOLA COSTESTI SRL	Roșiori de Vede, str. Vadu Vezii, nr. 1, jud. Teleorman, 145100	X			
33	TR 93	SC MARA PROD COM SRL	Alexandria, str. Abatorului, nr. 1 bis, jud. Teleorman, 140106		X	X	X
34	VN 3045	SC VANICAD SRL	Milcov, jud. Vrancea, 627205	X			
35	VS 2300	SC CARACUL SRL	Vaslui, jud. Vaslui, 730233	X	X		
36	CJ 109	SC ONCOS IMPEX SRL	Florești, str. Abatorului, nr. 2, jud. Cluj, 407280	X	X		

(*) SC TAZZ TRADE SRL has changed its name to SC ROFISH GROUP SRL.
SH = Slaughter houses.
CP = Cutting plants.
PP = Processing plants.
MM/MP = Minced meat/meat preparations.

ANNEX II

LIST OF FISHERY PRODUCTS ESTABLISHMENTS

No	Veterinary No	Name of establishments	Town/street or village/region	Activities	
				PP	FFPP
1	BR 184	SC ROFISH GROUP SRL (*)	Brăila, str. Fata Portului, nr. 2, jud. Brăila, 810015	X	
2	BR 185	SC ROFISH GROUP SRL (*)	Brăila, str. Fata Portului, nr. 2, jud. Brăila, 810015	X	
3	PH 1817	SC DIVERTAS SRL.	Comuna Fântânele, nr. 578, jud. Prahova, 107240	X	X

(*) SC TAZZ TRADE SRL has changed its name to SC ROFISH GROUP SRL.
PP = Processing plant.
FFPP = Fresh fish processing plant.'

2. Annex III is deleted.

3. Annex IV is replaced by the following:

'*ANNEX IV*

LIST OF COLD STORES

No	Veterinary No	Name of establishments	Town/street or village/region	Activities
				CS
1	BC 1034	SC AGRICOLA INT. SRL	Bacău, Calea Moldovei, nr. 16, jud. Bacău, 600352	X

CS = Cold stores.'

DECISION OF THE EUROPEAN CENTRAL BANK

of 25 November 2010

on the interim distribution of the income of the European Central Bank on euro banknotes in circulation and arising from securities purchased under the securities markets programme

(recast)

(ECB/2010/24)

(2011/10/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank (hereinafter the 'Statute of the ESCB'), and in particular Article 33 thereof,

Whereas:

(1) Decision ECB/2005/11 of 17 November 2005 on the distribution of the income of the European Central Bank on euro banknotes in circulation to the national central banks of the participating Member States [1] needs to be substantially amended to take account of the distribution of the European Central Bank's (ECB's) income arising from securities purchased in accordance with Decision ECB/2010/5 of 14 May 2010 establishing a securities markets programme [2]. It should be recast in the interests of clarity.

(2) Decision ECB/2010/29 of 13 December 2010 on the issue of euro banknotes [3] establishes the allocation of euro banknotes in circulation to the NCBs in proportion to their paid-up shares in the ECB's capital. Article 4 of Decision ECB/2010/29 and the Annex to that Decision allocates to the ECB 8 % of the total value of euro banknotes in circulation. The ECB holds intra-Eurosystem claims on NCBs in proportion to their shares in the subscribed capital key, for a value equivalent to the value of euro banknotes that it issues.

(3) Under Article 2(2) of Decision ECB/2010/23 of 25 November 2010 on the allocation of monetary income of the national central banks of Member States whose currency is the euro [4], the intra-Eurosystem balances on euro banknotes in circulation are remunerated at the reference rate. Under Article 2(3) of Decision ECB/2010/23, this remuneration is settled by TARGET2 payments.

(4) Recital 7 to Decision ECB/2010/23 states that the income accruing to the ECB on the remuneration of its intra-Eurosystem claims on NCBs related to its share of euro banknotes in circulation should in principle be distributed to the NCBs in accordance with the decisions of the Governing Council, in proportion to their shares in the subscribed capital key in the same financial year it accrues.

(5) In the same manner the ECB's income arising from securities purchased under the securities markets programme (SMP) should in principle be distributed to the NCBs in proportion to their shares in the subscribed capital key in the same financial year it accrues.

(6) In distributing the ECB's income on euro banknotes in circulation and the ECB's income arising from SMP securities, the ECB should take into account an estimate of its financial result for the year that makes due allowance for the need to allocate funds to a provision for foreign exchange rate, interest rate, credit and gold price risks, and for the availability of provisions that may be released to offset anticipated expenses.

(7) In determining the amount of the ECB's net profit to be transferred to the general reserve fund pursuant to Article 33.1 of the Statute of the ESCB, the Governing Council should consider that any part of that profit which corresponds to income on euro banknotes in circulation and income arising from SMP securities should be distributed to the NCBs in full,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision:

(a) 'NCB' means the national central bank of a Member State whose currency is the euro;

(b) 'intra-Eurosystem balances on euro banknotes in circulation' means the claims and liabilities arising between an NCB and the ECB and between an NCB and the other NCBs as a result of the application of Article 4 of Decision ECB/2010/29;

[1] OJ L 311, 26.11.2005, p. 41.
[2] OJ L 124, 20.5.2010, p. 8.
[3] Not yet published in the Official Journal.
[4] Not yet published in the Official Journal.

(c) 'ECB's income on euro banknotes in circulation' means the income accruing to the ECB on the remuneration of its intra-Eurosystem claims on NCBs related to its share of euro banknotes in circulation as a result of the application of Article 2 of Decision ECB/2010/23;

(d) 'ECB's income arising from SMP securities' means the net income arising from securities purchased by the ECB under the SMP in accordance with Decision ECB/2010/5.

Article 2

Interim distribution of the ECB's income on euro banknotes in circulation and the ECB's income arising from SMP securities

1. The ECB's income on euro banknotes in circulation and the ECB's income arising from SMP securities shall be due in full to the NCBs in the same financial year it accrues and shall be distributed to the NCBs in proportion to their paid-up shares in the subscribed capital of the ECB.

2. The ECB shall distribute to the NCBs its income on euro banknotes in circulation accrued each financial year on the second working day of the following year.

3. The ECB shall distribute to the NCBs its income arising from SMP securities earned in each financial year on the last working day in January of the following year.

4. The amount of the ECB's income on euro banknotes in circulation may be reduced in accordance with any decision by the Governing Council on the basis of the Statute of the ESCB in respect of expenses incurred by the ECB in connection with the issue and handling of euro banknotes.

Article 3

Derogation from Article 2

In derogation from Article 2:

1. The Governing Council shall decide before the end of the financial year whether all or part of the ECB's income arising from SMP securities and, if necessary, all or part of the ECB's income on euro banknotes in circulation should be retained to the extent necessary to ensure that the amount of the distributed income does not exceed the ECB's net profit for that year. Any such decision shall be taken where, on the basis of a reasoned estimate prepared by the Executive Board, the Governing Council expects that the ECB will have an overall annual loss or will make an annual net profit that is less than the estimated amount of its income on euro banknotes in circulation and the estimated amount of its income arising from SMP securities.

2. The Governing Council may decide before the end of the financial year to transfer all or part of the ECB's income arising from SMP securities and, if necessary, all or part of the ECB's income on euro banknotes in circulation to a provision for foreign exchange rate, interest rate, credit and gold price risks.

Article 4

Repeal

Decision ECB/2005/11 is hereby repealed. References to the repealed Decision shall be construed as references to this Decision.

Article 5

Entry into force

This Decision shall enter into force on 31 December 2010.

Done at Frankfurt am Main, 25 November 2010.

The President of the ECB

Jean-Claude TRICHET

DECISION OF THE EUROPEAN CENTRAL BANK

of 27 December 2010

on the transmission of confidential data under the common framework for business registers for statistical purposes

(ECB/2010/33)

(2011/11/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank (hereinafter the 'Statute of the ESCB'), and in particular Article 5 thereof,

Having regard to Regulation (EC) No 177/2008 of the European Parliament and of the Council of 20 February 2008 establishing a common framework for business registers for statistical purposes and repealing Council Regulation (EEC) No 2186/93 [1], and in particular Article 12 thereof,

Having regard to Commission Regulation (EC) No 192/2009 of 11 March 2009 implementing Regulation (EC) No 177/2008 of the European Parliament and of the Council establishing a common framework for business registers for statistical purposes, as regards the exchange of confidential data between the Commission (Eurostat) and Member States [2],

Having regard to Commission Regulation (EU) No 1097/2010 of 26 November 2010 implementing Regulation (EC) No 177/2008 of the European Parliament and of the Council establishing a common framework for business registers for statistical purposes, as regards the exchange of confidential data between the Commission (Eurostat) and central banks [3],

Having regard to Council Regulation (EC) No 2533/98 of 23 November 1998 concerning the collection of statistical information by the European Central Bank [4], and in particular to Article 8a(2), (3) and (5) and Article 8b thereof,

Having regard to the contribution of the General Council, pursuant to the first indent of Article 46.2 of the Statute of the ESCB,

Whereas:

(1) Regulation (EC) No 177/2008 establishes a new common framework for business registers of the multinational enterprise groups' data exclusively for statistical purposes in order to maintain the development of business registers in a harmonised framework.

(2) An exchange of confidential data between the Commission and national central banks of the Member States whose currency is the euro (hereinafter the 'NCBs'), and between the Commission and the European Central Bank (ECB), should contribute to ensuring the quality of multinational enterprise group information in the Union.

(3) In order to establish the format, security and confidentiality measures and procedures concerning the data transmitted from the Commission to the NCBs and the ECB, the Commission has adopted Regulation (EU) No 1097/2010 implementing Regulation (EC) No 177/2008.

(4) In view of the separate governance structures of the European System of Central Banks and the European Statistical System (ESS), it is necessary to define the format, security and confidentiality measures, and procedures concerning the data that the ECB and NCBs receive from the Commission and the data transmitted from the NCBs to the national statistical institutes and other national authorities which participate in the ESS as defined in Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities [5].

(5) The provisions of this Decision may be extended to apply to the central banks of Member States whose currency is not the euro by means of an agreement between those central banks and the ECB,

HAS ADOPTED THIS DECISION:

Article 1

Scope

1. The NCBs shall use the table in part B of the Annex to Regulation (EU) No 1097/2010 when transmitting the characteristics concerning multinational enterprise groups and their constituent units to the national statistical institute and other national authorities which participate in the ESS in their Member State (hereinafter the 'ESS member'), subject to the confidentiality regime set out in Regulation (EC) No 2533/98.

[1] OJ L 61, 5.3.2008, p. 6.
[2] OJ L 67, 12.3.2009, p. 14.
[3] OJ L 312, 27.11.2010, p. 1.
[4] OJ L 318, 27.11.1998, p. 8.
[5] OJ L 87, 31.3.2009, p. 164.

2. The NCBs shall be subject to Article 3 of this Decision, when transmitting these characteristics to the ESS member of their Member State for assessment, correction, completion and integration with the data that the ESS member transmits to the Commission (Eurostat) pursuant to Article 11 of Regulation (EC) No 177/2008.

Article 2

Format and procedures for transmission

1. The format set out in the Annex shall be used when data is transmitted from the NCBs to the ESS members.

2. When data is transmitted from the NCBs to the ESS members, the data and metadata shall be transmitted in accordance with the standards of the ESS and with the structure defined in the most recent version of the Eurostat Business Registers Recommendations Manual available from the Commission (Eurostat).

3. When data is transmitted from the NCBs to the ESS members, the NCBs shall follow the same naming conventions, structures and definitions of fields as referred to in Regulation (EC) No 192/2009.

4. The data and metadata transmitted pursuant to this Decision shall be exchanged in electronic form.

5. The data and metadata transmitted pursuant to this Decision shall be transmitted via the secure medium used for the transmission of confidential data, or via secured remote access.

Article 3

Security and confidentiality measures

1. The ECB and NCBs shall store the data they receive from the Commission (Eurostat) pursuant to Regulation (EC) No 177/2008 and Regulation (EU) No 1097/2010, and which have been flagged as confidential, in a secure area with restricted and controlled access.

2. Data received by the ECB and NCBs from the Commission (Eurostat) shall be used exclusively for statistical purposes.

3. The ECB and NCBs shall ensure that information on the security measures taken is included in the annual confidentiality report or that the Commission (Eurostat) and the appropriate national authorities are informed by other means.

Article 4

Final provision

This Decision shall enter into force on 1 January 2011.

Done at Frankfurt am Main, 27 December 2010.

The President of the ECB

Jean-Claude TRICHET

ANNEX

STRUCTURE AND FORMAT FOR THE TRANSMISSION OF DATA

The following data sets containing confidential information are included in the data quality management process of the Union register of multinational enterprise groups and their constituent units (hereinafter the 'EuroGroups register'):

— data set with results of the linkage process,

— data sets with information on legal units,

— data sets with information on control and ownership of units,

— data sets with information on enterprises,

— data sets with information on global enterprise groups,

— data sets with information on truncated enterprise groups.

A data set with the results on the truncated and global enterprise groups is generated at the end of each EuroGroups register data quality management cycle.

The format for the data sets is laid down in the Part A of the Annex to Regulation (EC) No 192/2009.

To improve the quality of multinational enterprise group information in the Union, the NCBs forward the data sets with corrected and completed information including confidentiality flags to the ESS member of their Member State. Pursuant to Part A of the Annex to Regulation (EU) No 1097/2010 the appropriate national authority assesses the corrections, completions and confidentiality flags received from the NCBs and, where necessary, integrates them in the data they transmit to the Commission (Eurostat) pursuant to Article 11 of Regulation (EC) No 177/2008.

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