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Contents

II *Non-legislative acts*

REGULATIONS

★ **Council Regulation (EU) No 401/2013 of 2 May 2013 concerning restrictive measures in respect of Myanmar/Burma and repealing Regulation (EC) No 194/2008** 1

★ **Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009** [1] 8

★ **Commission Implementing Regulation (EU) No 403/2013 of 2 May 2013 concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 (holder of authorisation DSM Nutritional Products)** [1] 26

★ **Commission Implementing Regulation (EU) No 404/2013 of 2 May 2013 on the derogations from the rules of origin laid down in Annex II to the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, that apply within quotas for certain products from Peru** 30

★ **Commission Implementing Regulation (EU) No 405/2013 of 2 May 2013 opening and providing for the administration of Union tariff quotas for agricultural products originating in Peru** ... 35

(Continued overleaf)

Price: EUR 3

[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.

★ **Commission Implementing Regulation (EU) No 406/2013 of 2 May 2013 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance prednisolone** [1] 42

★ **Commission Regulation (EU) No 407/2013 of 23 April 2013 correcting the Spanish and the Swedish versions of Regulation (EU) No 475/2012 amending Regulation (EC) No 1126/2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council as regards International Accounting Standard (IAS) 1 and International Accounting Standard (IAS) 19** [1] 44

Commission Implementing Regulation (EU) No 408/2013 of 2 May 2013 establishing the standard import values for determining the entry price of certain fruit and vegetables 45

Notice to readers — Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* 47

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) No 401/2013

of 2 May 2013

concerning restrictive measures in respect of Myanmar/Burma and repealing Regulation (EC) No 194/2008

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215 thereof,

Having regard to Council Decision 2013/184/CFSP of 22 April 2013 concerning restrictive measures against Myanmar/Burma [1],

Having regard to the joint proposal from the High Representative of the Union for Foreign Affairs and Security Policy and the Commission,

Whereas:

(1) Regulation (EC) No 194/2008 of 25 February 2008 renewing and strengthening the restrictive measures in respect of Burma/Myanmar [2] provides for certain measures to be taken in relation to Myanmar/Burma, including restrictions on certain exports from Myanmar/Burma and a freezing of the assets of certain individuals and entities.

(2) By Decision 2013/184/CFSP, the Council agreed, as a means of encouraging positive changes to continue, that all those restrictive measures should be lifted, with the exception of the arms embargo and the embargo on equipment which might be used for internal repression.

(3) Council Regulation (EC) No 194/2008 should therefore be repealed, and certain of its provisions replaced by this Regulation.

(4) In order to ensure that the measures provided for in this Regulation are effective, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the following definitions apply:

(1) 'import' means any entry of goods into the customs territory of the Union or other territories to which the Treaty applies, under the conditions laid down in Articles 349 and 355 thereof. It includes, within the meaning of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [3], placing in a free zone or free warehouse, placing under a suspensive procedure and release for free circulation, but it excludes transit and temporary storage;

(2) 'export' means any departure of goods from the customs territory of the Union or other territories to which the Treaty applies, under the conditions laid down in Articles 349 and 355 thereof. It includes, within the meaning of Regulation (EEC) No 2913/92, the departure of goods that requires a customs declaration and the departure of goods after their storage in a free zone of control type I or free warehouse, but it excludes transit;

(3) 'exporter' means any natural or legal person on whose behalf an export declaration is made, being the person who, at the time when the declaration is accepted, holds the contract with the consignee in the third country and has the power for determining the sending of the item out of the customs territory of the Union or other territories to which the Treaty applies;

(4) 'technical assistance' means any technical support related to repairs, development, manufacture, assembly, testing, maintenance, or any other technical service, and may take such forms as instruction, advice, training, transmission of working knowledge or skills or consulting services; technical assistance shall include verbal forms of assistance;

(5) 'territory of the Union' means the territories to which the Treaty is applicable, under the conditions laid down in the Treaty.

[1] OJ L 111, 23.4.2013, p. 75.
[2] OJ L 66, 10.3.2008, p. 1.
[3] OJ L 302, 19.10.1992, p. 1.

CHAPTER 1

Article 2

1. It shall be prohibited to sell, supply, transfer or export, directly or indirectly, equipment which might be used for internal repression as listed in Annex I, whether or not originating in the Union, to any natural or legal person, entity or body in, or for use in Myanmar/Burma.

2. Paragraph 1 shall not apply to protective clothing, including flak jackets and helmets, temporarily exported to Myanmar/Burma by United Nations personnel, personnel of the European Union or its Member States, representatives of the media and humanitarian and development workers and associated personnel for their personal use only.

Article 3

1. It shall be prohibited:

(a) to provide technical assistance related to military activities and to the provision, manufacture, maintenance and use of arms and related materiel of all types, including weapons and ammunition, military vehicles and equipment, paramilitary equipment, and spare parts for the aforementioned, directly or indirectly to any natural or legal person, entity or body in, or for use in Myanmar/Burma;

(b) to provide financing or financial assistance related to military activities, including, in particular, grants, loans and export credit insurance for any sale, supply, transfer or export of arms and related materiel, directly or indirectly to any natural or legal person, entity or body in, or for use in Myanmar/Burma.

2. It shall be prohibited:

(a) to provide technical assistance related to the equipment which might be used for internal repression as listed in Annex I, directly or indirectly to any natural or legal person, entity or body in, or for use in Myanmar/Burma;

(b) to provide financing or financial assistance related to the equipment listed in Annex I, including, in particular, grants, loans and export credit insurance, directly or indirectly to any natural or legal person, entity or body in, or for use in Myanmar/Burma.

3. It shall be prohibited to participate, knowingly and intentionally, in activities the object or effect of which is to circumvent the prohibitions referred to in paragraphs 1 and 2.

4. The prohibitions set out in paragraphs 1(b) and 2(b) shall not give rise to liability of any kind on the part of the natural or legal persons or entities concerned, if they did not know, and had no reasonable cause to suspect, that their actions would infringe those prohibitions.

Article 4

1. By way of derogation from Articles 2(1) and 3(2), and subject to Article 5, the competent authorities in the Member States, as indicated in the websites listed in Annex II, may authorise, under such conditions as they deem appropriate:

(a) the sale, supply, transfer or export of equipment which might be used for internal repression as listed in Annex I, intended solely for humanitarian or protective use, or for institution-building programmes of the United Nations and the European Union, or for European Union and United Nations crisis-management operations;

(b) the sale, supply, transfer or export of de-mining equipment and material for use in de-mining operations; and

(c) the provision of financing and financial assistance and technical assistance related to equipment, material, programmes and operations referred to in points (a) and (b).

2. By way of derogation from Article 3(1), and subject to Article 5, the competent authorities in the Member States, as listed in Annex II, may authorise, under such conditions as they deem appropriate, the provision of financing and financial assistance and technical assistance related to:

(a) non-lethal military equipment intended solely for humanitarian or protective use, or for institution-building programmes of the United Nations and the European Union;

(b) materiel intended for European Union and United Nations crisis-management operations.

CHAPTER 2

Article 5

The authorisations referred to in Article 4 shall not be granted for activities that have already taken place.

Article 6

The Commission and Member States shall immediately inform each other of the measures taken under this Regulation and shall supply each other with any other relevant information at their disposal in connection with this Regulation, in particular information in respect of violation and enforcement problems and judgments handed down by national courts.

Article 7

The Commission shall be empowered to amend Annex II on the basis of information supplied by Member States.

Article 8

1. Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

2. Member States shall notify the Commission of those rules without delay after the entry into force of this Regulation and shall notify it of any subsequent amendment.

Article 9

1. Member States shall designate the competent authorities referred to in this Regulation and identify them in, or through, the websites listed in Annex II.

2. Member States shall notify the Commission of their competent authorities without delay after the entry into force of this Regulation and shall notify it of any subsequent changes.

Article 10

This Regulation shall apply:

(a) within the territory of the Union, including its airspace;

(b) on board any aircraft or any vessel under the jurisdiction of a Member State;

(c) to any person inside or outside the territory of the Union who is a national of a Member State;

(d) to any legal person, entity or body which is incorporated or constituted under the law of a Member State;

(e) to any legal person, entity or body in respect of any business done in whole or in part within the Union.

Article 11

Regulation (EC) No 194/2008 is hereby repealed.

Article 12

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

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

Done at Brussels, 2 May 2013.

For the Council
The President
E. GILMORE

ANNEX I

List of equipment which might be used for internal repression as referred to in Articles 2, 3 and 4

1. Firearms, ammunition and related accessories therefor, as follows:

   1.1. Firearms not controlled by ML 1 and ML 2 of the EU Common Military List [1];

   1.2. Ammunition specially designed for the firearms listed in 1.1 and specially designed components therefor;

   1.3. Weapon-sights not controlled by the EU Common Military List.

2. Bombs and grenades not controlled by the EU Common Military List.

3. Vehicles as follows:

   3.1. Vehicles equipped with a water cannon, specially designed or modified for the purpose of riot control;

   3.2. Vehicles specially designed or modified to be electrified to repel borders;

   3.3. Vehicles specially designed or modified to remove barricades, including construction equipment with ballistic protection;

   3.4. Vehicles specially designed for the transport or transfer of prisoners and/or detainees;

   3.5. Vehicles specially designed to deploy mobile barriers;

   3.6. Components for the vehicles specified in 3.1 to 3.5 specially designed for the purposes of riot control.

   Note 1: This item does not control vehicles specially designed for the purposes of fire-fighting.

   Note 2: For the purposes of item 3.5 the term 'vehicles' includes trailers.

4. Explosive substances and related equipment as follows:

   4.1. Equipment and devices specially designed to initiate explosions by electrical or non-electrical means, including firing sets, detonators, igniters, boosters and detonating cord, and specially designed components therefor; except those specially designed for a specific commercial use consisting of the actuation or operation by explosive means of other equipment or devices the function of which is not the creation of explosions (e.g., car air-bag inflaters, electric-surge arresters of fire sprinkler actuators);

   4.2. Linear cutting explosive charges not controlled by the EU Common Military List;

   4.3. Other explosives not controlled by the EU Common Military List and related substances as follows:

      (a) amatol;

      (b) nitrocellulose (containing more than 12,5 % nitrogen);

      (c) nitroglycol;

      (d) pentaerythritol tetranitrate (PETN);

      (e) picryl chloride;

      (f) 2,4,6-trinitrotoluene (TNT).

5. Protective equipment not controlled by ML 13 of the EU Common Military List as follows:

   5.1. Body armour providing ballistic and/or stabbing protection;

   5.2. Helmets providing ballistic and/or fragmentation protection, anti-riot helmets, antiriot shields and ballistic shields.

   Note: This item does not control:

   — equipment specially designed for sports activities;

   — equipment specially designed for safety of work requirements.

[1] Common Military List of the European Union (adopted by the Council on 11 March 2013) (OJ C 30, 27.3.2013, p. 1).

6. Simulators, other than those controlled by ML 14 of the EU Common Military List, for training in the use of firearms, and specially designed software therefor.

7. Night vision, thermal imaging equipment and image intensifier tubes, other than those controlled by the EU Common Military List.

8. Razor barbed wire.

9. Military knives, combat knives and bayonets with blade lengths in excess of 10 cm.

10. Production equipment specially designed for the items specified in this list.

11. Specific technology for the development, production or use of the items specified in this list.

ANNEX II

Websites for information on the competent authorities referred to in Articles 4, 7 and 9 and address for notifications to the European Commission

BELGIUM

http://www.diplomatie.be/eusanctions

BULGARIA

http://www.mfa.bg/en/pages/135/index.html

CZECH REPUBLIC

http://www.mfcr.cz/mezinarodnisankce

DENMARK

http://um.dk/da/politik-og-diplomati/retsorden/sanktioner/

GERMANY

http://www.bmwi.de/DE/Themen/Aussenwirtschaft/aussenwirtschaftsrecht,did=404888.html

ESTONIA

http://www.vm.ee/est/kat_622/

IRELAND

http://www.dfa.ie/home/index.aspx?id=28519

GREECE

http://www.mfa.gr/en/foreign-policy/global-issues/international-sanctions.html

SPAIN

http://www.maec.es/es/MenuPpal/Asuntos/Sanciones%20Internacionales/Paginas/Sanciones_%20Internacionales.aspx

FRANCE

http://www.diplomatie.gouv.fr/autorites-sanctions/

ITALY

http://www.esteri.it/MAE/IT/Politica_Europea/Deroghe.htm

CYPRUS

http://www.mfa.gov.cy/sanctions

LATVIA

http://www.mfa.gov.lv/en/security/4539

LITHUANIA

http://www.urm.lt/sanctions

LUXEMBOURG

http://www.mae.lu/sanctions

HUNGARY

http://www.kulugyminiszterium.hu/kum/hu/bal/Kulpolitikank/nemzetkozi_szankciok/

MALTA

http://www.doi.gov.mt/EN/bodies/boards/sanctions_monitoring.asp

NETHERLANDS

http://www.rijksoverheid.nl/onderwerpen/internationale-vrede-en-veiligheid/sancties

AUSTRIA

http://www.bmeia.gv.at/view.php3?f_id=12750&LNG=en&version=

POLAND

http://www.msz.gov.pl

PORTUGAL

http://www.min-nestrangeiros.pt

ROMANIA

http://www.mae.ro/node/1548

SLOVENIA

http://www.mzz.gov.si/si/zunanja_politika_in_mednarodno_pravo/zunanja_politika/mednarodna_varnost/omejevalni_ukrepi/

SLOVAKIA

http://www.mzv.sk/sk/europske_zalezitosti/sankcie_eu-sankcie_eu

FINLAND

http://formin.finland.fi/kvyhteistyo/pakotteet

SWEDEN

http://www.ud.se/sanktioner

UNITED KINGDOM

http://www.fco.gov.uk/competentauthorities

Address for notifications to the European Commission:

European Commission
Service for Foreign Policy Instruments (FPI)
EEAS 02/309
B-1049 Brussels
Belgium
E-mail: relex-sanctions@ec.europa.eu

COMMISSION IMPLEMENTING REGULATION (EU) No 402/2013

of 30 April 2013

on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) ([1]), and in particular Article 6(4) thereof,

Whereas:

(1) In accordance with Directive 2004/49/EC, common safety methods (CSMs) should be gradually introduced to ensure that a high level of safety is maintained and, when and where necessary and reasonably practicable, improved.

(2) On 12 October 2010 the Commission issued a mandate to the European Railway Agency (the 'Agency') in accordance with Directive 2004/49/EC to revise Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council ([2]). The revision should cover the results of the analysis by the Agency under Article 9(4) of the Regulation of the overall effectiveness of the CSM for risk evaluation and assessment and experience with its application as well as further developments in the roles and the responsibilities of the assessment body referred to in Article 6 of that Regulation. The revision should also include the qualification requirements (by developing a recognition/accreditation scheme) for the assessment body according to its role in the CSM, with a view to improving clarity in order to avoid differences in application across the Member States, taking into account the interfaces with existing Union authorisation/certification procedures in the railway sector. If feasible, the revision of Regulation (EC) No 352/2009 should also cover further developments in risk acceptance criteria that could be used to assess the acceptability of a risk during explicit risk estimation and evaluation. The Agency submitted its recommendation on the revision of the CSM to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on that Agency recommendation.

(3) In accordance with Directive 2004/49/EC the basic elements for the safety management system should include procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change in operating conditions or new material imposes new risks on the infrastructure or on operations. That basic element of the safety management system is covered by this Regulation.

(4) Article 14a(3) of Directive 2004/49/EC requires entities in charge of maintenance to establish a system of maintenance in order to ensure that the vehicles for which they are in charge of maintenance are in a safe state of running. To manage changes in equipment, procedures, organisation, staffing or interfaces, the entities in charge of maintenance should have in place risk assessment procedures. That requirement for the system of maintenance is also covered by this Regulation.

(5) As a consequence of the application of Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways ([3]) and of Article 9(2) of Directive 2004/49/EC, particular attention should be paid to risk management at the interfaces between the actors which are involved in the application of this Regulation.

(6) Article 15 of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community ([4]) requires Member States to take all appropriate steps to ensure that the structural subsystems constituting the rail system may be placed in service only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them when integrated into the rail system. In particular, the Member States must check the technical compatibility of these subsystems with the railway system into which they are being integrated and the safe integration of these subsystems in accordance with the scope of this Regulation.

(7) The absence of a common approach for specifying and demonstrating compliance with safety levels and requirements of the railway system among the Member

([1]) OJ L 164, 30.4.2004, p. 44.
([2]) OJ L 108, 29.4.2009, p. 4.
([3]) OJ L 237, 24.8.1991, p. 25.
([4]) OJ L 191, 18.7.2008, p. 1.

States has proved to be one of the obstacles to liberalisation of the railway market. Such a common approach should be established through this Regulation.

(8) To facilitate mutual recognition between Member States, the methods used for identifying and managing risks and the methods for demonstrating that the railway system in the territory of the Union conforms to safety requirements should be harmonised among the actors involved in the development and operation of the railway system. As a first step, it is necessary to harmonise the procedures and methods for carrying out risk evaluation and implementing control measures whenever a change in operating conditions or new material imposes new risks on the infrastructure or on operations, as referred to in point (2)(d) of Annex III to Directive 2004/49/EC.

(9) If there is no existing notified national rule for defining whether or not a change is significant for the safety in a Member State, the company or organisation in charge of implementing the change (the 'proposer') should initially consider the potential impact of the change in question on the safety of the railway system. If the proposed change has an impact on safety, the proposer should assess, by expert judgement, the significance of the change based on a set of criteria that should be set out in this Regulation. This assessment should lead to one of three conclusions. In the first situation the change is not considered to be significant and the proposer should implement the change by applying its own safety method. In the second situation the change is considered to be significant and the proposer should implement the change by applying this Regulation, without the need for a specific intervention of the national safety authority. In the third situation the change is considered to be significant but there are provisions at the level of the European Union which require a specific intervention of the relevant national safety authority, such as a new authorisation for placing in service of a vehicle or a revision/update of the safety certificate of a railway undertaking or a revision/update of the safety authorisation of an infrastructure manager.

(10) Whenever the railway system already in use is subject to a change, the significance of the change should also be assessed taking into account all safety-related changes affecting the same part of the system since the entry into force of this Regulation or since the last application of the risk management process set out in this Regulation, whichever is the latest. The purpose is to assess whether or not the totality of such changes amounts to a significant change requiring the full application of the CSM for risk evaluation and assessment.

(11) The risk acceptability of a significant change should be evaluated by using one or more of the following risk acceptance principles: the application of codes of practice, a comparison with similar parts of the railway system, or an explicit risk estimation. All principles have been used successfully in a number of railway applications, as well as in other transport modes and other industries. The 'explicit risk estimation' principle is frequently used for complex or innovative changes. The proposer should be responsible for the choice of the principle to apply.

(12) When a widely recognised code of practice is applied, it should therefore be possible to reduce the impact of applying the CSM, in accordance with the principle of proportionality. In the same way, where there are provisions at the level of the Union which require specific intervention by the national safety authority, that authority should be allowed to act as the independent assessment body in order to reduce double checking, undue costs to the industry and time to market.

(13) To report to the Commission on the effectiveness and application of this Regulation, and where applicable to make recommendations to improve it, the Agency should be able to gather relevant information from the various actors involved, including from the national safety authorities, from the certification bodies of entities in charge of maintenance of freight wagons and from other entities in charge of maintenance that do not fall within the scope of Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons [1].

(14) Accreditation of an assessment body should normally be granted by the national accreditation body which has exclusive competence to assess if the assessment body meets the requirements set by harmonised standards. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [2] contains detailed provisions on the competence of such national accreditation bodies.

(15) Where harmonised Union legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means to carry out this evaluation themselves. In such cases, the Member State should provide the Commission and the other Member States with all the documentary evidence necessary for verification of the competence of the recognition body it selects for implementation of the Union legislation. In order to achieve a similar level of quality and trust as expected through accreditation, the

[1] OJ L 122, 11.5.2011, p. 22.
[2] OJ L 218, 13.8.2008, p. 30.

requirements and rules for the evaluation and surveillance of assessment bodies in the case of recognition should be equivalent to those used for accreditation.

(16) An independent and competent external or internal individual, organisation or entity, a national safety authority, a notified body or a body designated according to Article 17 of Directive 2008/57/EC could act as an assessment body provided it fulfils the criteria required in Annex II.

(17) Recognition of internal assessment bodies in compliance with this Regulation does not require an immediate revision of already delivered safety certificates to railway undertakings, safety authorisations to infrastructure managers and certificates to entities in charge of maintenance. Their revision can be made at the next application for renewal or update of the safety certificate, safety authorisation or certificate of the entity in charge of maintenance.

(18) In existing legislation there are no limits in the number of assessment bodies accredited or recognised in each Member State and there are no obligations to have at least one. Where the assessment body is not already designated by existing Union or national legislation, the proposer may appoint any assessment body in the Union or in a third country accredited under equivalent criteria and meeting equivalent requirements to those contained in this regulation. The Member State should be able to use accreditation or recognition or any combination of these two options.

(19) Regulation (EC) No 352/2009 has become obsolete and should therefore be replaced by this Regulation.

(20) In view of the new requirements introduced by the present Regulation in terms of accreditation and recognition of the assessment body, the implementation of this Regulation should be deferred in order to give sufficient time to the actors concerned to put in place and implement this new common approach.

(21) The measures provided for in this Regulation are in accordance with the opinion of the Committee established in accordance with Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

1. This Regulation establishes a revised common safety method (CSM) for risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC.

2. This Regulation shall facilitate the access to the market for rail transport services through harmonisation of:

(a) the risk management processes used to assess the impact of changes on safety levels and compliance with safety requirements;

(b) the exchange of safety-relevant information between different actors within the rail sector in order to manage safety across the different interfaces which may exist within this sector;

(c) the evidence resulting from the application of a risk management process.

Article 2

Scope

1. This Regulation shall apply to the proposer as defined in Article 3(11) when making any change to the railway system in a Member State.

Such changes may be of a technical, operational or organisational nature. As regards organisational changes, only those changes which could impact the operational or maintenance processes shall be subjected to consideration under the rules of Article 4.

2. When, on the basis of an assessment under the criteria set out in Article 4(2)(a) to (f):

(a) the change is considered significant, the risk management process set out in Article 5 shall be applied;

(b) the change is considered not significant, keeping adequate documentation to justify the decision shall be sufficient.

3. This Regulation shall apply also to structural sub-systems to which Directive 2008/57/EC applies:

(a) if a risk assessment is required by the relevant technical specification for interoperability (TSI); in this case the TSI shall, where appropriate, specify which parts of this Regulation apply;

(b) if the change is significant as set out in Article 4(2), the risk management process set out in Article 5 shall be applied within the placing in service of structural sub-systems to ensure their safe integration into an existing system, by virtue of Article 15(1) of Directive 2008/57/EC.

4. The application of this Regulation in the case referred to in paragraph 3(b) of this Article shall not lead to requirements contradictory to those laid down in the relevant TSIs. If such contradictions occur, the proposer shall inform the Member State concerned which may then decide to ask for a revision of the TSI in accordance with Article 6(2) or Article 7 of Directive 2008/57/EC or a derogation in accordance with Article 9(2) of that Directive.

5. The railway systems excluded from the scope of Directive 2004/49/EC according to its Article 2(2) are excluded from the scope of this Regulation.

6. The provisions of Regulation (EC) No 352/2009 shall continue to apply in relation to projects which are at an advanced stage of development within the meaning of Article 2(t) of Directive 2008/57/EC at the date of application of this Regulation.

Article 3

Definitions

For the purpose of this Regulation the definitions in Article 3 of Directive 2004/49/EC apply.

The following definitions also apply:

(1) 'risk' means the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm;

(2) 'risk analysis' means systematic use of all available information to identify hazards and to estimate the risk;

(3) 'risk evaluation' means a procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved;

(4) 'risk assessment' means the overall process comprising a risk analysis and a risk evaluation;

(5) 'safety' means freedom from unacceptable risk of harm;

(6) 'risk management' means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;

(7) 'interfaces' means all points of interaction during a system or subsystem life cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;

(8) 'actors' means all parties which are, directly or through contractual arrangements, involved in the application of this Regulation;

(9) 'safety requirements' means the safety characteristics (qualitative or quantitative) of a system and its operation (including operational rules) and maintenance necessary in order to meet legal or company safety targets;

(10) 'safety measures' means a set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk;

(11) 'proposer' means one of the following:

(a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC;

(b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive 2004/49/EC;

(c) a contracting entity or a manufacturer which invites a notified body to apply the 'EC' verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;

(d) an applicant for an authorisation for the placing in service of structural sub-systems;

(12) 'safety assessment report' means the document containing the conclusions of the assessment performed by an assessment body on the system under assessment;

(13) 'hazard' means a condition that could lead to an accident;

(14) 'assessment body' means the independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements;

(15) 'risk acceptance criteria' means the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further;

(16) 'hazard record' means the document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced;

(17) 'hazard identification' means the process of finding, listing and characterising hazards;

(18) 'risk acceptance principle' means the rules used in order to arrive at the conclusion whether or not the risk related to one or more specific hazards is acceptable;

(19) 'code of practice' means a written set of rules that, when correctly applied, can be used to control one or more specific hazards;

(20) 'reference system' means a system proven in use to have an acceptable safety level and against which the acceptability of the risks from a system under assessment can be evaluated by comparison;

(21) 'risk estimation' means the process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration;

(22) 'technical system' means a product or an assembly of products including the design, implementation and support documentation; the development of a technical system starts with its requirements specification and ends with its acceptance; although the design of relevant interfaces with human behaviour is considered, human operators and their actions are not included in a technical system; the maintenance process is described in the maintenance manuals but is not itself part of the technical system;

(23) 'catastrophic consequence' means fatalities and/or multiple severe injuries and/or major damage to the environment resulting from an accident;

(24) 'safety acceptance' means status given to the change by the proposer based on the safety assessment report provided by the assessment body;

(25) 'system' means any part of the railway system which is subjected to a change whereby the change may be of a technical, operational or organisational nature;

(26) 'notified national rule' means any national rule notified by Member States under Council Directive 96/48/EC [1] or, Directive 2001/16/EC of the European Parliament and of the Council [2] and Directives 2004/49/EC and 2008/57/EC;

(27) 'certification body' means a certification body as defined in Article 3 of Regulation (EU) No 445/2011;

(28) 'conformity assessment body' means a conformity assessment body as defined in Article 2 of Regulation (EC) No 765/2008;

(29) 'accreditation' means accreditation as defined in Article 2 of Regulation (EC) No 765/2008;

(30) 'national accreditation body' means a national accreditation body as defined in Article 2 of Regulation (EC) No 765/2008;

(31) 'recognition' means an attestation by a national body other than the national accreditation body that the assessment body meets the requirements set out in Annex II to this Regulation to carry out the independent assessment activity specified in Article 6(1) and (2).

Article 4

Significant changes

1. If there is no notified national rule for defining whether a change is significant or not in a Member State, the proposer shall consider the potential impact of the change in question on the safety of the railway system.

If the proposed change has no impact on safety, the risk management process described in Article 5 need not be applied.

2. If the proposed change has an impact on safety, the proposer shall decide, by expert judgement, on the significance of the change based on the following criteria:

(a) failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system under assessment;

(b) novelty used in implementing the change: this concerns both what is innovative in the railway sector, and what is new for the organisation implementing the change;

(c) complexity of the change;

(d) monitoring: the inability to monitor the implemented change throughout the system life-cycle and intervene appropriately;

(e) reversibility: the inability to revert to the system before the change;

(f) additionality: assessment of the significance of the change taking into account all recent safety-related changes to the system under assessment and which were not judged to be significant.

3. The proposer shall keep adequate documentation to justify its decision.

Article 5

Risk management process

1. The proposer shall be responsible for applying this Regulation, including the assessment of the significance of the change based on the criteria in Article 4, and for conducting the risk management process set out in Annex I.

2. The proposer shall ensure that risks introduced by its suppliers and its service providers, including their subcontractors, are also managed in compliance with this Regulation. To this end, the proposer may require through contractual arrangements that its suppliers and its service providers, including their subcontractors, participate in the risk management process set out in Annex I.

Article 6

Independent assessment

1. An assessment body shall carry out an independent assessment of the suitability of both the application of the risk management process as set out in Annex I and of its results. This assessment body shall meet the criteria listed in Annex II. Where the assessment body is not already designated by existing Union or national legislation, the proposer shall appoint its own assessment body at the earliest appropriate stage of the risk assessment process.

2. To perform the independent assessment, the assessment body shall:

(a) ensure it has a thorough understanding of the significant change based on the documentation provided by the proposer;

(b) conduct an assessment of the processes used for managing safety and quality during the design and implementation of the significant change, if those processes are not already certified by a relevant conformity assessment body;

(c) conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change.

Having completed its assessment in accordance with points (a), (b) and (c), the assessment body shall deliver the safety assessment report provided for in Article 15 and Annex III.

3. Duplication of work between the following assessments shall be avoided:

(a) the assessment of conformity of the safety management system and of the system of maintenance of entities in charge of maintenance as required by Directive 2004/49/EC; and

(b) the conformity assessment carried out by a notified body as defined by Article 2(j) of Directive 2008/57/EC or a body designated in accordance with Article 17 of that Directive; and

[1] OJ L 235, 17.9.1996, p. 6.
[2] OJ L 110, 20.4.2001, p. 1.

(c) any independent assessment carried out by the assessment body in accordance with this Regulation.

4. Without prejudice to Union legislation, the proposer may choose the national safety authority as assessment body where that national safety authority offers this service and where the significant changes concern the following cases:

(a) a vehicle needs an authorisation for placing in service, as referred to in Articles 22(2) and 24(2) of Directive 2008/57/EC;

(b) a vehicle needs an additional authorisation for placing in service, as referred to in Articles 23(5) and 25(4) of Directive 2008/57/EC;

(c) the safety certificate has to be updated due to alteration of the type or extent of the operation, as referred to in Article 10(5) of Directive 2004/49/EC;

(d) the safety certificate has to be revised due to substantial changes to the safety regulatory framework, as referred to in Article 10(5) of Directive 2004/49/EC;

(e) the safety authorisation has to be updated due to substantial changes to the infrastructure, signalling or energy supply, or to the principles of their operation and maintenance, as referred to in Article 11(2) of Directive 2004/49/EC;

(f) the safety authorisation has to be revised due to substantial changes to the safety regulatory framework, as referred to in Article 11(2) of Directive 2004/49/EC.

Where a significant change concerns a structural subsystem that needs an authorisation for placing in service as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC, the proposer may choose the national safety authority as assessment body, where that national safety authority offers this service, unless the proposer has already given that task to a notified body in accordance with Article 18(2) of that Directive.

Article 7

Accreditation/recognition of the assessment body

The assessment body provided for in Article 6 shall be either:

(a) accredited by the national accreditation body referred to in Article 13(1) using the criteria defined in Annex II; or

(b) recognised by the recognition body referred to in Article 13(1) using the criteria defined in Annex II; or

(c) the national safety authority under the requirement of Article 9(2).

Article 8

Acceptance of accreditation/recognition

1. When granting the safety certificate or the safety authorisation in accordance with Commission Regulation (EU) No 1158/2010 [1] or Commission Regulation (EU) No 1169/2010 [2], a national safety authority shall accept accreditation or recognition by a Member State in accordance with Article 7, as proof of the ability of the railway undertaking or infrastructure manager to act as an assessment body.

2. When granting the certificate to an entity in charge of maintenance in accordance with Regulation (EU) No 445/2011, the certification body shall accept such accreditation or recognition by a Member State, as proof of the ability of the entity in charge of maintenance to act as assessment body.

Article 9

Types of recognition of the assessment body

1. The following types of recognition of the assessment body may be used:

(a) recognition by the Member State of an entity in charge of maintenance, an organisation or a part of it or an individual;

(b) recognition by the national safety authority of the ability of an organisation or a part of it or an individual to conduct independent assessment through the assessment and supervision of the safety management system of a railway undertaking or an infrastructure manager;

(c) when the national safety authority is acting as certification body in conformity with Article 10 of Regulation (EU) No 445/2011, recognition by the national safety authority of the ability of an organisation or a part of it or an individual to conduct independent assessment through assessment and surveillance of the system of maintenance of an entity in charge of maintenance;

(d) recognition by a recognition body designated by the Member State of the ability of an entity in charge of maintenance, an organisation or a part of it or an individual to conduct independent assessment.

2. When the Member State recognises the national safety authority as an assessment body, it is the responsibility of that Member State to ensure that the national safety authority fulfills the requirements set out in Annex II; In this case, the assessment body functions of the national safety authority shall be demonstrably independent of the other functions of the national safety authority.

Article 10

Validity of recognition

1. In the cases referred in Article 9(1)(a) and (d) and Article 9(2), the period of validity of recognition shall not exceed 5 years from the date it is granted.

2. In the case referred in Article 9(1)(b):

(a) the statement of recognition for a railway undertaking or an infrastructure manager shall be displayed on the relevant safety certificate in field 5 '*Additional Information*' of the

[1] OJ L 326, 10.12.2010, p. 11.
[2] OJ L 327, 11.12.2010, p. 13.

harmonised format of safety certificates provided in Annex I to Commission Regulation (EC) No 653/2007 [1] and in an appropriate part of the safety authorisations;

(b) the period of validity of recognition shall be limited to the validity of the safety certificate or authorisation under which it is granted. In this case, the request of recognition shall be made at the next application for renewal or update of the safety certificate or authorisation.

3. In the cases referred in Article 9(1)(c):

(a) the statement of recognition for an entity in charge of maintenance shall be displayed on the relevant certificate in field 5 'Additional Information' of the harmonised format of certificates for entities in charge of maintenance provided in Annex V, or in Annex VI where relevant, of Regulation (EU) No 445/2011;

(b) the period of validity of recognition shall be limited to the validity of the certificate issued by the certification body under which it is granted. In this case, the request of recognition shall be made at the next application for renewal or update of that certificate.

Article 11

Surveillance by recognition body

1. By analogy to the requirements in Article 5(3) and (4) of Regulation (EC) No 765/2008 for accreditation, the recognition body shall conduct periodic surveillance in order to verify that the assessment body it recognised continues to satisfy the criteria set out in Annex II during the validity of the recognition.

2. If the assessment body no longer satisfies the criteria set out in Annex II, the recognition body shall limit the scope of application of the recognition, suspend or withdraw the recognition, depending on the degree of non-compliance.

Article 12

Relaxed criteria where a significant change is not to be mutually recognised

Where the risk assessment for a significant change is not to be mutually recognised, the proposer shall appoint an assessment body meeting at least the competency, independency and impartiality requirements of Annex II. The other requirements of paragraph 1 in Annex II may be relaxed in agreement with the national safety authority in a non-discriminatory way.

Article 13

Provision of information to the Agency

1. Where applicable, by no later than 21 May 2015, Member States shall inform the Agency which is their national accreditation body and/or recognition body or recognition bodies for the purposes of this Regulation, as well as of the assessment bodies they recognised in conformity with Article 9(1)(a). They shall also notify any change to that situation within one month of the change. The Agency shall make this information publicly available.

2. By no later than 21 May 2015, the national accreditation body shall inform the Agency of the assessment bodies accredited, as well as of the area of competence for which those assessment bodies are accredited as provided for in points 2 and 3 of Annex II. They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.

3. By no later than 21 May 2015, the recognition body shall inform the Agency of the assessment bodies recognised, as well as of the area of competence for which those assessment bodies are recognised as provided for in points 2 and 3 of Annex II. They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.

Article 14

Support from the Agency to accreditation or recognition of the assessment body

1. The Agency shall organise peer evaluations between the recognition bodies based on the same principles as set out in Article 10 of Regulation (EC) No 765/2008.

2. The Agency shall organise, in collaboration with the European cooperation for Accreditation (EA), training on this Regulation for the national accreditation bodies and for the recognition bodies at least at each new revision of this Regulation.

Article 15

Safety assessment reports

1. The assessment body shall provide the proposer with a safety assessment report in accordance with the requirements set out in Annex III. The proposer shall be responsible for determining if and how to take into account the conclusions of the safety assessment report for the safety acceptance of the assessed change. The proposer shall justify and document the part of the safety assessment report for which the proposer eventually disagrees.

2. In the case referred to in point (b) of Article 2(3), in accordance with paragraph 5 of this Article, the declaration referred to in Article 16 shall be accepted by the national safety authority in its decision to authorise the placing in service of structural subsystems and vehicles.

3. Without prejudice to Article 16 of Directive 2008/57/EC, the national safety authority may not request additional checks or risk analyses unless it is able to demonstrate the existence of a substantial safety risk.

4. In the case referred to in point (a) of Article 2(3), in accordance with paragraph 5 of this Article, the declaration referred to in Article 16 shall be accepted by the notified body in charge of delivering the conformity certificate, unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.

[1] OJ L 153, 14.6.2007, p. 9.

5. When a system or part of a system has already been accepted following the risk management process specified in this Regulation, the resulting safety assessment report shall not be called into question by any other assessment body in charge of performing a new assessment for the same system. Mutual recognition shall be conditional upon demonstration that the system will be used under the same functional, operational and environmental conditions as the already accepted system, and that equivalent risk acceptance criteria have been applied.

Article 16

Declaration by the proposer

Based on the results of the application of this Regulation and on the safety assessment report provided by the assessment body, the proposer shall produce a written declaration that all identified hazards and associated risks are controlled to an acceptable level.

Article 17

Risk control management and audits

1. The railway undertakings and infrastructure managers shall include audits of the application of this Regulation in their recurrent auditing scheme for the safety management system as referred to in Article 9 of Directive 2004/49/EC.

2. The entities in charge of maintenance shall include audits of the application of this Regulation in their recurrent auditing scheme for the system of maintenance as referred to in Article 14a(3) of Directive 2004/49/EC.

3. As part of the tasks defined in Article 16(2)(e) of Directive 2004/49/EC, the national safety authority shall supervise the application of this Regulation by railway undertakings, infrastructure managers and the entities in charge of maintenance that do not fall within the scope of Regulation (EU) No 445/2011 but are identified in its National Vehicle Register.

4. As part of the tasks defined in Article 7(1) of Regulation (EU) No 445/2011, the certification body of an entity in charge of maintenance of freight wagons shall perform surveillance of the application of this Regulation by the entity in charge of maintenance.

Article 18

Feedback and technical progress

1. Each infrastructure manager and each railway undertaking shall, in its annual safety report referred to in Article 9(4) of Directive 2004/49/EC, report briefly on its experience with the application of this Regulation. The report shall also include a synthesis of the decisions on the level of significance of the changes.

2. Each national safety authority shall, in its annual safety report referred to in Article 18 of Directive 2004/49/EC, report on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.

3. The annual maintenance report of entities in charge of maintenance of freight wagons referred to in point I(7)(4)(k) in Annex III to Regulation (EU) No 445/2011, shall include information about the experience of entities in charge of maintenance in applying this Regulation. The Agency shall gather this information in coordination with the respective certification bodies.

4. The other entities in charge of maintenance that do not fall within the scope of Regulation (EU) No 445/2011 shall also share their experience with the Agency on the application of this Regulation. The Agency shall coordinate the sharing of experience with these entities in charge of maintenance and with the national safety authorities.

5. The Agency shall collect all information on the experience of the application of this Regulation and shall, when necessary, make recommendations to the Commission with a view to improving this Regulation.

6. Before 21 May 2018 the Agency shall submit to the Commission a report containing:

(a) an analysis of the experience with the application of this Regulation, including cases where the CSM has been applied by proposers on a voluntary basis before the relevant date of application provided for in Article 20;

(b) an analysis of the experience of proposers concerning decisions on the level of significance of changes;

(c) an analysis of the cases where codes of practice have been used as set out in point 2.3.8 of Annex I;

(d) an analysis of the experience with the accreditation and recognition of assessment bodies;

(e) an analysis of the overall effectiveness of this Regulation.

The national safety authorities shall support the Agency in collecting such information.

Article 19

Repeal

Regulation (EC) No 352/2009 is repealed with effect from 21 May 2015.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 20

Entry into force and application

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

It shall apply from 21 May 2015.

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

Done at Brussels, 30 April 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX I

1. GENERAL PRINCIPLES APPLICABLE TO THE RISK MANAGEMENT PROCESS

1.1. General principles and obligations

1.1.1. The risk management process shall start from a definition of the system under assessment and comprise the following activities:

(a) the risk assessment process, which shall identify the hazards, the risks, the associated safety measures and the resulting safety requirements to be fulfilled by the system under assessment;

(b) demonstration of the compliance of the system with the identified safety requirements; and

(c) management of all identified hazards and the associated safety measures.

This risk management process is iterative and is depicted in the diagram of the Appendix. The process ends when compliance of the system with all the safety requirements necessary to accept the risks linked to the identified hazards is demonstrated.

1.1.2. The risk management process shall include appropriate quality assurance activities and be carried out by competent staff. It shall be independently assessed by one or more assessment bodies.

1.1.3. The proposer in charge of the risk management process shall maintain a hazard record in accordance with point 4.

1.1.4. The actors who already have in place methods or tools for risk assessment may continue to apply them if such methods or tools are compatible with the provisions of this Regulation and subject to the following conditions:

(a) the risk assessment methods or tools are described in a safety management system accepted by a national safety authority in accordance with Article 10(2)(a) or Article 11(1)(a) of Directive 2004/49/EC; or

(b) the risk assessment methods or tools are required by a TSI or comply with publicly available recognised standards specified in notified national rules.

1.1.5. Without prejudice to civil liability in accordance with the legal requirements of the Member States, the risk assessment process shall fall within the responsibility of the proposer. In particular the proposer shall decide, with agreement of the actors concerned, who will be in charge of fulfilling the safety requirements resulting from the risk assessment. The safety requirements assigned by the proposer to those actors shall not go beyond the scope of their responsibility and domain of control. This decision shall depend on the type of safety measures selected to control the risks to an acceptable level. The demonstration of compliance with the safety requirements shall be conducted in accordance with point 3.

1.1.6. The first step of the risk management process shall be to identify in a document, to be drawn up by the proposer, the different actors' tasks, and their risk management activities. The proposer is responsible for coordinating close collaboration between the different actors involved, according to their respective tasks, in order to manage the hazards and their associated safety measures.

1.1.7. Evaluation of the correct application of the risk management process falls within the responsibility of the assessment body.

1.2. Interfaces management

1.2.1. For each interface relevant to the system under assessment and without prejudice to specifications of interfaces defined in relevant TSIs, the rail-sector actors concerned shall cooperate in order to identify and manage jointly the hazards and related safety measures that need to be handled at these interfaces. The management of shared risks at the interfaces shall be coordinated by the proposer.

1.2.2. If, in order to fulfil a safety requirement, an actor identifies the need for a safety measure that it cannot implement itself, it shall, after agreement with another actor, transfer the management of the related hazard to the latter in accordance with the process set out in point 4.

1.2.3. For the system under assessment, any actor who discovers that a safety measure is non-compliant or inadequate is responsible for notifying it to the proposer, who shall in turn inform the actor implementing the safety measure.

1.2.4. The actor implementing the safety measure shall then inform all the actors affected by the problem either within the system under assessment or, as far as known by the actor, within other existing systems using the same safety measure.

1.2.5. When agreement cannot be reached between two or more actors it is the responsibility of the proposer to find a solution.

1.2.6. When a requirement in a notified national rule cannot be fulfilled by an actor, the proposer shall seek advice from the relevant competent authority.

1.2.7. Independently from the definition of the system under assessment, the proposer is responsible for ensuring that the risk management covers the system itself and its integration into the railway system as a whole.

2. DESCRIPTION OF THE RISK ASSESSMENT PROCESS

2.1. General description

2.1.1. The risk assessment process is the overall iterative process that comprises:

(a) the system definition;

(b) the risk analysis including the hazard identification;

(c) the risk evaluation.

The risk assessment process shall interact with hazard management in accordance with point 4.1.

2.1.2. The system definition shall address at least the following issues:

(a) system objective (intended purpose);

(b) system functions and elements, where relevant (including human, technical and operational elements);

(c) system boundary including other interacting systems;

(d) physical (interacting systems) and functional (functional input and output) interfaces;

(e) system environment (for example energy and thermal flow, shocks, vibrations, electromagnetic interference, operational use);

(f) existing safety measures and, after the necessary relevant iterations, definition of the safety requirements identified by the risk assessment process;

(g) assumptions that determine the limits for the risk assessment.

2.1.3. A hazard identification shall be carried out on the defined system, in accordance with point 2.2.

2.1.4. The risk acceptability of the system under assessment shall be evaluated by using one or more of the following risk acceptance principles:

(a) the application of codes of practice (point 2.3);

(b) a comparison with similar systems (point 2.4);

(c) an explicit risk estimation (point 2.5).

In accordance with the principle referred to in point 1.1.5, the assessment body shall refrain from imposing the risk acceptance principle to be used by the proposer.

2.1.5. The proposer shall demonstrate in the risk evaluation that the selected risk acceptance principle is adequately applied. The proposer shall also check that the selected risk acceptance principles are used consistently.

2.1.6. The application of these risk acceptance principles shall identify possible safety measures that make the risk(s) of the system under assessment acceptable. Among these safety measures, those selected to control the risk(s) shall become the safety requirements to be fulfilled by the system. Compliance with these safety requirements shall be demonstrated in accordance with point 3.

2.1.7. The iterative risk assessment process is considered to be completed when it is demonstrated that all safety requirements are fulfilled and no additional reasonably foreseeable hazards have to be considered.

2.2. **Hazard identification**

2.2.1. The proposer shall systematically identify, using wide-ranging expertise from a competent team, all reasonably foreseeable hazards for the whole system under assessment, its functions where appropriate and its interfaces.

All identified hazards shall be registered in the hazard record in accordance with point 4.

2.2.2. To focus the risk assessment efforts upon the most important risks, the hazards shall be classified according to the estimated risk arising from them. Based on expert judgement, hazards associated with a broadly acceptable risk need not be analysed further but shall be registered in the hazard record. Their classification shall be justified in order to allow independent assessment by an assessment body.

2.2.3. As a criterion, risks resulting from hazards may be classified as broadly acceptable when the risk is so small that it is not reasonable to implement any additional safety measure. The expert judgement shall take into account that the contribution of all the broadly acceptable risks does not exceed a defined proportion of the overall risk.

2.2.4. During the hazard identification, safety measures may be identified. They shall be registered in the hazard record in accordance with point 4.

2.2.5. The hazard identification only needs to be carried out at a level of detail necessary to identify where safety measures are expected to control the risks in accordance with one of the risk acceptance principles referred to in point 2.1.4. Iteration may be necessary between the risk analysis and the risk evaluation phases until a sufficient level of detail is reached for the identification of hazards.

2.2.6. Whenever a code of practice or a reference system is used to control the risk, hazard identification may be limited to:

(a) verification of the relevance of the code of practice or reference system;

(b) identification of the deviations from the code of practice or from the reference system.

2.3. **Use of codes of practice and risk evaluation**

2.3.1. The proposer, with the support of other involved actors, shall analyse whether one, several or all hazards are appropriately covered by the application of relevant codes of practice.

2.3.2. The codes of practice shall satisfy at least the following requirements:

(a) They must be widely recognised in the railway domain. If this is not the case, the codes of practice will have to be justified and be acceptable to the assessment body;

(b) They must be relevant for the control of the considered hazards in the system under assessment. Successful application of a code of practice for similar cases to manage changes and control effectively the identified hazards of a system in the sense of this Regulation is sufficient for it to be considered as relevant;

(c) Upon request, they must be available to assessment bodies for them to either assess or, where relevant, mutually recognise, in accordance with Article 15(5), the suitability of both the application of the risk management process and of its results.

2.3.3. Where compliance with TSIs is required by Directive 2008/57/EC and the relevant TSI does not impose the risk management process established by this Regulation, the TSIs may be considered as codes of practice for controlling hazards, provided requirement (b) of point 2.3.2 is fulfilled.

2.3.4. National rules notified in accordance with Article 8 of Directive 2004/49/EC and Article 17(3) of Directive 2008/57/EC may be considered as codes of practice provided the requirements of point 2.3.2 are fulfilled.

2.3.5. If one or more hazards are controlled by codes of practice fulfilling the requirements of point 2.3.2, then the risks associated with these hazards shall be considered acceptable. This means that:

(a) these risks need not be analysed further;

(b) the use of the codes of practice shall be registered in the hazard record as safety requirements for the relevant hazards.

2.3.6. Where an alternative approach is not fully compliant with a code of practice, the proposer shall demonstrate that the alternative approach pursued leads to at least the same level of safety.

2.3.7. If the risk for a particular hazard cannot be made acceptable by the application of codes of practice, additional safety measures shall be identified by applying one of the two other risk acceptance principles.

2.3.8. When all hazards are controlled by codes of practice, the risk management process may be limited to:

(a) hazard identification in accordance with point 2.2.6;

(b) registration of the use of the codes of practice in the hazard record in accordance with point 2.3.5;

(c) documentation of the application of the risk management process in accordance with point 5;

(d) an independent assessment in accordance with Article 6.

2.4. **Use of reference system and risk evaluation**

2.4.1. The proposer, with the support of other involved actors, shall analyse whether one, several or all hazards are appropriately covered by a similar system that could be taken as a reference system.

2.4.2. A reference system shall satisfy at least the following requirements:

(a) it has already been proven in-use to have an acceptable safety level and would therefore still qualify for approval in the Member State where the change is to be introduced;

(b) it has similar functions and interfaces as the system under assessment;

(c) it is used under similar operational conditions as the system under assessment;

(d) it is used under similar environmental conditions as the system under assessment.

2.4.3. If a reference system fulfils the requirements listed in point 2.4.2, then for the system under assessment:

(a) the risks associated with the hazards covered by the reference system shall be considered as acceptable;

(b) the safety requirements for the hazards covered by the reference system may be derived from the safety analyses or from an evaluation of safety records of the reference system;

(c) these safety requirements shall be registered in the hazard record as safety requirements for the relevant hazards.

2.4.4. If the system under assessment deviates from the reference system, the risk evaluation shall demonstrate that the system under assessment reaches at least the same safety level as the reference system, applying another reference system or one of the two other risk acceptance principles. The risks associated with the hazards covered by the reference system shall, in that case, be considered as acceptable.

2.4.5. If at least the same safety level as the reference system cannot be demonstrated, additional safety measures shall be identified for the deviations, applying one of the two other risk acceptance principles.

2.5. **Explicit risk estimation and evaluation**

2.5.1. If the hazards are not covered by one of the two risk acceptance principles laid down in points 2.3 and 2.4, the demonstration of risk acceptability shall be performed by explicit risk estimation and evaluation. Risks resulting from these hazards shall be estimated either quantitatively or qualitatively, taking existing safety measures into account.

2.5.2. The acceptability of the estimated risks shall be evaluated using risk acceptance criteria either derived from or based on requirements contained in Union legislation or in notified national rules. Depending on the risk acceptance criteria, the acceptability of the risk may be evaluated either individually for each associated hazard or the combination of all hazards as a whole considered in the explicit risk estimation.

If the estimated risk is not acceptable, additional safety measures shall be identified and implemented in order to reduce the risk to an acceptable level.

2.5.3. If the risk associated with one hazard or a combination of several hazards is considered acceptable, the identified safety measures shall be registered in the hazard record.

2.5.4. If hazards arise from failures of technical systems not covered by codes of practice or the use of a reference system, the following risk acceptance criterion shall apply for the design of the technical system:

For technical systems where a functional failure has a credible direct potential for a catastrophic consequence, the associated risk does not have to be reduced further if the rate of that failure is less than or equal to 10^{-9} per operating hour.

2.5.5. Without prejudice to the procedure specified in Article 8 of Directive 2004/49/EC, a more demanding criterion then the one laid down in point 2.5.4 may be requested, through a notified national safety rule, in order to maintain a national safety level. In the case of additional authorisations for placing in service of vehicles, the procedures of Articles 23 and 25 of Directive 2008/57/EC shall apply.

2.5.6. If a technical system is developed by applying the 10^{-9} criterion laid down in point 2.5.4, the principle of mutual recognition is applicable in accordance with Article 15(5).

Nevertheless, if the proposer can demonstrate that the national safety level in the Member State of application can be maintained with a rate of failure higher than 10^{-9} per operating hour, this criterion may be used by the proposer in that Member State.

2.5.7. The explicit risk estimation and evaluation shall satisfy at least the following requirements:

(a) the methods used for explicit risk estimation shall reflect correctly the system under assessment and its parameters (including all operational modes);

(b) the results shall be sufficiently accurate to serve as robust decision support. Minor changes in input assumptions or prerequisites shall not result in significantly different requirements.

3. DEMONSTRATION OF COMPLIANCE WITH SAFETY REQUIREMENTS

3.1. Prior to the safety acceptance of the change, fulfilment of the safety requirements resulting from the risk assessment phase shall be demonstrated under the supervision of the proposer.

3.2. This demonstration shall be carried out by each of the actors responsible for fulfilling the safety requirements, as decided in accordance with point 1.1.5.

3.3. The approach chosen for demonstrating compliance with the safety requirements as well as the demonstration itself shall be independently assessed by an assessment body.

3.4. Any inadequacy of safety measures expected to fulfil the safety requirements or any hazards discovered during the demonstration of compliance with the safety requirements shall lead to reassessment and evaluation of the associated risks by the proposer in accordance with point 2. The new hazards shall be registered in the hazard record in accordance with point 4.

4. HAZARD MANAGEMENT

4.1. Hazard management process

4.1.1. Hazard record(s) shall be created or updated (where they already exist) by the proposer during design and implementation until acceptance of the change or delivery of the safety assessment report. A hazard record shall track the progress in monitoring risks associated with the identified hazards. Once the system has been accepted and is in operation, the hazard record shall be further maintained by the infrastructure manager or the railway undertaking in charge of the operation of the system under assessment as an integrated part of its safety management system.

4.1.2. The hazard record shall include all hazards, together with all related safety measures and system assumptions identified during the risk assessment process. It shall contains a clear reference to the origin of the hazards and to the selected risk acceptance principles and clearly identify the actor(s) in charge of controlling each hazard.

4.2. **Exchange of information**

All hazards and related safety requirements that cannot be controlled by one actor alone shall be communicated to another relevant actor in order to find jointly an adequate solution. The hazards registered in the hazard record of the actor who transfers them shall only be regarded as controlled when the evaluation of the risks associated with these hazards is made by the other actor and the solution is agreed by all concerned.

5. **EVIDENCE FROM THE APPLICATION OF THE RISK MANAGEMENT PROCESS**

5.1. The risk management process used to assess the safety levels and compliance with safety requirements shall be documented by the proposer in such a way that all the necessary evidence showing the suitability of both the application of the risk management process and of its results are accessible to an assessment body.

5.2. The documentation produced by the proposer under point 5.1 shall at least include:

(a) a description of the organisation and the experts appointed to carry out the risk assessment process;

(b) results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level;

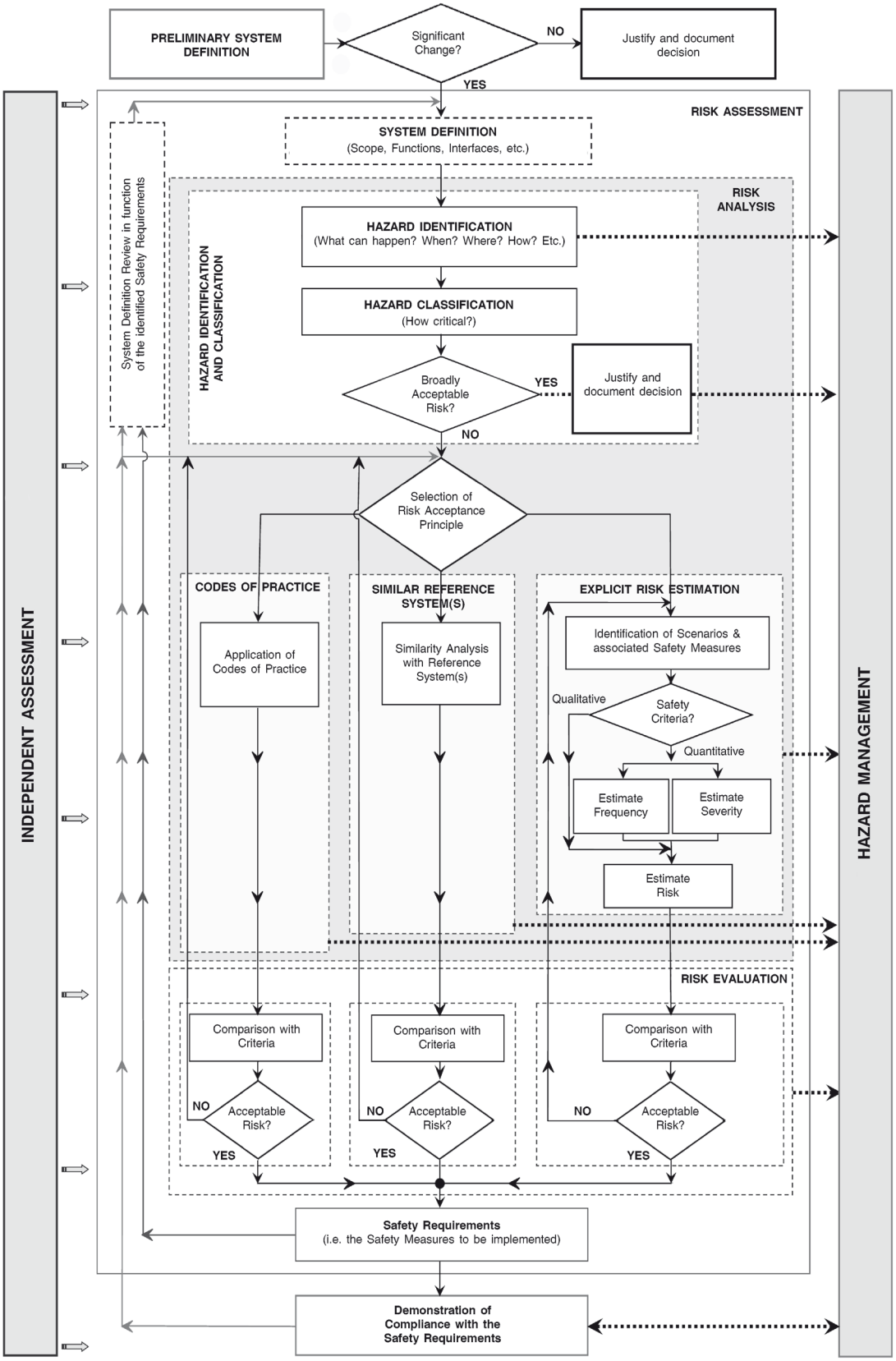
(c) evidence of compliance with all the necessary safety requirements;

(d) all assumptions relevant for system integration, operation or maintenance, which were made during system definition, design and risk assessment.

5.3. The assessment body shall establish its conclusion in a safety assessment report as defined in Annex III.

Appendix

Risk management process and independent assessment



ANNEX II

CRITERIA FOR ACCREDITATION OR RECOGNITION OF THE ASSESSMENT BODY

1. The assessment body shall fulfil all requirements of the ISO/IEC 17020:2012 standard and of its subsequent amendments. The assessment body shall exercise professional judgement in performing the inspection work defined in that standard. The assessment body shall fulfil both the general criteria concerning competence and independence in that standard and the following specific competence criteria:

   (a) competence in risk management: knowledge and experience of the standard safety analysis techniques and of the relevant standards;

   (b) all relevant competences for assessing the parts of the railway system affected by the change;

   (c) competence in the correct application of safety and quality management systems or in auditing management systems.

2. By analogy to Article 28 of Directive 2008/57/EC concerning the notification of notified bodies, the assessment body shall be accredited or recognised for the different areas of competence within the railway system, or parts of it for which an essential safety requirement exists, including the area of competence involving the operation and maintenance of the railway system.

3. The assessment body shall be accredited or recognised for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole. This shall include competence of the assessment body in checking the following:

   (a) organisation, that is the arrangements necessary to ensure a coordinated approach to achieving system safety through a uniform understanding and application of risk control measures for subsystems;

   (b) methodology, that is evaluation of the methods and resources deployed by various stakeholders to support safety at subsystem and system level; and

   (c) the technical aspects necessary for assessing the relevance and completeness of risk assessments and the level of safety for the system as a whole.

4. The assessment body may be accredited or recognised for one, several or all of the areas of competence listed in points 2 and 3.

ANNEX III

SAFETY ASSESSMENT REPORT OF THE ASSESSMENT BODY

The safety assessment report of the assessment body shall contain at least the following information:

(a) identification of the assessment body;

(b) the independent assessment plan;

(c) the definition of the scope of the independent assessment as well as its limitations;

(d) the results of the independent assessment including in particular:

  (i) detailed information on the independent assessment activities for checking the compliance with the provisions of this Regulation;

  (ii) any identified cases of non-compliances with the provisions of this Regulation and the assessment body's recommendations;

(e) the conclusions of the independent assessment.

COMMISSION IMPLEMENTING REGULATION (EU) No 403/2013

of 2 May 2013

concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 (holder of authorisation DSM Nutritional Products)

(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 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) A preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 74252) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 1259/2004 ([3]), on turkeys for fattening by Commission Regulation (EC) No 1206/2005 ([4]), and on laying hens and weaned piglets by Commission Regulation (EC) No 1876/2006 ([5]). That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) (formerly ATCC 74252), as a feed additive for chickens for fattening, turkeys for fattening, laying hens and piglets and, in accordance with Article 7 of that Regulation, for a new use for all poultry species for fattening and laying, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 October 2012 ([6]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) does not have an adverse effect on animal health, human health or the environment, and that it has a potential to favourably affect animal performance in target species. However, based on the incomplete information provided by the applicant, the Authority was not in a position to specify the minimum enzyme activities. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) As a new authorisation is granted in accordance with Regulation (EC) No 1831/2003, Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 should therefore be amended accordingly.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 239, 9.7.2004, p. 8.
([4]) OJ L 197, 28.7.2005, p. 12.
([5]) OJ L 360, 19.12.2006, p. 126.
([6]) *EFSA Journal 2012*; 10(11):2930.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendments to Regulation (EC) No 1259/2004

Regulation (EC) No 1259/2004 is amended as follows:

1. Article 2 is replaced by the following:

   '*Article 2*

   The preparations belonging to the group "Enzymes", as set out in Annexes III, IV, V and VI are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.';

2. Annex II is deleted.

Article 3

Amendment to Regulation (EC) No 1206/2005

In the Annex to Regulation (EC) No 1206/2005 all the data contained in the entry E1602 are deleted.

Article 4

Amendments to Regulation (EC) No 1876/2006

Regulation (EC) No 1876/2006 is amended as follows:

1. Article 3 is deleted;

2. Annex III is deleted.

Article 5

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 23 November 2013 in accordance with the rules applicable before 23 May 2013, may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

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, 2 May 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content / Maximum content (Units of activity/kg of complete feedingstuff with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1602i	DSM Nutritional Products	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-glucanase EC 3.2.1.4	*Additive composition* Preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* (ATCC 74444) having a minimum activity of: endo-1,4-beta-xylanase 2 700 U ([1])/ml or g additive endo-1,3(4)-beta-glucanase 700 U ([2])/ml or g additive endo-1,4-beta-glucanase 800 U ([3])/ml or g additive (Liquid and solid form) *Characterisation of the active substance* endo-1,4-betaxylanase, endo-1,4-betaglucanase and endo-1,3(4)-betaglucanase, produced by *Trichoderma reesei* (ATCC 74444) *Analytical method* ([4]) Characterisation of the active substances in the feedingstuff: — Colorimetric method measuring water soluble dye released by the action of endo-1,4-beta-xylanase from cross-linked birchwood azoxylan substrate	Poultry for fattening other than turkeys for fattening	—	endo-1,4-beta-xylanase: 135 U endo-1,3(4)-beta-glucanase: 35 U endo-1,4-beta-glucanase: 40 U	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans). 3. For use in weaned piglets up to 35 kg. 4. For safety: breathing protection and gloves shall be used during handling.	23 May 2023
				Poultry for laying		endo-1,4-beta-xylanase: 216 U endo-1,3(4)-beta-glucanase: 56 U endo-1,4-beta-glucanase: 64 U			
				Turkeys for fattening Piglets (weaned)		endo-1,4-beta-xylanase: 270 U endo-1,3(4)-beta-glucanase: 70 U endo-1,4-beta-glucanase: 80 U			

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
			— Colorimetric method measuring water soluble dye released by the action of endo-1,3(4)-beta-glucanase from cross-linked azobarley glucan substrate — Colorimetric method measuring water soluble dye released by the action of endo-1,4-beta-glucanase from cross-linked azocarboxymethylcellulose substrate.						

(1) 1 U is the amount of enzyme which liberates 1 micromoles of glucose from wheat arabinoxylan per minute at pH 5,0 and 40 °C.
(2) 1 U is the amount of enzyme which liberates 1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.
(3) 1 U is the amount of enzyme which liberates 1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.
(4) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 404/2013

of 2 May 2013

on the derogations from the rules of origin laid down in Annex II to the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, that apply within quotas for certain products from Peru

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2012/735/EU of 31 May 2012 on the signing, on behalf of the Union, and provisional application of the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part [1], and in particular Article 6 thereof,

Whereas:

(1) By Decision 2012/735/EU, the Council authorised the signature, on behalf of the Union, of the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part ('the Agreement'). Pursuant to Decision 2012/735/EU, the Agreement is to be applied on a provisional basis, pending the completion of the procedures for its conclusion. The Agreement applies on a provisional basis from 1 March 2013.

(2) Annex II to the Agreement concerns the definition of the concept of 'originating products' and methods of administrative cooperation. For a number of products, Appendix 2A and Appendix 5 to that Annex provide for derogations from the rules of origin set out in that Annex in the framework of annual quotas. It is therefore necessary to lay down the conditions for the application of those derogations for imports from Peru.

(3) The quotas set out in Appendix 2A and Appendix 5 to Annex II to the Agreement should be managed by the Commission on a first-come, first-served basis in accordance with Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code [2].

(4) Entitlement to benefit from the tariff concessions should be subject to the presentation of the relevant proof of origin to the customs authorities, as provided for in the Agreement.

(5) Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [3], as amended by Commission Implementing Regulation (EU) No 927/2012 [4], contains new CN codes which are different from those referred to in the Agreement. Those new codes should therefore be reflected in Part B of the Annex to this Regulation.

(6) Since the Agreement takes effect on 1 March 2013, this Regulation should apply from the same date.

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

HAS ADOPTED THIS REGULATION:

Article 1

1. The rules of origin in Appendix 2A to Annex II to the Trade Agreement between the European Union and its Member States, of the one part, and Columbia and Peru, of the other part (hereinafter referred to as 'the Agreement'), shall apply to the products listed in Part A of the Annex to this Regulation.

2. The rules of origin set out in Appendix 5 to Annex II to the Agreement shall apply to the products listed in Part B of the Annex to this Regulation.

Article 2

To benefit from the derogation set out in Article 1, the products listed in the Annex shall be accompanied by a proof of origin as set out in Annex II to the Agreement.

Article 3

The quotas listed in the Annex shall be managed by the Commission in accordance with the provisions of Articles 308a to 308c of Regulation (EEC) No 2454/93.

[1] OJ L 354, 21.12.2012, p. 1.
[2] OJ L 253, 11.10.1993, p. 1.
[3] OJ L 256, 7.9.1987, p. 1.
[4] OJ L 304, 31.10.2012, p. 1.

Article 4

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

It shall apply from 1 March 2013.

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

Done at Brussels, 2 May 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Peru

Notwithstanding the rules for the interpretation of the Combined Nomenclature, the wording of the description of the products is to be considered as having no more than an indicative value, the scope of the preferential scheme being determined, within the context of this Annex, by CN codes as they exist at the time of adoption of this Regulation. Where ex CN codes are indicated, the scope of the preferential scheme is to be determined by application of the CN code and a corresponding description taken together.

PART A

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
09.7170	3920	Other plates, sheets, film, foil and strip, of plastics, non-cellular and not-reinforced, laminated, supported or similarly combined with other materials	From 1 March to end of February	15 000
09.7171	ex 5607 50 [1] and 5608	Twine and nets	From 1 March to end of February	650
09.7172	6108 22 00	Women's or girl's briefs and panties, knitted or crocheted, of man-made fibres	From 1 March to end of February	200
09.7173	6112 31	Men's or boy's swimwear, knitted or crocheted, of synthetic fibres	From 1 March to end of February	25
09.7174	6112 41	Woman's or girl's swimwear, knitted or crocheted, of synthetic fibres	From 1 March to end of February	100
09.7175	6115 10	Graduated compression hosiery (for example, stockings for varicose veins), knitted or crocheted	From 1 March to end of February	25
09.7176	6115 21 00	Other pantyhose and tights, of synthetic fibres, measuring per single yarn less than 67 decitex, knitted or crocheted	From 1 March to end of February	40
09.7177	6115 22 00	Other pantyhose and tights, of synthetic fibres, measuring per single yarn 67 decitex or more, knitted or crocheted	From 1 March to end of February	15
09.7178	6115 30	Other women's full-length or knee-length hosiery, measuring per single yarn less than 67 decitex, knitted or crocheted	From 1 March to end of February	25
09.7179	6115 96	Other, of synthetic fibres, knitted or crocheted	From 1 March to end of February	175
09.7192	7321	Stoves, ranges, grates, cookers (including those with subsidiary boilers for central heating), barbecues, braziers, gas rings, plate warmers and similar nonelectric domestic appliances, and parts thereof, of iron or steel	From 1 March to end of February	20 000 number of items

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
09.7193	7323	Table, kitchen or other household articles and parts thereof, of iron or steel; iron or steel wool; pot scourers and scouring or polishing pads, gloves and the like, of iron or steel	From 1 March to end of February	50 000
09.7194	7325	Other cast articles of iron or steel	From 1 March to end of February	50 000

([1]) TARIC codes 5607 50 11 10, 5607 50 19 10, 5607 50 30 10 and 5607 50 90 91.

PART B

Order No	CN code	Description of goods	Quota period	Annual quota volume (in metric tonnes)
09.7195	0303 54 10	Frozen mackerel *Scomber scombrus* and *Scomber japonicas*	From 1 March to end of February	4 000
09.7196	0303 89 45	Frozen anchovies (*Engraulis* spp.)	From 1 March to end of February	120
09.7197	0303 55 10 0303 55 90 ([1])	Atlantic horse mackerel (*Trachurus trachurus*), frozen Horse mackerel (*Caranx trachurus*), frozen	From 1 March to end of February	60
09.7198	0307 49 59	Frozen squid (*Ommastrephes* spp. with the exclusion of *Ommastrephes sagittatus, Nototodarus* spp. and *Sepioteuthis* spp.), whether in shell or not	From 1 March to end of February	4 200
09.7199	0307 49 99	Squid (*Ommastrephes* spp. with the exclusion of *Ommastrephes sagittatus, Nototodarus* spp. and *Sepioteuthis* spp.), dried, salted or in brine, whether in shell or not	From 1 March to end of February	2 500
09.7200	1604 15 11	Fillets of mackerel of the species *Scomber scombrus* and *Scomber japonicus*, prepared or preserved	From 1 March to end of February	2 000
09.7201	1604 15 19	Mackerel of the species *Scomber scombrus* and *Scomber japonicus*, prepared or preserved, whole or in pieces, but not minced, other than fillets	From 1 March to end of February	800
09.7202	1604 15 90	Mackerel of the species *Scomber australasicus*, prepared or preserved, whole or in pieces, but not minced	From 1 March to end of February	20
09.7203	1604 16 00	Anchovies, prepared or preserved, whole or in pieces, but not minced	From 1 March to end of February	400
09.7204	1604 20 40	Prepared or preserved anchovies, other than whole or in pieces	From 1 March to end of February	30

Order No	CN code	Description of goods	Quota period	Annual quota volume (in metric tonnes)
09.7205	0307 19 10 0307 29 05 0307 49 05 0307 59 05 0307 60 10 0307 79 10 0307 89 10 0307 99 10 1605 51 00 1605 52 00 1605 53 10 (2) 1605 53 90 (3) 1605 54 00 1605 55 00 1605 56 00 1605 57 00 1605 58 00 1605 59 00	Molluscs, prepared or preserved, at the exception of mussels of the species *Mytilus* spp. and *Perna* spp.)	From 1 March to end of February	500

(1) TARIC code 0303 55 90 10.
(2) TARIC code 1605 53 10 95.
(3) TARIC code 1605 53 90 95.

COMMISSION IMPLEMENTING REGULATION (EU) No 405/2013

of 2 May 2013

opening and providing for the administration of Union tariff quotas for agricultural products originating in Peru

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2012/735/EU of 31 May 2012 on the signing, on behalf of the Union, and provisional application of the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part [1], and in particular Article 6 thereof,

Whereas:

(1) By Decision 2012/735/EU, the Council authorised the signing, on behalf of the Union, of the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part ('the Agreement'). Pursuant to Decision 2012/735/EU, the Agreement is to be applied on a provisional basis, pending the completion of the procedures for its conclusion. The Agreement applies on a provisional basis from 1 March 2013.

(2) Subsection 2 of Section B of Appendix 1 to Annex I to the Agreement concerns the tariff elimination schedule of the EU party for goods originating in Peru. For a number of specific products, it provides for the application of tariff quotas. It is therefore necessary to open tariff quotas for such products.

(3) The tariff quotas should be managed by the Commission on a first-come, first-served basis in accordance with Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code [2].

(4) Entitlement to benefit from the tariff concessions should be subject to the presentation of the relevant proof of origin to the customs authorities, as provided for in the Agreement.

(5) Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [3], as amended by Commission Implementing Regulation (EU) No 927/2012 [4], contains new CN codes which are different from those referred to in the Agreement. The new codes should therefore be reflected in the Annex to this Regulation.

(6) Since the Agreement takes effect on 1 March 2013, this Regulation should apply from the same date.

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

HAS ADOPTED THIS REGULATION:

Article 1

Union tariff quotas are opened for the goods originating in Peru and listed in the Annex.

Article 2

The customs duties applicable to imports into the Union of goods originating in Peru and listed in the Annex shall, within the respective tariff quota set out in the Annex to this Regulation, be suspended.

Article 3

The tariff quotas in the Annex shall be managed by the Commission in accordance with Articles 308a to 308c of Regulation (EEC) No 2454/93.

Article 4

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

It shall apply from 1 March 2013.

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

Done at Brussels, 2 May 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 354, 21.12.2012, p. 1.
[2] OJ L 253, 11.10.1993, p. 1.
[3] OJ L 256, 7.9.1987, p. 1.
[4] OJ L 304, 31.10.2012, p. 1.

ANNEX

Notwithstanding the rules for the interpretation of the Combined Nomenclature, the wording of the description of the products is to be considered as having no more than an indicative value, the scope of the preferential scheme being determined, within the context of this Annex, by CN codes as they exist at the time of adoption of this Regulation.

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
09.7210	0201 0202 0206 10 95 0206 29 91 0210 20 0210 99 51 0210 99 90 1602 50 10 1602 90 61	Meat of bovine animals, fresh, chilled or frozen	From 1.3.2013 to 31.12.2013	1 792 (1)
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	2 365 (1), (2)
09.7211	0403 90	Buttermilk, curdled milk and cream, kephir and other fermented or acidified milk and cream, whether or not concentrated or containing added sugar or other sweetening matter or flavoured or containing added fruit, nuts or cocoa	From 1.3.2013 to 31.12.2013	1 584
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	2 090 (3)
09.7212	0405	Butter and other fats and oils derived from milk; dairy spreads	From 1.3.2013 to 31.12.2013	417
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	550 (4)
09.7213	0406	Cheese and curd	From 1.3.2013 to 31.12.2013	2 084
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	2 750 (5)
09.7214	0703 20	Garlic	From 1.3.2013 to 31.12.2013	625
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	825 (6)
09.7215	2105	Ice cream and other edible ice, whether or not containing cocoa	From 1.3.2013 to 31.12.2013	125

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	165 (7)
09.7216	1005 90	Maize (corn), other than seed	From 1.3.2013 to 31.12.2013	8 334
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	11 000 (8)
09.7217	0711 51	Mushrooms of the genus *Agaricus, provisionally preserved, but unsuitable in that state for immediate consumption*	From 1.3.2013 to 31.12.2013	84
	2003 10	Mushrooms of the genus *Agaricus*, prepared or preserved otherwise than by vinegar or acetic acid	From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	110 (9)
09.7218	0402 10 0402 21 0402 99	Milk and cream, concentrated or containing added sugar or other sweetening matter, in powder, granules or other solid forms	From 1.3.2013 to 31.12.2013	2 500
	0402 29	Milk and cream, containing added sugar or other sweetening matter, in other forms than powder, granules or other solid forms	From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	3 300 (10)
09.7219	0402 91	Milk and cream, concentrated but not containing added sugar or other sweetening matter, in other forms than powder, granules or other solid forms	From 1.3.2013 to 31.12.2013	5 000
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	6 600 (11)
09.7220	0203 11 10 0203 12 11 0203 12 19 0203 19 11 0203 19 13 0203 19 15 0203 19 55 0203 19 59 0203 21 10	Meat of domestic swine, fresh, chilled or frozen	From 1.3.2013 to 31.12.2013	3 334
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	4 400 (12)

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
	0203 22 11 0203 22 19 0203 29 11 0203 29 13 0203 29 15 0203 29 55 0203 29 59			
09.7221	Ex 0207	Meat and edible offal other than livers, of the poultry of heading 0105, fresh, chilled or frozen	From 1.3.2013 to 31.12.2013	6 250
	0210 99 39 1602 20 1602 31 1602 32 1602 39	Other meat, salted, in brine, dried or smoked; other edible flours and meals of meat or meat offal Other prepared or preserved meat, meat offal or blood, of liver of any animal or of poultry of heading 0105	From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	8 250 [13]
09.7222	Ex 1006	Rice, other than rice in the husk (paddy or rough) for sowing	From 1.3.2013 to 31.12.2013	28 334
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	37 400 [14]
09.7223	2208 40 51 2208 40 99	Rum and other spirits obtained by distilling fermented sugar-cane products, in containers holding more than 2 litres	From 1.3.2013 to 31.12.2013	834 hectolitres (expressed in equivalent pure alcohol)
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	1 100 hectolitres (expressed in equivalent pure alcohol [15]
09.7224	0710 40 0711 90 30 2001 90 30 2004 90 10 2005 80	Sweetcorn	From 1.3.2013 to 31.12.2013	584
	2008 99 85	Maize (corn), other than sweetcorn (*Zea mays* var. *saccharata*), otherwise prepared or preserved, not containing added spirit and added sugar	From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	770 [16]

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
09.7225	0403 10	Yogurt	From 1.3.2013 to 31.12.2013	25
			From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	33 [17]
09.7226	1701 13 1701 14 1701 91 1701 99	Cane sugar, not containing added flavouring or colouring matter; cane or beet sugar and chemically pure sucrose, in solid form, other than raw sugar not containing added flavouring or colouring matter	From 1.3.2013 to 31.12.2013	18 334 (expressed in raw sugar equivalent)
	1702 30	Glucose and glucose syrup, not containing fructose or containing in the dry state less than 20 % by weight of fructose	From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	22 660 (expressed in raw sugar equivalent [18])
	1702 40 90	Glucose and glucose syrup other than isoglucose, containing in the dry state at least 20 % but less than 50 % by weight of fructose, excluding invert sugar		
	1702 50	Chemically pure fructose		
	1702 90 30 1702 90 50 1702 90 71 1702 90 75 1702 90 79 1702 90 80 1702 90 95	Other sugars, including invert sugar and other sugar and sugar syrup blends containing in the dry state 50 % by weight of fructose, excluding chemically pure maltose		
09.7227	Ex 1704 90 99	Other sugar confectionery, not containing cocoa, containing 70 % or more by weight of sucrose	From 1.3.2013 to 31.12.2013	8 334
	1806 10 30 1806 10 90	Cocoa powder, containing 65 % or more by weight of sucrose or isoglucose expressed as sucrose	From 1.1. to 31.12.2014 and for each period thereafter from 1.1. to 31.12.	10 300 [10]
	Ex 1806 20 95	Other preparations in blocks, slabs or bars weighing more than 2 kg or in liquid, paste, powder, granular or other bulk in containers or immediate packings, of a content exceeding 2 kg, containing less than 18 % by weight of cocoa butter and 70 % or more by weight of sucrose		

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
	Ex 1901 90 99	Other food preparations of flour, groats, meal, starch or malt extract, not containing cocoa or containing less than 40 % of cocoa calculated on a totally defatted basis, containing 70 % or more by weight of sucrose; other food preparations of goods of headings 0401 to 0404, not containing cocoa or containing less than 5 % by weight of cocoa calculated on a totally defatted basis, containing 70 % or more by weight of sucrose		
	Ex 2006 00 31 Ex 2006 00 38	Fruit (excluding tropical fruit and ginger), vegetables, nuts (excluding tropical nuts), fruit-peel and other parts of plants, preserved by sugar (drained, glacé or crystallised), containing 70 % or more by weight of sucrose		
	Ex 2007 91 10 Ex 2007 99 20 Ex 2007 99 31 Ex 2007 99 33 Ex 2007 99 35 Ex 2007 99 39	Jams, fruit jellies, marmalades, fruit or nut purée and fruit or nut pastes, obtained by cooking, containing 70 % or more by weight of sucrose		
	Ex 2009	Fruit juices (excluding tomato juice, juices of tropical fruit and mixtures of juices of tropical fruit) and vegetable juices of a value not exceeding EUR 30 per 100 kg net weight, unfermented and not containing added spirit, containing 30 % or more by weight of added sugar		
	Ex 2101 12 98 Ex 2101 20 98	Preparations with a basis of coffee, tea or mate, containing 70 % or more by weight of sucrose		
	2106 90 30 2106 90 59	Flavoured or coloured isoglucose syrups; other flavoured or colours sugar syrups other than lactose syrup, glucose syrup and maltod-extrine syrup		
	Ex 2106 90 98	Other food preparations not elsewhere specified or included, containing 70 % or more by weight of sucrose		

Order No	CN code	Description of goods	Quota period	Annual quota volume (in tonnes net weight if not otherwise specified)
	Ex 3302 10 29	Mixtures of odoriferous substances and mixtures with a basis of one or more of these substances, of a kind used in the drink industries, containing all flavouring agents characterising a beverage, of an actual alcoholic strength by volume not exceeding 0,5 %, containing 70 % or more by weight of sucrose		

(1) Expressed in carcase weight equivalent as follows: 100 kg of bone-in meat shall be equivalent to 70 kg of boneless meat.
(2) With an increase of 215 metric tonnes each year as from 2015.
(3) With an increase of 190 metric tonnes each year as from 2015.
(4) With an increase of 50 metric tonnes each year as from 2015.
(5) With an increase of 250 metric tonnes each year as from 2015.
(6) With an increase of 75 metric tonnes each year as from 2015.
(7) With an increase of 15 metric tonnes each year as from 2015.
(8) With an increase of 1 000 metric tonnes each year as from 2015.
(9) With an increase of 10 metric tonnes each year as from 2015.
(10) With an increase of 300 metric tonnes each year as from 2015.
(11) With an increase of 600 metric tonnes each year as from 2015.
(12) With an increase of 400 metric tonnes each year as from 2015.
(13) With an increase of 750 metric tonnes each year as from 2015.
(14) With an increase of 3 400 metric tonnes each year as from 2015.
(15) With an increase of 100 hectolitres (expressed in equivalent pure alcohol) each year as from 2015.
(16) With an increase of 70 metric tonnes each year as from 2015.
(17) With an increase of 3 metric tonnes each year as from 2015.
(18) With an increase of 660 metric tonnes (expressed in raw sugar equivalent) each year as from 2015.

COMMISSION IMPLEMENTING REGULATION (EU) No 406/2013

of 2 May 2013

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance prednisolone

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council [1], and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) The maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 [2].

(3) Prednisolone is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine species, applicable to muscle, fat, liver, kidney and milk.

(4) An application for the extension of the existing entry for prednisolone applicable to *equidae* has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use recommended the establishment of a MRL for prednisolone for *equidae* species, applicable to muscle, fat, liver and kidney.

(6) The entry for prednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the MRL for *equidae*.

(7) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as 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*.

It shall apply from 3 July 2013.

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

Done at Brussels, 2 May 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 152, 16.6.2009, p. 11.
[2] OJ L 15, 20.1.2010, p. 1.

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry corresponding to prednisolone is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
'Prednisolone	Prednisolone	Bovine	4 µg/kg 4 µg/kg 10 µg/kg 10 µg/kg 6 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Corticoids/ Glucocorticoids'
		Equidae	4 µg/kg 8 µg/kg 6 µg/kg 15 µg/kg	Muscle Fat Liver Kidney		

COMMISSION REGULATION (EU) No 407/2013

of 23 April 2013

correcting the Spanish and the Swedish versions of Regulation (EU) No 475/2012 amending Regulation (EC) No 1126/2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council as regards International Accounting Standard (IAS) 1 and International Accounting Standard (IAS) 19

(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 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards [1] and in particular Article 3(1) thereof,

Whereas:

(1) Errors appear in the Spanish and in the Swedish language versions of Commission Regulation (EU) No 475/2012 [2], more precisely in Article 2 thereof as regards the application date of the amendments made by that Regulation to Commission Regulation (EC) No 1126/2008 [3].

(2) The Swedish language version of that Regulation also contains some misprints.

(3) Regulation (EU) No 475/2012 should therefore be corrected accordingly.

(4) As companies are required to apply the amendments made by points 1 and 2 of Article 1 of Regulation (EU) No 475/2012, at the latest, as from the commencement date of their first financial year starting on or after 1 July 2012, this Regulation should apply retroactively from 1 July 2012.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Accounting Regulatory Committee,

HAS ADOPTED THIS REGULATION:

Article 1

[Concerns only the Spanish and the Swedish language versions.]

Article 2

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

It shall apply from 1 July 2012.

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

Done at Brussels, 23 April 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 243, 11.9.2002, p. 1.
[2] OJ L 146, 6.6.2012, p. 1.
[3] OJ L 320, 29.11.2008, p. 1.

COMMISSION IMPLEMENTING REGULATION (EU) No 408/2013

of 2 May 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, 2 May 2013.

For the Commission,
On behalf of the President,
Jerzy PLEWA
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	77,4
	TN	86,6
	TR	125,9
	ZZ	96,6
0707 00 05	AL	65,0
	EG	158,2
	TR	129,8
	ZZ	117,7
0709 93 10	TR	128,0
	ZZ	128,0
0805 10 20	EG	55,2
	IL	70,0
	MA	58,2
	TN	67,7
	TR	70,6
	ZZ	64,3
0805 50 10	TR	95,2
	ZA	116,4
	ZZ	105,8
0808 10 80	AR	113,8
	BR	104,2
	CL	119,4
	CN	77,7
	MK	30,3
	NZ	137,3
	US	207,3
	ZA	110,0
	ZZ	112,5

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

NOTICE TO READERS

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