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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.

GUIDELINES

EN

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 101/2013

of 4 February 2013

concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases

(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 29 April 2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin [1], and in particular Article 3(2) thereof,

Whereas:

(1) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2] lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the principle concerning the general implementation of procedures based on hazard analysis and critical control point (HACCP).

(2) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. It provides that food business operators are not to use any substance other than potable water to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with that Regulation.

(3) In addition, Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [3] lays down the microbiological criteria for certain microorganisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Regulation (EC) No 852/2004. It provides that food business operators are to ensure that foodstuffs are to comply with those microbiological criteria.

(4) On 14 December 2010, the Commission received an application for approval of the use of lactic acid to reduce surface contamination of bovine carcases and meat.

(5) On 26 July 2011, the European Food Safety Authority (EFSA) adopted a Scientific Opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination from beef carcases, cuts and trimmings [4].

(6) In its Opinion, EFSA concludes that the treatments using lactic acid for decontamination are of no safety concern, provided that the substance used complies with Union specifications for food additives. In addition, EFSA concludes that treatments with lactic acid provide a significant reduction of microbiological contamination compared to no treatment or to treatment with potable water and that it is unlikely that such treatments would contribute to the development of microbial resistance.

(7) EFSA recommends that food business operators validate the antimicrobial efficacy of such treatments under their specific processing conditions and verify lactic acid concentration, temperature of application and other factors affecting its efficacy as a decontaminating agent. The EFSA Opinion also concluded that there are no negative implications resulting from this use of lactic acid on the environment.

(8) According to the EFSA Opinion, the residual amount absorbed in the beef meat from lactic acid treatment will not be higher than 190 mg/kg. Such amount is considered residual compared to the active amount necessary for the purpose of reducing microbial surface contamination. Furthermore, it does not have any technological effect in the final product. In addition, the

[1] OJ L 139, 30.4.2004, p. 55.
[2] OJ L 139, 30.4.2004, p. 1.
[3] OJ L 338, 22.12.2005, p. 1.
[4] *EFSA Journal* 2011; 9(7):2317.

residual amount of lactic acid used for reducing microbial surface contamination is negligible compared to the amount of lactic acid naturally present in beef and it is of no safety concern. In certain meat preparations, lactic acid salts are authorised as food additives for the purpose of preservation. For this purpose, levels of 20 000 mg/kg are commonly used. Therefore, the use of lactic acid for the purpose of reducing microbial surface contamination is clearly distinct from its use as a food additive.

(9) In view of the EFSA Opinion, taking into account that lactic acid can provide a significant reduction of possible microbiological contamination, it is appropriate to approve its use to reduce surface contamination. Such use should however be subjected to certain conditions. Its use should be limited to the use on carcases or half carcases or quarters at the level of the slaughterhouse and it should be integrated into good hygienic practices and HACCP-based systems.

(10) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council [1] lays down specifications for food additives relating, in particular, to origin, purity criteria and any other necessary information.

(11) In accordance with the EFSA Opinion, lactic acid used to reduce surface contamination in bovine carcases should comply with the specifications for lactic acid laid down in Union legislation. Consequently, where lactic acid is used to reduce microbiological surface contamination pursuant to this Regulation, it is appropriate that such lactic acid complies with the specifications laid down in Regulation (EU) No 231/2012.

(12) The use of lactic acid to reduce microbiological surface contamination on bovine carcases or half carcases or quarters must not affect the food business operator's duty to comply with the requirements of Union legislation on food hygiene, as laid down in Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 2073/2005 and should in no way be considered as a substitution for good hygienic slaughtering practices and operating procedures or as an alternative to comply with the requirements of those Regulations.

(13) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman. The Commission therefore submitted to the Council a proposal relating to this measure and forwarded it to the European Parliament at the same time.

(14) In view of the fact that the Council did not act and the European Parliament did not oppose the measure within the applicable time-periods, the Commission should adopt the measure,

HAS ADOPTED THIS REGULATION:

Article 1

Food business operators may use lactic acid to reduce microbiological surface contamination on bovine carcases or half carcases or quarters at the level of the slaughterhouse in compliance with the conditions set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 4 February 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 83, 22.3.2012, p. 1.

ANNEX

PART I

Conditions of use of lactic acid to reduce microbiological surface contamination of bovine carcases or half carcases or quarters at the level of the slaughterhouse

1. Lactic acid solutions must only be prepared from lactic acid which complies with the specifications set out in Regulation (EU) No 231/2012.

2. Lactic acid solutions must:

   (a) only be applied on entire carcases or half-carcases or quarters of meat from domestic bovine animals (including *Bubalus* and *Bison* species) at the level of the slaughterhouse;

   (b) only be applied either by spraying or misting using from 2 % to 5 % lactic acid solution in potable water at temperatures of up to a maximum of 55 °C;

   (c) be applied under controlled and verifiable conditions integrated in a HACCP-based management system including, at least, the criteria set out in Part II.

3. Lactic acid solutions must not be applied to carcases with visible faecal contamination.

4. The application of lactic acid solutions must not result in any irreversible physical modification of the meat.

PART II

Minimum HACCP criteria and control parameters

1. Sampling of carcases for the purposes of assessing compliance with microbiological criteria within the meaning of Regulation (EC) No 2073/2005 must be carried out before the application of lactic acid solutions on the carcases or half-carcases or quarters.

2. Lactic acid concentration during treatment must be, as part of the HACCP plan, verified by periodic monitoring, documented and recorded.

3. The temperature of the lactic acid solution during treatment must, as part of the HACCP plan, be continuously monitored by instrumental measurements, documented and recorded.

PART III

Information on the treatment

Food business operators operating slaughterhouses in which lactic acid solutions are used to reduce microbial surface contamination of entire carcases or half-carcases or quarters must inform the food business operator receiving the treated carcases or half-carcases or quarters of such use. This information should be documented.

COMMISSION IMPLEMENTING REGULATION (EU) No 102/2013

of 4 February 2013

amending Regulation (EU) No 206/2010 as regards the entry for the United States in the list of third countries, territories or parts thereof authorised for the introduction of live ungulates into the Union, the model veterinary certificate 'POR-X' and the protocols for testing for vesicular stomatitis

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC [1], and in particular the first and second subparagraphs of Article 3(1), the first subparagraph of Article 6(1), Article 7(e), Article 9 and Article 13(1)(e) thereof,

Whereas:

(1) Directive 2004/68/EC lays down the animal health requirements for the importation into and transit through the Union of certain live ungulates. It provides that specific provisions, including model veterinary certificates, may be laid down for the import into the Union of live ungulates of the species listed in Annex I thereto from authorised third countries.

(2) Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements [2] lays down amongst others the veterinary certification requirements for the introduction into the Union of certain consignments of live cloven-hoofed animals of the species listed in Annex I to Directive 2004/68/EC. Annex I to Regulation (EU) No 206/2010 sets out a list of third countries, territories or parts thereof from which such consignments may be introduced into the Union. It also provides models of veterinary certificates to accompany those consignments.

(3) Currently, ungulates can only be imported into the Union from third countries, or in case of regionalisation parts of third countries, that are free of vesicular stomatitis for at least six months prior to dispatch of the animals.

(4) The United States requested to be authorised for imports into the Union of live pigs for breeding and production.

(5) Outbreaks of vesicular stomatitis have been notified by the United States. However those outbreaks are sporadic and limited to certain areas. The risk of introduction into the Union of vesicular stomatitis via imports of live pigs from that third country is negligible, if the biosecurity measures which are described in Chapter 8.15.6 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) are applied including confinement of the pigs during the pre-export residence period in premises free of the disease, vector protection during pre-export quarantine and transport to the place of loading and testing of all animals to be exported.

(6) Part 1 of Annex I to Regulation (EU) No 206/2010 should therefore be amended to add the United States to the list of third countries, territories or parts thereof from which consignments of live ungulates may be introduced into the Union indicating the appropriate guarantees as regards testing for vesicular stomatitis. The implementation of those guarantees should be confirmed in the veterinary certificate for live pigs for breeding and production accompanying the animals at the time of introduction into the Union.

(7) The model veterinary certificate for the import of live domestic porcine animals, 'POR-X', set out in Part 2 of Annex I to Regulation (EU) No 206/2010, should therefore be amended accordingly to introduce the conditions for pre-export residence and quarantine as well as the laboratory test requirements.

(8) In addition, Article 5 of Regulation (EU) No 206/2010 provides that where sampling and testing is required by the veterinary certificates set out in Annex I to that Regulation, they are to be carried out in conformity with the protocols for the standardisation of materials and testing procedures set out in Part 6 of that Annex. It is therefore necessary to amend Part 6 of Annex I to Regulation (EU) No 206/2010 in order to add the relevant protocol and testing procedure for vesicular stomatitis. The test should be carried out and interpreted in accordance with the protocols for serological tests for vesicular stomatitis prescribed for international trade in Chapter 2.1.19 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

(9) Regulation (EU) No 206/2010 should therefore be amended accordingly.

(10) 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. 321.
[2] OJ L 73, 20.3.2010, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 206/2010 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 4 February 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annex I to Regulation (EU) No 206/2010 is amended as follows:

(1) in Part 1, the following entry for the United States is added:

'US – United States	US-0	Whole country	POR-X	D'	

(2) Part 2 is amended as follows:

(a) the text concerning 'POR-X' is replaced by the following:

' "POR-X": Model of veterinary certificate for domestic porcine animals (Sus scrofa) intended for breeding and/or production after importation or intended for transit through the Union from one third country to another third country.'

(b) in the list of SG (Supplementary guarantees), the following text is added:

' "D": guarantees regarding vesicular stomatitis test on animals certified according to the model of veterinary certificate POR-X (point II.2.1(b)).'

(c) the model veterinary certificate 'POR-X' is replaced by the following:

'**Model POR-X**

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.			I.2. Certificate reference No	I.2.a.	
			I.3. Central competent authority		
			I.4. Local competent authority		
I.5. Consignee Name Address Postal code Tel.			I.6.		
I.7. Country of origin	ISO code	I.8. Region of origin / Code	I.9. Country of destination	ISO code	I.10. Region of destination / Code
I.11. Place of origin Name Address		Approval number	I.12.		
I.13. Place of loading Address		Approval number	I.14. Date of departure		
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references			I.16. Entry BIP in EU I.17.		
I.18. Description of commodity			I.19. Commodity code (HS code) **01.03**		
			I.20. Quantity		
I.21.			I.22. Number of packages		
I.23. Identification of container/seal number			I.24.		
I.25. Commodities certified for: Breeding ☐					
I.26.			I.27. For import or admission into EU ☐		

I.28. Identification of the commodities

Species (scientific name)	Identification system	Identification number	Age	Sex

COUNTRY **Model POR-X**

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

Part II: Certification

II.1. **Public Health Attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described in this certificate:

II.1.1. come from holdings which have been free from any official prohibition on health grounds, for the last 42 days in the case of brucellosis, for the last 30 days in the case of anthrax and for the past six months in the case of rabies and, the animals have not been in contact with animals from holdings which did not satisfy these conditions;

II.1.2. have not received:

— any stilbene or thyrostatic substances,

— oestrogenic, androgenic, gestagenic or **β**-agonist substances for purposes other than therapeutic or zootechnic treatment (as defined in Directive 96/22/EC).

II.2. **Animal Health attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described above meet the following requirements:

II.2.1. they come from the territory with code: ..... (1) which, at the date of issuing this certificate:

(2) *either* [(a) has been free for 24 months from foot-and-mouth disease, for 12 months from rinderpest, African swine fever, classical swine fever, swine vesicular disease and vesicular exanthema, and]

(2) *or* [(a) (i) has been free [for 24 months from foot-and-mouth disease] (2), for 12 months from rinderpest, African swine fever, vesicular exanthema, [classical swine fever] (2) and [swine vesicular disease] (2), and

(ii) has been considered free from [foot-and-mouth disease] (2), [classical swine fever] (2) and [swine vesicular disease] (2), since ..... (dd/mm/yyyy), without having had cases/outbreaks from that date, and authorised to export these animals by Commission Regulation (EU) No …/… of ..... (dd/mm/yyyy), and]

(2) *either* [(b) for 6 months from vesicular stomatitis, and]

(2) (9) *or* [(b) the animals have been kept for the 21 days, or since birth if younger than 21 days of age, prior to entering the pre-export quarantine in a holding in which no case of vesicular stomatitis was officially reported during that period and during the pre-export quarantine of not less than 30 days prior to shipment in a quarantine station protected from vector insects where they were subjected with negative results at a serum dilution of 1 in 32 to a virus neutralisation test for vesicular stomatitis carried out as referred to in Part 6 of Annex I to Regulation (EU) No 206/2010 on samples taken at least 21 days after commencement of the quarantine; and]

(c) where during the last 12 months, no vaccination against these diseases has been carried out and imports of domestic cloven-hoofed animals vaccinated against these diseases are not permitted;

II.2.2. they have remained in the territory described under point II.2.1 since birth, or for at least the last six months before dispatch to the Union and without contact with imported cloven-hoofed animals for the last 30 days;

II.2.3. they have remained in the holding(s) described under box reference I.11 since birth, or for at least 40 days prior to dispatch, and, during this period, in the holding(s) and in an area with a 10 km radius around the holding(s) of origin, there has been no case/outbreak of the diseases referred to in point II.2.1;

II.2.4. A they are not animals to be killed under a national programme for the eradication of diseases, nor have they been vaccinated against the diseases referred to in point II.2.1;

(2) (3) [II.2.4. B they have been subjected within the past 30 days to a test for swine vesicular disease antibodies and a test for classical swine fever antibodies with negative results in both cases;]

(2) (4) [II.2.4. C they have been subjected within the past 30 days to a buffered Brucella antigen test for porcine brucellosis with negative results;]

II.2.5 they come from herds which are not restricted under the national brucellosis eradication programme;

II.2.6 they are/were (2) dispatched from their holding(s) of origin, without passing through any market,

(2) *either* [directly to the Union,]

(2) *or* [to the officially authorised assembly centre described under box reference I.13 situated within the territory described under point II.2.1,]

COUNTRY **Model POR-X**

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

and, until dispatched to the Union:

(a) they did not come in contact with other cloven-hoofed animals not complying with the health requirements as described in this certificate, and

(b) they were not at any place where, or around which within a 10 km radius, during the previous 40 days there has been a case/outbreak of any of the diseases referred to in point II.2.1, and

(c) in the case the country has not been free for 6 months of vesicular stomatitis, they were transported to the place of loading protected from vector insects;

II.2.7. any transport vehicles or containers in which they were loaded were cleaned and disinfected before loading with an officially authorised disinfectant;

II.2.8. they were examined by an official veterinarian within 24 hours of loading and showed no clinical sign of disease;

II.2.9. they have been loaded for dispatch to the Union on ..... (dd/mm/yyyy) ([5]) in the means of transport described under box reference I.15 that were cleaned and disinfected before loading with an officially authorised disinfectant and so constructed that faeces, urine, litter or fodder could not flow or fall out of the vehicle or container during transportation.

II.3. **Animal transport attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described above have been treated before and at the time of loading in accordance with the relevant provisions of Regulation (EC) No 1/2005, in particular as regards watering and feeding, and they are fit for the intended transport.

([2]) ([6]) [II.4. **Specific requirements**

II.4.1. Aujeszky's disease is notifiable in the country referred to in box reference I.7;

II.4.2. according to official information, no clinical, pathological or serological evidence of Aujeszky's disease has been recorded for the last 12 months in the holding(s) of origin referred to in box reference I.11., and in those holdings situated in its vicinity within 5 km;

II.4.3. the animals referred to in box reference I.28:

(a) prior to dispatch for exportation, have remained since birth in the holding(s) of origin referred to in box reference I.11. or they have remained in this(ese) holdings(s) for the last 3 months and in others of equivalent status since birth,

(b) have been isolated in accommodation approved by the competent authority for the last 30 days immediately prior to dispatch for export, without direct or indirect contact with other Suidae animals,

(c) have been subjected to an ELISA test for the presence of Ig ([7]) on sera taken at least 21 days after entry into isolation, with negative results; and, all animals in isolation have also given negative results to this test, and

(d) have not been vaccinated against Aujeszky's disease and have not been in contact with vaccinated animals and the herd of origin has not been vaccinated during the previous 12 months.]

([2]) ([8]) [II.4.4. ..... (further requirements and/or tests)
.....]

Notes

This certificate is meant for live domestic porcine animals (*Sus scrofa*) intended for breeding or production.

After importation the animals must be conveyed without delay to the holding of destination where they shall remain for a minimum period of 30 days before further movement outside the holding, except in the case of animals dispatched directly to a slaughterhouse or of animals transiting the Union from one third country to another third country.

Part I:

— Box reference I.8: Provide the code of territory as appearing in Part 1 of Annex I to Regulation (EU) No 206/2010.

— Box reference I.13: The assembly centre, if any, must fulfil the conditions for its approval, as laid down in Part 5 of Annex I to Regulation (EU) No 206/2010.

COUNTRY **Model POR-X**

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

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the BIP of entry into the Union.

— Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) should be included.

— Box reference I.28.: *Identification system*: the animals must bear:

  — An individual number which permits tracing of their premises of origin. Specify the identification system (such as tag, tattoos, brand, chip, transponder).

  — An ear tag that includes the ISO code of the exporting country. The individual number must permit tracing of their premises of origin.

— Box reference I.28: *Age*: months.

— Box reference I.28.: *Sex* (M = male, F = female, C = castrated).

Part II:

([1]) Code of the territory as it appears in Part 1 of Annex I to Regulation (EU) No 206/2010.

([2]) Keep as appropriate.

([3]) Supplementary guarantees to be provided when required in column 5 'SG' of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry **'B'**.

([4]) Supplementary guarantees to be provided when required in column 5 'SG' of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry **'C'**.

([5]) Date of loading. Imports of these animals shall not be allowed when the animals were loaded either prior to the date of authorisation for exportation to the Union of the third country, territory or part thereof referred to in boxes I.7. and I.8., or during a period where restrictive measures have been adopted by the Union against imports of these animals from this third country, territory or part thereof.

([6]) When required by the EU Member State of destination or Switzerland, in accordance with Decision 2008/185/EC and the Agreement between the Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132) except for those countries with **'IX'** in column 6 'Specific conditions' of Part 1 of Annex I to Regulation (EU) No 206/2010.

([7]) To be carried out according to the standards laid down in Annex III to Decision 2008/185/EC. In the case of pigs aged over 4 months, the test used shall be the whole virus ELISA.

([8]) Further requirements requested by Finland in respect of transmissible gastro-enteritis.

([9]) Supplementary guarantees to be provided when required in column 5 'SG' of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry **'D'**.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

(3) in Part 6, the following text is added:

'Vesicular stomatitis (VS)

The virus neutralisation (VN) test shall be carried out in accordance with the testing protocols for vesicular stomatitis set out in Chapter 2.1.19 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

Sera that prevent cytopathic effect (CPE) at dilutions of 1 in 32 or greater shall be considered to contain antibodies to the vesicular stomatitis virus.'

COMMISSION IMPLEMENTING REGULATION (EU) No 103/2013

of 4 February 2013

amending Regulation (EC) No 786/2007 as regards the name of the holder of the authorisation of a preparation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1] and in particular Article 13(3) thereof,

Whereas:

(1) ChemGen Corp. has submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Regulation (EC) No 786/2007 [2] concerning the 10 year authorisation of a preparation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell), belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers'.

(2) The applicant claims that, with effect from 10 February 2012, ChemGen Corp. was acquired by Eli Lilly and Company Ltd which now owns the marketing rights for that additive. The applicant has submitted relevant data supporting its request.

(3) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.

(4) To allow Eli Lilly and Company Ltd to exploit its marketing rights it is necessary to change the terms of the authorisation.

(5) Regulation (EC) No 786/2007 should therefore be amended accordingly.

(6) Since safety reasons do not require the immediate application of the amendment made by this Regulation to Regulation (EC) No 786/2007, it is appropriate to provide for a transitional period during which existing stocks may be used up.

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

HAS ADOPTED THIS REGULATION:

Article 1

In column 2 of the Annex to Regulation (EC) No 786/2007 the words 'ChemGen Corp., represented by Disproquima S.L.' are replaced by 'Eli Lilly and Company Ltd'.

Article 2

Existing stocks of the additive which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

Article 3

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

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

Done at Brussels, 4 February 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 175, 5.7.2007, p. 8.

COMMISSION IMPLEMENTING REGULATION (EU) No 104/2013

of 4 February 2013

amending Regulation (EU) No 185/2010 as regards the screening of passengers and persons other than passengers by Explosive Trace Detection (ETD) equipment in combination with Hand Held Metal Detection (HHMD) equipment

(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 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 [1], and in particular Article 4(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 272/2009 of 2 April 2009 supplementing the common basic standards on civil aviation security laid down in the Annex to Regulation (EC) No 300/2008 of the European Parliament and of the Council [2] provides that the implementing rules to be adopted pursuant to Article 4(3) of Regulation (EC) No 300/2008 may allow the use of explosive trace detection (ETD) equipment and hand held metal detection (HHMD) equipment for screening of persons (passengers and persons other than passengers).

(2) Experience has shown that hand searches of passengers and persons other than passengers are not always the most efficient means of screening certain parts of the person, in particular where those parts are not readily accessible such as certain headgear, plaster casts or prosthesis.

(3) Trials have demonstrated the effectiveness of the combined use of ETD and HHMD in such cases. Moreover, the use of ETD and HHMD may facilitate the screening process and be experienced to be a less intrusive means of screening than a hand search, thus constituting an improvement in the experience of persons screened.

(4) It is thus useful and justified to allow these methods for screening of those parts of the person where a hand search is considered inefficient and/or undesirable such as certain headgear, plaster casts or prosthesis.

(5) This Regulation respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, notably the human dignity, the freedom of religion, the non-discrimination, the rights of persons with disabilities, and the right to liberty and security. In so far as it limits those rights and principles, such limitation is made genuinely to meet objectives of general interest and the need to protect the rights and freedoms of others, respecting the conditions laid down in Article 52 of the Charter. This Regulation must be applied in accordance with those rights and principles.

(6) Commission Regulation (EU) No 185/2010 [3] should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Civil Aviation Security set up by Article 19(1) of Regulation (EC) No 300/2008,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 185/2010 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 4 February 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 97, 9.4.2008, p. 72.
[2] OJ L 91, 3.4.2009, p. 7.
[3] OJ L 55, 5.3.2010, p. 1.

ANNEX

The Annex to Regulation (EU) No 185/2010 is amended as follows:

(1) letter (f) is added to point 1.3.1.1 as follows:

'(f) explosive trace detection (ETD) equipment combined with hand held metal detection (HHMD) equipment.';

(2) point 1.3.1.2 is replaced by the following:

'1.3.1.2. Points 4.1.1.3 – 4.1.1.6 and 4.1.1.10 – 4.1.1.11 shall apply to the screening of persons other than passengers.';

(3) letter (e) is added to point 4.1.1.2 as follows:

'(e) explosive trace detection (ETD) equipment combined with hand held metal detection (HHMD) equipment.';

(4) new point 4.1.1.11 with the following wording is added:

'4.1.1.11. Explosive trace detection (ETD) equipment in combination with hand held metal detection (HHMD) equipment may only be used in cases where the screener considers a hand search of a given part of the person to be inefficient and/or undesirable.'.

COMMISSION IMPLEMENTING REGULATION (EU) No 105/2013

of 4 February 2013

amending Implementing Regulation (EU) No 371/2011 as regards the name of the holder of the authorisation of dimethylglycine sodium salt

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1] and in particular Article 13(3) thereof,

Whereas:

(1) Taminco N.V. has submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Implementing Regulation (EU) No 371/2011 [2] concerning the 10 year authorisation of dimethylglycine sodium salt, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives'.

(2) The applicant claims that it transformed its legal form into a private limited liability company with effect from 1 October 2012. The applicant has submitted relevant data supporting its request.

(3) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.

(4) To allow the applicant to exploit its marketing rights under the name of Taminco BVBA it is necessary to change the terms of the authorisation.

(5) Implementing Regulation (EU) No 371/2011 should therefore be amended accordingly.

(6) Since safety reasons do not require the immediate application of the amendment made by this Regulation to Implementing Regulation (EU) No 371/2011, it is appropriate to provide for a transitional period during which existing stocks may be used up.

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

HAS ADOPTED THIS REGULATION:

Article 1

In column 2 of the Annex to Implementing Regulation (EU) No 371/2011 the words 'Taminco N.V.' are replaced by 'Taminco BVBA'.

Article 2

Existing stocks of the additive which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

Article 3

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

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

Done at Brussels, 4 February 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 102, 16.4.2011, p. 6.

COMMISSION IMPLEMENTING REGULATION (EU) No 106/2013

of 4 February 2013

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 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 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, 4 February 2013.

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	MA	47,6
	PS	160,8
	TN	74,1
	TR	116,6
	ZZ	99,8
0707 00 05	MA	124,7
	TR	170,3
	ZZ	147,5
0709 91 00	EG	113,1
	ZZ	113,1
0709 93 10	MA	52,7
	TR	157,3
	ZZ	105,0
0805 10 20	EG	52,3
	IL	64,5
	MA	64,2
	TN	46,0
	TR	66,3
	ZZ	58,7
0805 20 10	IL	130,2
	MA	91,5
	ZZ	110,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	153,7
	IL	121,2
	KR	135,0
	MA	110,6
	TR	77,9
	ZZ	119,7
0805 50 10	TR	69,5
	ZZ	69,5
0808 10 80	AR	86,6
	CN	92,2
	MK	30,8
	US	177,5
	ZZ	96,8
0808 30 90	CN	58,9
	TR	174,9
	US	140,7
	ZA	106,8
	ZZ	120,3

(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'.

GUIDELINES

GUIDELINE OF THE EUROPEAN CENTRAL BANK

of 23 January 2013

amending Guideline ECB/2012/18 on additional temporary measures relating to Eurosystem refinancing operations and eligibility of collateral

(ECB/2013/2)

(2013/74/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first indent of Article 127(2) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular the first indent of Article 3.1 and Articles 12.1, 14.3 and 18.2 thereof,

Whereas:

(1) Article 2 of Guideline ECB/2012/18 of 2 August 2012 on additional temporary measures relating to Eurosystem refinancing operations and eligibility of collateral [1] provides that the Eurosystem may decide that counterparties may reduce the amount of, or terminate, certain longer-term refinancing operations before maturity (such reduction of the amount or termination hereinafter also collectively referred to as 'early repayment'). Article 2 further specifies that the conditions for such early repayment are to be published in the announcement of the relevant tender or in another format deemed appropriate by the Eurosystem.

(2) The procedure applicable to the early repayment by counterparties should be further specified in order to ensure that the same conditions are applied by all national central banks of Member States whose currency is the euro (hereinafter the 'NCBs') in respect of early repayment. In particular, the financial penalties regime set out in Appendix 6 to Annex I to Guideline ECB/2011/14 of 20 September 2011 on monetary policy instruments and procedures of the Eurosystem [2] should apply where counterparties fail to settle, in full or in part, the amount to be repaid to the relevant NCB by the due date where they have opted for early repayment.

(3) Therefore, Guideline ECB/2012/18 should be amended accordingly,

HAS ADOPTED THIS GUIDELINE:

Article 1

Amendment

Article 2 of Guideline ECB/2012/18 is replaced by the following:

'Article 2

Option to reduce the amount of, or terminate longer-term refinancing operations

1. The Eurosystem may decide that, under certain conditions, counterparties may reduce the amount of, or terminate, certain longer-term refinancing operations before maturity (such reduction of the amount or termination hereinafter also collectively referred to as "early repayment"). The tender announcement shall specify whether the option to reduce the amount of, or terminate, the operations in question before maturity applies, as well as the date from when such option may be exercised. This information may alternatively be provided in another format deemed appropriate by the Eurosystem.

2. A counterparty may exercise the option to reduce the amount of, or terminate, longer-term refinancing operations before maturity by notifying the relevant NCB of the amount it intends to repay under the early repayment procedure, as well as of the date on which it intends to make such early repayment, at least one week in advance of that early repayment date. Unless otherwise specified by the Eurosystem, an early repayment may be effected on any day that coincides with the settlement day of a Eurosystem main refinancing operation, provided that the counterparty makes the notification referred to in this paragraph at least one week in advance of that date.

3. The notification referred to in paragraph 2 shall become binding on the counterparty one week before the early repayment date it refers to. Failure by the counterparty to settle, in full or in part, the amount due under the early repayment procedure by the due date may result in the imposition of a financial penalty as set out in Section 1 of Appendix 6 to Annex I to Guideline ECB/2011/14. The provisions of Section 1 of Appendix 6 which apply to infringements of rules related to tender operations shall

[1] OJ L 218, 15.8.2012, p. 20.
[2] OJ L 331, 14.12.2011, p. 1.

apply where a counterparty fails to settle, in full or in part, the amount due on the early repayment date referred to in paragraph 2. The imposition of a financial penalty shall be without prejudice to the NCB's right to exercise the remedies provided for on the occurrence of an event of default as set out in Annex II to Guideline ECB/2011/14.'.

Article 2

Taking effect and implementation

1. This Guideline shall take effect on the day of its notification to the NCBs.

2. The NCBs shall take the necessary measures to comply with this Guideline and apply them from 7 March 2013. They shall notify the ECB of the texts and means relating to those measures by 21 February 2013 at the latest.

Article 3

Addressees

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 23 January 2013.

For the Governing Council of the ECB
The President of the ECB
Mario DRAGHI

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