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Price: EUR 3

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⁽¹⁾ Text with EEA relevance

EN

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 721/2012

of 6 August 2012

prohibiting fishing activities for longliners flying the flag of or registered in Greece or Malta, fishing for bluefin tuna in the Atlantic Ocean, east of longitude 45° W, and in the Mediterranean Sea

THE EUROPEAN COMMISSION,

sustainable exploitation of living aquatic resources based on the precautionary approach.

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

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

Whereas:

(1) Council Regulation (EU) No 44/2012 of 17 January 2012 fixing for 2012 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish stocks and groups of fish stocks which are subject to international negotiations or agreements ⁽²⁾ fixes the amount of bluefin tuna which may be fished in 2012 in the Atlantic Ocean, east of longitude 45° W, and the Mediterranean Sea by European Union fishing vessels.

(2) Council Regulation (EC) No 302/2009 of 6 April 2009 concerning a multiannual recovery plan for bluefin tuna in the eastern Atlantic and Mediterranean, amending Regulation (EC) No 43/2009 and repealing Regulation (EC) No 1559/2007 ⁽³⁾, requires Member States to inform the Commission of the individual quota allocated to their vessels over 24 m and, for catching vessels less than 24 m, at least of the quota allocated to producer organisations or groups of vessels fishing with similar gear.

(3) The common fisheries policy is designed to ensure the long-term viability of the fisheries sector through

(4) In accordance with Article 36, paragraph 2 of Regulation (EC) No 1224/2009, where the Commission finds that, on the basis of information provided by Member States and of other information in its possession fishing opportunities available to the European Union, a Member State or group of Member States are deemed to have been exhausted for one or more gears or fleets, the Commission shall inform the Member States concerned thereof and shall prohibit fishing activities for the respective area, gear, stock, group of stocks or fleet involved in those specific fishing activities.

(5) The information in the Commission's possession indicates that the fishing opportunities for bluefin tuna in the Atlantic Ocean, east of longitude 45° W, and the Mediterranean Sea allocated to longliners flying the flag of or registered in Greece or Malta have been exhausted.

(6) On 3 May 2012 Greece informed the Commission of the fact that it had imposed a stop on the fishing activities of its longline vessels active in the 2012 bluefin tuna fishery, with effect from that day at 00.00.

(7) On 2 July 2012 Malta informed the Commission of the fact that it had imposed a stop on the fishing activities of its longline vessels active in the 2012 bluefin tuna fishery, with effect from 1 July at 00.00.

(8) Without prejudice to the action by Greece and Malta mentioned above, it is necessary that the Commission confirms the prohibition of fishing for bluefin tuna in the Atlantic Ocean, east of longitude 45° W and the Mediterranean Sea as from 3 May 2012 at 00.00 for longliners flying the flag of or registered in Greece and as from 1 July 2012 at 00.00 for longliners flying the flag of or registered in Malta,

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 25, 27.1.2012, p. 55.

⁽³⁾ OJ L 96, 15.4.2009, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Fishing for bluefin tuna in the Atlantic Ocean, east of longitude 45° W, and the Mediterranean by longliners flying the flag of or registered in Greece shall be prohibited as from 3 May 2012 at 00.00 at the latest.

It shall also be prohibited to retain on board, place in cages for fattening or farming, tranship, transfer or land such stock caught by those vessels as from that date.

Article 2

Fishing for bluefin tuna in the Atlantic Ocean, east of longitude 45° W, and the Mediterranean by longliners flying the flag of or registered in Malta shall be prohibited as from 1 July 2012 at 00.00 at the latest.

It shall also be prohibited to retain on board, place in cages for fattening or farming, tranship, transfer or land such stock caught by those vessels as from that date.

Article 3

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

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

Done at Brussels, 6 August 2012.

*For the Commission,
On behalf of the President,
Antonio TAJANI
Vice-President*

COMMISSION REGULATION (EU) No 722/2012

of 8 August 2012

concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of laws of the Member States relating to active implantable medical devices ⁽¹⁾, and in particular Article 10c thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽²⁾, and in particular Article 14b thereof,

Whereas:

- (1) Specific rules for medical devices manufactured utilising tissues of animal origin were initially adopted by Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin ⁽³⁾. This Directive was applicable only to medical devices falling within the scope of Directive 93/42/EEC.
- (2) In order to maintain a high level of safety and health protection against the risk of transmitting animal spongiform encephalopathies to patients or other persons via medical devices manufactured utilising non-viable animal tissues or derivatives rendered non-viable, including custom-made devices and devices intended for clinical investigation, it is necessary to update the rules laid down in Directive 2003/32/EC on the basis of the experience with the application of this Directive and to apply them also to active implantable medical devices manufactured utilising tissues of animal origin that fall within the scope of Directive 90/385/EEC.
- (3) Taking into account that this measure lays down clear and detailed rules that do not give room for diverging transposition by Member States, a Regulation is the appropriate legal instrument which shall replace Directive 2003/32/EC.

- (4) Prior to being placed on the market or put into service, active implantable medical devices and medical devices of class III in accordance with the classification rules set out in Annex IX to Directive 93/42/EEC, whether they originate in the European Union or are imported from third countries, are subject to the conformity assessment procedures laid down in Article 9(1) of Directive 90/385/EEC and in Article 11(1) of Directive 93/42/EEC, respectively. Annex 1 to Directive 90/385/EEC and Annex I to Directive 93/42/EEC, respectively, set out the essential requirements that active implantable medical devices and other medical devices must meet in this regard.
- (5) With regard to active implantable medical devices and other medical devices manufactured utilising tissues of animal origin it is necessary to adopt more detailed specifications in relation to the requirements set out in point 6 of Annex 1 to Directive 90/385/EEC and points 8.1 and 8.2 of Annex I to Directive 93/42/EEC. Moreover, it is appropriate to specify certain aspects relating to the risk analysis and risk management in the framework of the conformity assessment procedures referred to in Article 9 of Directive 90/385/EEC and Article 11 of Directive 93/42/EEC, respectively.
- (6) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption ⁽⁴⁾ sets out provisions on the sourcing of materials used in medical devices. It is appropriate to lay down additional provisions on the use of such materials as starting tissue for the manufacture of medical devices.
- (7) European and international scientific bodies, such as the European Medicines Agency ⁽⁵⁾, the European Food Safety Agency ⁽⁶⁾, the former Scientific Steering Committee ⁽⁷⁾ and the former Scientific Committee on Medicinal Products and Medical Devices ⁽⁸⁾, adopted several opinions on specified risk materials and on minimising the risk of transmitting animal spongiform encephalopathy agents which are of relevance to the safety of medical devices.

⁽⁴⁾ OJ L 300, 14.11.2009, p. 1.

⁽⁵⁾ Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) (OJ C 73, 5.3.2011, p. 1).

⁽⁶⁾ <http://www.efsa.europa.eu/en/topics/topic/bse.htm>

⁽⁷⁾ http://ec.europa.eu/food/fs/bse/scientific_advice08_enprint.html

⁽⁸⁾ See http://ec.europa.eu/health/scientific_committees/emerging/opinions/scmpmd/index_en.htm

⁽¹⁾ OJ L 189, 20.7.1990, p. 17.

⁽²⁾ OJ L 169, 12.7.1993, p. 1.

⁽³⁾ OJ L 105, 24.4.2003, p. 18.

- (8) The Member States should verify that the notified bodies designated to assess the conformity of medical devices manufactured utilising animal tissues have the necessary expertise and up-to-date knowledge to perform this task.
- (9) The period for scrutiny granted to the competent authorities of the Member States in relation to the notified bodies' summary evaluation report should be shorter for medical devices manufactured using starting material which is certified by the European Directorate for the Quality of Medicines than in cases where uncertified material is used. In both cases, there should be a possibility to shorten the standstill period.
- (10) To facilitate the smooth transition to the new requirements it is appropriate to provide for an adequate transitional period allowing for active implantable medical devices already covered by an EC design-examination certificate or by an EC type examination certificate to continue to be placed on the market and put into service.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices set up by Article 6(2) of Directive 90/385/EEC,
- (a) 'cell' means the smallest organised unit of any living form which is capable of independent existence and of replacement of its own substance in a suitable environment;
- (b) 'tissue' means an organisation of cells, extra-cellular constituents or both;
- (c) 'derivative' means a material obtained from animal tissue through one or more treatments, transformations or steps of processing;
- (d) 'non-viable' means having no potential for metabolism or multiplication;
- (e) 'TSEs' means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ⁽¹⁾;
- (f) 'TSE infectious agents' means unclassified pathogenic agents which are capable of transmitting TSEs;
- (g) 'reduction, elimination or removal' means a process by which the number of TSE infectious agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction;

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation lays down particular requirements in relation to the placing on the market and/or putting into service of medical devices, including active implantable medical devices, manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

2. This Regulation shall apply to animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats.

3. Collagen, gelatine and tallow used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption laid down in Regulation (EC) No 1069/2009.

4. This Regulation shall not apply to any of the following:

- (a) Tallow derivatives, processed under conditions at least as vigorous as those laid down in Section 3 of Annex I;
- (b) medical devices referred to in paragraph 1, which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

Article 2

For the purposes of this Regulation, the following definitions apply in addition to the definitions set out in Directive 90/385/EEC and Directive 93/42/EEC:

- (h) 'inactivation' means a process by which the ability to cause infection or pathogenic reaction by TSE infectious agents is reduced;
- (i) 'source country' means the country or countries in which the animal was born, has been reared and/or has been slaughtered;
- (j) 'starting materials' means raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in Article 1(1) are produced.

Article 3

1. Before lodging an application for a conformity assessment pursuant to Article 9(1) of Directive 90/385/EEC or Article 11(1) of Directive 93/42/EEC, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or his authorised representative shall carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.

2. For custom-made devices and devices intended for clinical investigation which fall under Article 1(1), the statement of the manufacturer or his authorised representative and the documentation in accordance with Annex 6 to Directive 90/385/EEC or Annex VIII to Directive 93/42/EEC, respectively, shall also address compliance with the particular requirements set out in section 1 of Annex I to this Regulation.

Article 4

1. Member States shall verify that bodies notified under Article 11 of Directive 90/385/EEC or Article 16 of Directive 93/42/EEC have up-to-date knowledge of the medical devices

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

referred to in Article 1(1), in order to assess the conformity of those devices with the provisions of Directive 90/385/EEC or Directive 93/42/EEC, respectively, and with the particular requirements laid down in Annex I to this Regulation. Member States shall regularly verify that those bodies maintain the required up-to-date knowledge and expertise.

Where, on the basis of that verification, it is necessary for a Member State to amend the tasks of a notified body, that Member State shall notify the Commission and the other Member States accordingly.

2. The Member States shall inform the Commission and the other Member States regarding the outcome of the verification referred to in the first sentence of paragraph 1 by 28 February 2013.

Article 5

1. Conformity assessment procedures for medical devices referred to in Article 1(1) shall include the evaluation of compliance of the devices with the essential requirements of Directive 90/385/EEC or Directive 93/42/EEC, respectively, and the particular requirements laid down in Annex I to this Regulation.

2. Notified bodies shall assess the documentation submitted by the manufacturer to verify that the benefits of the device outweigh the residual risks. Particular account shall be taken of:

- (a) the manufacturer's risk analysis and risk management process;
- (b) the justification for the use of animal tissues or derivatives, taking into consideration lower risk tissues or synthetic alternatives;
- (c) the results of elimination and inactivation studies or results of the analysis of relevant literature;
- (d) the manufacturer's control of the sources of raw materials, finished products, production process, testing, and subcontractors;
- (e) the need to audit matters related to the sourcing and processing of animal tissues and derivatives, processes to eliminate or inactivate pathogens, including those activities carried out by suppliers.

3. Notified bodies shall, during the evaluation of the risk analysis and risk management in the framework of the conformity assessment procedure, take account of the TSE certificate of suitability issued by the European Directorate for the Quality of Medicines, hereinafter 'TSE certificate of suitability', for starting materials, where available.

Where additional information is necessary to assess the suitability of the starting material for a given medical device, notified bodies may require submission of additional information to allow the evaluation as set out in paragraphs 1 and 2.

4. Before issuing an EC design-examination certificate or an EC type-examination certificate, the notified bodies shall, through their competent authority, hereinafter 'coordinating competent authority', inform the competent authorities of the other Member States and the Commission of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.

5. The competent authorities of the Member States may submit comments on the summary evaluation report referred to in paragraph 4 within the following deadlines:

- (a) in relation to medical devices using starting materials for which a TSE certificate of suitability as referred to in paragraph 3 has been submitted, within four weeks from the date on which the notified body informed the coordinating competent authority pursuant to paragraph 4;
- (b) in relation to medical devices using starting materials for which a TSE certificate of suitability has not been submitted, within 12 weeks from the date on which the notified body informed the coordinating competent authority pursuant to paragraph 4.

The competent authorities of the Member States and the Commission may agree on shortening the time periods set out in points (a) and (b).

6. The notified bodies shall give due consideration to any comments received in accordance with paragraph 5. They shall convey an explanation as regards this consideration, including any due justification not to take account of one or more of the comments received, and their final decisions to the coordinating competent authority, which shall then make these available to the Commission and the competent authorities from which comments were received.

7. The manufacturer shall collect, evaluate and submit to the notified body information regarding changes with regard to the animal tissue or derivatives used for the device or with regard to the TSE risk in relation to the device. Where such information leads to an increase of the overall TSE risk, the provisions of paragraphs 1-6 are applicable.

Article 6

Without prejudice to Article 7(2), Member States shall take all necessary steps to ensure that medical devices referred to in Article 1(1) are placed on the market and/or put into service only if they comply with the provisions of Directive 90/385/EEC or Directive 93/42/EEC, respectively, and the particular requirements laid down in this Regulation.

Article 7

1. Holders of EC design-examination certificates or EC type-examination certificates issued before 29 August 2013 for active implantable medical devices referred to in Article 1(1) shall apply to their notified body for a complementary EC design-examination certificate or EC type-examination certificate attesting compliance with the particular requirements laid down in Annex I to this Regulation.

2. Until 29 August 2014, Member States shall accept the placing on the market and the putting into service of active implantable medical devices referred to in Article 1(1) which are covered by an EC design-examination certificate or an EC type-examination certificate issued before 29 August 2013.

Article 8

Directive 2003/32/EC is repealed with effect from 29 August 2013.

References to the repealed Directive are to be construed as references to this Regulation.

Article 9

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

It shall apply from 29 August 2013 except for Article 4 which shall apply from the date of entry into force of this Regulation.

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

Done at Brussels, 8 August 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX I

1. RISK ANALYSIS AND RISK MANAGEMENT

1.1. **Justification for the use of animal tissues or derivatives**

The manufacturer must justify, on the basis of his overall risk analysis and risk management strategy for a specific medical device, the decision to use animal tissues or derivatives, referred to in Article 1, (specifying animal species, tissues and sourcing) taking into account the clinical benefit, potential residual risk and suitable alternatives (such as lower risk tissues or synthetic alternatives).

1.2. **Process of risk assessment**

In order to ensure a high level of protection for patients and users, the manufacturer of devices utilising animal tissues or derivatives referred to in point 1.1 must implement an appropriate and well documented risk analysis and risk management strategy, to address all relevant aspects relating to TSE. He must identify the hazards and evaluate the risks associated with those tissues or derivatives, establish documentation on measures taken to minimise the risk of transmission and demonstrate the acceptability of the residual risk associated with the device utilising such tissues or derivatives, taking into account the intended use and the benefit of the device.

The safety of a device, in terms of its potential for passing on a TSE infectious agent, is dependent on all the factors described in sections 1.2.1 to 1.2.8, which the manufacturer must analyse, evaluate and manage. These measures in combination determine the device safety.

At a minimum, the manufacturer must consider the following key steps:

- (a) selecting starting materials (tissues or derivatives) considered appropriate regarding their potential contamination with TSE infectious agents (see 1.2.1, 1.2.2, 1.2.3 and 1.2.4) taking into account further collection, handling, transport, storage and processing;
- (b) applying a production process to remove or inactivate TSE infectious agents on controlled sourced tissues or derivatives (see 1.2.5);
- (c) maintaining a system to collect and evaluate production and post-production information regarding changes which may affect the assessment of the suitability of steps referred to in points (a) and (b).

Furthermore, the manufacturer must take into account the characteristics of the device and its intended use (see 1.2.6, 1.2.7 and 1.2.8).

In performing the risk analysis and risk management strategy, the manufacturer must give due consideration to the relevant published opinions adopted by the relevant European or international scientific committees or bodies, such as the Scientific Steering Committee (SSC), the European Food Safety Agency (EFSA), the European Medicines Agency (EMA), the World Organisation for Animal Health (OIE) and the World Health Organisation (WHO).

1.2.1. *Animals as a source of material*

The TSE risk is related to the source species, strains and nature of the starting tissue. As the accumulation of TSE infectivity occurs over an incubation period of several years, sourcing from young healthy animals is considered to be a factor reducing the risk. Risk animals such as fallen stock, emergency slaughtered and TSE suspected animals must be excluded as a source of material.

1.2.2. *Geographical sourcing*

When assessing the risk of the source country, Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk ⁽¹⁾ is to be taken into account.

1.2.3. *Nature of starting tissue*

The manufacturer must take into account the classification of the risks relating to different types of starting tissue as defined in the WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform

⁽¹⁾ OJ L 172, 30.6.2007, p. 84.

Encephalopathies (2006), as amended. Sourcing of animal tissue must be performed in such a manner as to maintain control over the traceability and integrity of source tissue. Where appropriate, the animals shall be subjected to veterinary ante- and post-mortem inspection.

In addition, Regulation (EC) No 1069/2009 applies.

Without prejudice to the provision in the following paragraph, only category 3 material in accordance with Article 10 of Regulation (EC) No 1069/2009 shall be used.

The manufacturer must not source animal tissue or derivatives classified as potentially high TSE infective, unless sourcing of these materials is necessary in exceptional circumstances, taking into account the important benefit for the patient and the absence of an alternative starting tissue.

For bovine, ovine and caprine animals, the list of specified risk material (SRM) laid down in Annex V to Regulation (EC) No 999/2001 is to be considered as being potentially of high TSE infectivity.

1.2.4. *Slaughtering and processing controls to prevent cross contamination*

The manufacturer must ensure that the risk of cross-contamination during slaughtering, collection, processing, handling, storage and transport is minimised.

1.2.5. *Inactivation or removal of TSE infectious agents*

1.2.5.1. For devices which cannot withstand an inactivation or elimination process without undergoing unacceptable degradation, the manufacturer must rely principally on the control of sourcing.

1.2.5.2. For other devices, if claims are made by the manufacturer for the ability of manufacturing processes to remove or inactivate TSE infectious agents, these must be substantiated by appropriate documentation.

Relevant information from an analysis of appropriate scientific literature can be used to support inactivation and elimination factors, where the specific processes referred to in the literature are comparable to those used for the device. This search and analysis shall also cover the available scientific opinions that may have been adopted by an European or international scientific committee or body. These opinions are to serve as a reference, in cases where there are conflicting opinions.

If the literature search fails to substantiate the claims, the manufacturer must set up a specific inactivation or elimination study, as appropriate, on a scientific basis and the following need to be considered:

- (a) the identified hazard associated with the tissue;
- (b) identification of the relevant model agents;
- (c) rationale for the choice of the particular combinations of model agents;
- (d) identification of step and/or stage chosen to eliminate or inactivate the TSE infectious agents;
- (e) documentation of the parameters for any TSE inactivation or elimination validation study;
- (f) calculation of the reduction factors.

The manufacturer must apply appropriate documented procedures to ensure that the validated processing parameters are applied during routine manufacture.

A final report must identify manufacturing parameters and limits that are critical to the effectiveness of the inactivation or elimination process.

1.2.6. *Quantities of animal tissues or derivatives required to produce one unit of the medical device*

The manufacturer must evaluate the quantity of raw tissues or derivatives of animal origin required to produce a single unit of the medical device. The manufacturer must assess whether the production process has the potential to concentrate levels of TSE infectious agents present in the animal starting tissues or derivatives.

1.2.7. *Tissues or derivatives of animal origin coming into contact with the patients and users*

The manufacturer must consider:

- (a) the maximum quantity of animal tissues or derivatives coming into contact with the patient or user when using a single medical device;
- (b) the contact area: its surface, type (e.g. skin, mucous tissue, brain) and condition (e.g. healthy or damaged);
- (c) the type of the tissues or derivatives coming into contact with the patients or users;
- (d) the period of time the device is intended to remain in contact with the body (including bioresorption effect); and
- (e) the number of medical devices that could be used in a given procedure or, if possible, over the lifetime of a patient or user.

1.2.8. *Route of administration*

In the risk assessment, the manufacturer must take into account the route of administration as indicated in the product information.

1.3. **Review of the risk assessment**

The manufacturer must establish and maintain a systematic procedure to review information gained about the medical device or similar devices in the post-production phase. The information must be evaluated for possible relevance to safety, especially in any of the following cases:

- (a) previously unrecognised hazards are identified;
- (b) the estimated risk arising from a hazard has changed or is no longer acceptable;
- (c) the original assessment is otherwise invalidated.

In the cases set out in points (a), (b) or (c), the manufacturer shall feed back the results of the evaluation as an input to the risk management process.

In the light of this new information, a review of the appropriate risk management measures for the device must be considered (including rationale for choosing an animal tissue or derivative). If there is a potential that the residual risk or its acceptability has changed, the impact on previously implemented risk control measures must be re-evaluated and justified.

The results of this evaluation must be documented.

2. **EVALUATION BY NOTIFIED BODIES**

For the medical devices referred to in Article 1(1), manufacturers must provide to the notified bodies referred to in Article 4 all relevant information to allow evaluation of their risk analysis and risk management strategy in accordance with Article 5(2).

2.1. **Information of the Notified Body regarding changes and new information**

Any change in relation to processes of sourcing, collection, handling, processing and inactivation or elimination and any new information on TSE risk collected by the manufacturer and relevant for the medical device that could modify the result of the manufacturer's risk assessment must be transmitted to the notified body and, where applicable, needs to be approved by the notified body prior to its implementation.

2.2. **Renewal of certificates**

In the context of its decision regarding the extension for a further period of maximum five years of an EC design-examination certificate or an EC type-examination certificate in accordance with Article 9(8) of Directive 90/385/EEC or Article 11(11) of Directive 93/42/EEC, respectively, the notified body shall review for the purpose of this Regulation at least the following aspects:

- (a) updated justification for the use of animal tissue or derivative, including a comparison with lower risk tissues or synthetic alternatives;
- (b) updated risk analysis;
- (c) updated clinical evaluation;
- (d) updated test data and/or rationales, for example in relation to the current harmonised standards;
- (e) identification of any changes made since the issue of the original certificate (or last renewal) that could impact the TSE risk;
- (f) evidence that the design dossier remains state of the art in relation to TSE risks.

2.3. **Increase of the overall TSE risk**

Where on the basis of information submitted in accordance with section 2.1 or 2.2 a notified body establishes that the overall TSE risk in relation to a medical device is increased, this notified body shall follow the procedure set out in Article 5.

3. **RIGOROUS PROCESSES FOR TALLOW DERIVATIVES AS REFERRED TO IN ARTICLE 1, PARAGRAPH 4, OF THIS REGULATION**

- Trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production),
 - Saponification with NaOH 12 M (glycerol and soap production)
 - Batch process: at not less than 95 °C for not less than 3 hours,
 - Continuous process: at not less than 140 °C, under pressure for not less than 8 minutes or equivalent,
 - Distillation at 200 °C.
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ANNEX II

Summary Evaluation Report in accordance with Article 5(4) of Regulation (EU) No 722/2012**Details relating to the submitting notified body**

1. Name of notified body	2. Notified body number	3. Country
4. Sent by	5. Contact person	6. Telephone
7. Fax	8. E-mail	9. Client reference (name of manufacturer and, if applicable, of authorised representative)

10. Confirmation that, in accordance with Article 11 of Directive 90/385/EEC and Article 16 of Directive 93/42/EEC, respectively, and Article 4 of Regulation (EU) No 722/2012, the submitting notified body has been designated by its competent authority for the conformity assessment of

- ☐ active implantable medical devices manufactured utilising tissues of animal origin subject to Regulation (EU) No 722/2012,
- ☐ medical devices manufactured utilising tissues of animal origin subject to Regulation (EU) No 722/2012

Data relating to the (active implantable) medical device

11. (a) ☐ Active implantable medical device ☐ Other medical device
11. (b) Product description and composition
12. Information on intended use
13. Starting material
13. (a) EDQM certificate available ☐ YES ☐ NO (If the EDQM certificate is available, it must be submitted with this summary evaluation report.)
13. (b) Information regarding — the nature of the starting tissue(s): — animal species(s): — geographical source(s):
14. A description of the key elements adopted to minimise the risk of infection:
15. An estimate of the TSE risk arising from the use of the product, taking into account the likelihood of contamination of the product, the nature and duration of patient exposure:
16. A justification for the use of animal tissues or derivatives in the medical device, including a rationale for the acceptability of the overall TSE risk estimate, the evaluation of alternative materials and the expected clinical benefit:
17. The approach to the auditing of source establishments and suppliers for the animal material used by the device manufacturer:

Notified Body Statement

18. Conclusion of this assessment:

Based on the evaluation of data and the assessment process it is our preliminary decision that the application meets the requirements of conformity with

☐ Council Directive 90/385/EEC

☐ Council Directive 93/42/EEC

and Regulation (EU) No 722/2012.

Date of submission

19. This report was sent on to the Coordinating Competent Authority of to inform the Competent Authorities of the other Member States and the Commission and to seek their comments, if any.

COMMISSION IMPLEMENTING REGULATION (EU) No 723/2012**of 8 August 2012****recognising a traditional term provided for in Council Regulation (EC) No 1234/2007 (Cream — TDT-US-N0017)**

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⁾, and in particular Article 118u(2) in conjunction with Article 4 thereof,

Whereas:

- (1) Two representative professional organisations established in the United States of America, WineAmerica and California Export Association, submitted to the Commission an application, received on 22 June 2010, for protection of the traditional term 'Cream' in relation to grapevine products of category '3. Liqueur wine' provided for in Annex XIb to Regulation (EC) No 1234/2007 bearing a name of origin listed in Annex V to the Agreement between the European Community and the United States of America on trade in wine, approved by Council Decision 2006/232/EC ⁽²⁾.
- (2) In accordance with Article 33 of Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products ⁽³⁾, the application was published in the *Official Journal of the European Union* ⁽⁴⁾. No objection was submitted within two months from the date of publication.

- (3) The application for the protection of the traditional term 'Cream' which relates to American wines satisfies the conditions laid down in Article 118u(1) of Regulation (EC) No 1234/2007 and in Articles 31 and 35 of Regulation (EC) No 607/2009. The application for protection should be accepted and the traditional term 'Cream' should therefore be entered into the electronic database 'E-Bacchus' for wines produced by the members of the two representative professional organisations that submitted the application.
- (4) Article 30(2) of Regulation (EC) No 607/2009 requires the Commission to make public the information regarding the representative trade organisation and its members. That information should be made public in the electronic database 'E-Bacchus'.
- (5) The measure provided for in this Regulation is in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The application for protection of the traditional term 'Cream' is hereby accepted for American grapevine products of category '3. Liqueur wine' provided for in Annex XIb to Regulation (EC) No 1234/2007. The term 'Cream' shall be entered into the electronic database 'E-Bacchus' as indicated in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 8 August 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 87, 24.3.2006, p. 1.

⁽³⁾ OJ L 193, 24.7.2009, p. 60.

⁽⁴⁾ OJ C 276, 13.10.2010, p. 6.

ANNEX

Protected Traditional Term

— Cream

Language referred to in Article 31(1) of Regulation (EC) No 607/2009

— English

Grapevine product category or categories concerned by the protection (Annex XIb to Regulation (EC) No 1234/2007)

— 3. Liqueur wine

List of protected designations of origin or geographical indications concerned

— Names of origin as listed in Annex V to the Agreement between the European Community and the United States of America on trade in wine

Reference to the applicable rules in the Member State or third country

— Resolution of WineAmerica on Wine Production Definitions for the European Community adopted on 24 March 2009,

— Decision of California Wine Export Program adopted on 7 May 2009.

Summary of the definition or conditions of use

— 'Cream' describes a style of US fortified sweet wine. The wine will be pale yellow to light amber in colour, rich and sweet to taste and typically with a vinous to fruity aroma. However, the wines may reflect the characteristics of careful ageing showing 'developed' characters. The wine can be blended from more than one vintage and typically sustaining sweet vinous characters. Ageing takes place in a variety of vessels. Fortification must be from grape spirit.

Name of the country or countries of origin

— United States of America

The list of the members of the representative trade organisation established in the third country that are entitled to use the protected traditional term is accessible on:

<http://ec.europa.eu/agriculture/markets/wine/e-bacchus/>

COMMISSION IMPLEMENTING REGULATION (EU) No 724/2012**of 8 August 2012****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 8 August 2012.

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

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

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

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	TR	55,3
	XS	32,3
	ZZ	43,8
0707 00 05	TR	100,7
	ZZ	100,7
0709 93 10	TR	108,5
	ZZ	108,5
0805 50 10	AR	90,6
	TR	92,0
	UY	84,4
	ZA	102,1
	ZZ	92,3
0806 10 10	CL	226,1
	EG	189,7
	IL	138,6
	MA	157,7
	MX	186,3
	TN	203,8
	TR	139,3
	ZZ	177,4
0808 10 80	AR	187,2
	BR	85,1
	CL	114,3
	NZ	119,8
	US	153,9
	ZA	100,3
0808 30 90	ZZ	126,8
	AR	129,0
	CL	164,0
	CN	91,7
	NZ	165,5
	TR	193,5
	ZA	99,0
0809 29 00	ZZ	140,5
	CA	627,1
	TR	347,2
0809 30	ZZ	487,2
	TR	166,3
0809 40 05	ZZ	166,3
	BA	66,3
	IL	69,8
	MK	70,3
	ZZ	68,8

⁽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 IMPLEMENTING REGULATION (EU) No 725/2012**of 8 August 2012****amending the representative prices and additional import duties for certain products in the sugar sector fixed by Implementing Regulation (EU) No 971/2011 for the 2011/12 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 2011/12 marketing year are fixed by Commission Implementing Regulation (EU) No 971/2011 ⁽³⁾. Those prices and duties were last amended by Commission Implementing Regulation (EU) No 720/2012 ⁽⁴⁾.

- (2) The data currently available to the Commission indicate that those amounts should be amended in accordance with Article 36 of Regulation (EC) No 951/2006.

- (3) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

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 Implementing Regulation (EU) No 971/2011 for the 2011/12 marketing year, are hereby amended as set out in the Annex hereto.

Article 2

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

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

Done at Brussels, 8 August 2012.

*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 254, 30.9.2011, p. 12.

⁽⁴⁾ OJ L 211, 8.8.2012, 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 9 August 2012

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 12 10 ⁽¹⁾	40,90	0,00
1701 12 90 ⁽¹⁾	40,90	2,34
1701 13 10 ⁽¹⁾	40,90	0,00
1701 13 90 ⁽¹⁾	40,90	2,63
1701 14 10 ⁽¹⁾	40,90	0,00
1701 14 90 ⁽¹⁾	40,90	2,63
1701 91 00 ⁽²⁾	48,19	3,01
1701 99 10 ⁽²⁾	48,19	0,00
1701 99 90 ⁽²⁾	48,19	0,00
1702 90 95 ⁽³⁾	0,48	0,22

⁽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 IMPLEMENTING DECISION

of 7 August 2012

amending Implementing Decision 2012/262/EU amending Decision 2008/589/EC establishing a specific control and inspection programme related to the cod stocks in the Baltic Sea

(2012/468/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 ⁽¹⁾, and in particular Article 95 thereof,

Whereas:

- (1) Commission Decision 2008/589/EC ⁽²⁾ established a specific control and inspection programme applicable for a period of four years to ensure the harmonised implementation of the multiannual plan set up by Council Regulation (EC) No 1098/2007 ⁽³⁾ for the cod stocks in the Baltic Sea and the fisheries exploiting those stocks.
- (2) To address the clerical error occurred during the adoption procedure of Commission Implementing Decision 2012/262/EU ⁽⁴⁾ and consequently to bring that Decision in conformity with the opinion of the Committee for Fisheries and Aquaculture, the text 'or likely to be engaged' should be deleted from paragraph 3 of Article 1 of that Decision.
- (3) Implementing Decision 2012/262/EU should therefore be amended accordingly.
- (4) The measures provided for in this Decision have been established in concert with the Member States concerned.

- (5) The measures provided for in this Decision are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS DECISION:

Article 1

Paragraph 3 of Article 1 of Implementing Decision 2012/262/EU is replaced by the following:

- '3. Article 2 is replaced by the following:

"Article 2

Scope

1. The specific control and inspection programme shall cover control and inspection of:
 - (a) fishing activities by vessels referred to in Article 2 of Regulation (EC) No 1098/2007 and by fishing vessels of all length engaged in the catch of salmon;
 - (b) all related activities including the landing, weighing, marketing, transport and storage of fishery products and the recording of landing and sales.
2. The specific control and inspection programme shall apply for five years."

Article 2

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

Done at Brussels, 7 August 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 190, 18.7.2008, p. 11.

⁽³⁾ OJ L 248, 22.9.2007, p. 1.

⁽⁴⁾ OJ L 130, 17.5.2012, p. 22.

CORRIGENDA**Corrigendum to Council Implementing Regulation (EU) No 673/2012 of 23 July 2012 implementing Article 32(1) of Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria***(Official Journal of the European Union L 196 of 24 July 2012)*

On page 11, Annex, 'Entities', entry 2, fourth column, 'Date of listing':
the date '24.7.2012' shall be added.

Corrigendum to Council Implementing Decision 2012/424/CFSP of 23 July 2012 implementing Decision 2011/782/CFSP concerning restrictive measures against Syria*(Official Journal of the European Union L 196 of 24 July 2012)*

On page 84, Annex, 'Entities', entry 2, fourth column, 'Date of listing':
the date '24.7.2012' shall be added.

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