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Contents

[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.

DIRECTIVES

DECISIONS

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2015/6

of 31 October 2014

amending Annex I to Regulation (EC) No 443/2009 of the European Parliament and of the Council in order to take into account the evolution of the mass of new passenger cars registered in 2011, 2012 and 2013

(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 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO_2 emissions from light-duty vehicles ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) The average mass value used for the purpose of calculating the specific emissions of CO_2 for each new passenger car is to be adjusted every three years to take into account any changes in the average mass of the new vehicles registered in the Union.

(2) It is evident from the monitoring of the mass in running order of new passenger cars registered in calendar years 2011, 2012 and 2013 that the average mass has increased and that the figure M_0 referred to in point 1(b) of Annex I to Regulation (EC) No 443/2009 should therefore be adjusted.

(3) Exceptionally for this first adjustment, it is appropriate to take into account that the quality of the data monitored in the years 2011, 2012 and 2013 has differed. The new value should therefore be determined by taking into account only those mass values that it has been possible to verify by the manufacturers concerned, whilst excluding values from the calculation that were obviously incorrect, i.e. values exceeding 2 840 kg or lower than 500 kg as well as values relating to vehicles that did not fall within the scope of Regulation (EC) No 443/2009. The new value is moreover based on the weighted average taking into account the number of new registrations in each of the reference years.

(4) Against that background, the M_0 value to be applied from 1 January 2016 should be increased by 20,4 kg from 1 372,0 to 1 392,4,

HAS ADOPTED THIS REGULATION:

Article 1

Point 1(b) of Annex I to Regulation (EC) No 443/2009 is replaced by the following:

'(b) From 2016:

$$\text{Specific emission of } CO_2 = 130 + a \times (M - M_0)$$

([1]) OJ L 140, 5.6.2009, p. 1.

Where:

M = mass of the vehicle in kilograms (kg)

M_0 = 1 392,4

a = 0,0457'.

Article 2

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

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

Done at Brussels, 31 October 2014.

For the Commission

The President

José Manuel BARROSO

COMMISSION REGULATION (EU) 2015/7

of 6 January 2015

authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 18(4) thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Pursuant to Article 13(3) of Regulation (EC) No 1924/2006, Commission Regulation (EU) No 432/2012 ([2]) was adopted, which established a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health.

(3) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims are to be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) In order to stimulate innovation, health claims which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data should undergo an accelerated type of authorisation.

(6) Following an application from Aptonia, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise (Question No EFSA-Q-2013-00234) ([3]). The claim proposed by the applicant was worded as follows: 'Glycaemic carbohydrates increase muscle glycogen repletion following strenuous exercise'.

(7) On 25 October 2013, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented, a cause and effect relationship had been established between the consumption of glycaemic carbohydrates and the claimed effect. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted claims, established by Regulation (EU) No 432/2012.

(8) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that the wording and the presentation are taken into account in that respect. Therefore, where the wording of claims used by the applicant has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use as those listed in the Annex to this Regulation.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1).
([3]) The EFSA Journal 2013;11(10):3409.

(9) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should be updated in order to take into account this Regulation.

(10) The comments from the applicant and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(11) Regulation (EU) No 432/2012 should therefore be amended accordingly.

(12) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim set out in the Annex to this Regulation shall be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

The Annex to Regulation (EU) No 432/2012 is amended in accordance with the Annex to this Regulation.

Article 3

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

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

Done at Brussels, 6 January 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In the Annex to Regulation (EU) No 432/2012, the following entry is inserted in an alphabetical order:

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
'Carbohydrates	Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle	The claim may be used only for food which provides carbohydrates which are metabolised by humans (excluding polyols). Information shall be given to the consumer that the beneficial effect is obtained with the consumption of carbohydrates, from all sources, at a total intake of 4 g per kg body weight, at doses, within the first 4 hours and no later than 6 hours, following highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.	The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.	2013;11(10):3409'	

COMMISSION REGULATION (EU) 2015/8

of 6 January 2015

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 18(4) thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims are to be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority. In some cases, the scientific risk assessment alone cannot provide all the information on which a risk management decision should be based and therefore other legitimate factors relevant to the matter under consideration should also be taken into account.

(4) Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266) ([2]). The claim proposed by the applicant was worded as follows: 'Glucose is metabolised within body's normal energy metabolism'.

(5) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented, a cause and effect relationship had been established between the consumption of glucose and contribution to energy-yielding metabolism. The target population is the general population.

(6) Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00267) ([3]). The claim proposed by the applicant was worded as follows: 'Glucose supports normal physical activity'.

(7) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(8) Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00268) ([4]). The claim proposed by the applicant was worded as follows: 'Glucose contributes to normal energy-yielding metabolism'.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2012;10(5):2694.
([3]) *EFSA Journal* 2012;10(5):2695.
([4]) *EFSA Journal* 2012;10(5):2696.

(9) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(10) Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00269) ([1]). The claim proposed by the applicant was worded as follows: 'Glucose contributes to normal energy-yielding metabolism during exercise'.

(11) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(12) Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00270) ([2]). The claim proposed by the applicant was worded as follows: 'Glucose contributes to normal muscle function'.

(13) On 11 May 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that a claim on glucose and contribution to energy-yielding metabolism has already been assessed with a favourable outcome and referred to its opinion on a health claim related to glucose and contribution to energy-yielding metabolism (Question No EFSA-Q-2012-00266).

(14) Pursuant to Articles 6(1) and 13(1) of Regulation (EC) No 1924/2006 health claims need to be based on generally accepted scientific evidence. Authorisation may also legitimately be withheld if health claims do not comply with other general and specific requirements of Regulation (EC) No 1924/2006, even in the case of a favourable scientific assessment by the Authority. Health claims inconsistent with generally accepted nutrition and health principles should not be made. The Authority concluded that a cause and effect relationship has been established between the consumption of glucose and contribution to energy-yielding metabolism. However, the use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced. Therefore, such a health claim does not comply with point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006 which foresees that the use of claims should not be ambiguous or misleading. Furthermore, even if the concerned health claim was to be authorised only under specific conditions of use and/or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently the claim should not be authorised.

(15) The health claims covered by this Regulation are health claims as referred to in Article 13(1)(a) of Regulation (EC) No 1924/2006, which, provided that they comply with that Regulation, are subject to the transitional period laid down in Article 28(5) of that Regulation until the adoption of the list of permitted health claims.

(16) The list of permitted health claims has been established by Commission Regulation (EU) No 432/2012 ([3]) and is applicable since 14 December 2012. As regards claims referred to in Article 13(5) of Regulation (EC) No 1924/2006 for which the evaluation by the Authority or consideration by the Commission has not been completed by 14 December 2012 and which by virtue of this Regulation are not included in the list of permitted health claims, it is appropriate to provide for a transitional period during which they may still be used, in order to allow both food business operators and the competent national authorities to adapt to the prohibition of such claims.

(17) The comments from the applicant and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

([1]) *EFSA Journal* 2012;10(5):2697.
([2]) *EFSA Journal* 2012;10(5):2698.
([3]) Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1).

(18) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claims set out in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

2. However, the health claims referred to in paragraph 1 used prior to the entry into force of this Regulation, may continue to be used for a maximum period of six months after the entry into force of this Regulation.

Article 2

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

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

Done at Brussels, 6 January 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucose	Glucose is metabolised within body's normal energy metabolism	Q-2012-00266
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucose	Glucose supports normal physical activity	Q-2012-00267
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucose	Glucose contributes to normal energy-yielding metabolism	Q-2012-00268
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucose	Glucose contributes to normal energy-yielding metabolism during exercise	Q-2012-00269
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucose	Glucose contributes to normal muscle function	Q-2012-00270

COMMISSION REGULATION (EU) 2015/9

of 6 January 2015

amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to the Act of Accession of Croatia, and in particular Article 50 thereof,

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) ([1]), and in particular Article 15(1)(b), (c), (d) and (g), Article 18(3)(b)(i), Article 19(4)(c), Article 20(11), Article 21(6)(d), Article 23(3), Article 27(c), Article 31(2), Article 40(f), Article 41(3) and Article 42(2) thereof,

Whereas:

(1) Regulation (EC) No 1069/2009 lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products. It also determines an end point in the manufacturing chain for certain derived products, beyond which they are no longer subject to the requirements of that Regulation.

(2) Commission Regulation (EU) No 142/2011 ([2]) lays down implementing rules for Regulation (EC) No 1069/2009, including rules on the adoption of alternative methods of use or disposal of animal by-products or derived products and the requirements for placing on the market of organic fertilisers and certain other animal by-products.

(3) In accordance with Article 19(1)(d) of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of Category 3 materials, as referred to in Article 10(f) of that Regulation, by the other means set out in Chapter IV of Annex VI to Regulation (EU) No 142/2011. In accordance with Article 36(3) of Regulation (EU) No 142/2011, this possibility was limited to the transitional period until 31 December 2014. Certain Member States authorise the collection, transport and disposal by the other means set out in Chapter IV of Annex VI to Regulation (EU) No 142/2011 of small quantities of former foodstuffs up to 20 kg per week.

(4) In the absence of reported negative consequences for animal health and taking into account that in certain instances the disposal in accordance with Article 14 of Regulation (EC) No 1069/2009 would be unacceptably onerous compared to local disposal, it appears justified to establish the transitional derogation as a permanent option, provided such disposal does not cause unacceptable health risks. Article 15 of Regulation (EU) No 142/2011, providing special rules for the application of Article 19(1)(a), (b), (c), (e) and (f) of Regulation (EC) No 1069/2009, should therefore be supplemented with reference to the measures provided for in Chapter IV of Annex VI to Regulation (EU) No 142/2011, which should also be amended accordingly. After consultation with Member Stats and stakeholders organisations, the option that Member States may decide to increase the volume to a maximum of 50 kg per week shall be removed when the transitional derogation becomes a permanent option. In addition, paragraph 3 of Article 36 of Regulation (EU) No 142/2011 should be deleted.

([1]) OJ L 300, 14.11.2009, p. 1.

([2]) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

(5) Given the low risk of possible contacts of farmed animals with organic fertilisers and soil improvers handled by certain operators and users, in particular when they operate outside the food and feed chain, the competent authorities should be allowed to exempt those operators and users from the registration obligation under Article 23 of Regulation (EC) No 1069/2009. Those operators and users should be added to the list of operators exempted from the obligation to notify the competent authorities in accordance with Article 20(4) of Regulation (EU) No 142/2011. Article 20(4) of Regulation (EU) No 142/2011 should be amended accordingly.

(6) Growing media, including potting soil, with a small content of animal by-products or derived products packaged for use by the final consumer do not present a risk of being used as feed for farmed animals. The limitation to a content of less than 5 % in volume of derived products of Category 2 or 3 materials in the growing media, including potting soil, mitigates the risk to use it as feed for farmed animals, since the high content of soil and other materials renders such products unpalatable for farmed animals. In the production of growing media, processed manure may be used. However, the processed manure shall not be the only component of the growing media. It should present not more than 50 % in volume in the growing media. Processed manure shall not be used for the production of growing media when the place of origin is subject to prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting farmed animals. Therefore, such products may be exempted from veterinary controls for placing on the market other than imports. Article 22(2) of Regulation (EU) No 142/2011 should be amended accordingly.

(7) The definitions of 'intermediate products' and 'trade samples' in points 35 and 39 respectively of Annex I to Regulation (EU) No 142/2011 should be clarified in order to avoid unjustified trade barriers. The definition of 'intermediate products' includes also a destination of those intermediate products. It is justified to extend the current definition with possible additional uses in the cosmetic industry. Derived products which comply with the requirements of Council Directive 76/768/EEC ([1]) may be in accordance with Article 5(1) of Regulation (EC) No 1069/2009 declared as the end point in the manufacturing chain. Furthermore, it is necessary to clarify that pet food may be introduced into the EU as a trade sample for purposes of feeding trials, testing of machinery or of equipment. The definition of 'intermediate products' and 'trade samples' in points 35 and 39 of Annex I to Regulation (EU) No 142/2011 should be amended accordingly.

(8) Although, in accordance with Article 3(6) of Regulation (EC) No 1069/2009, equidae are considered to be farmed animals, certain individual equine animals enjoy a particular close relationship to their keepers. It is therefore justified to provide the possibility of cremating dead equidae in incinerators approved for that purpose by the competent authority, provided the equidae originate from holdings which are not subject to prohibition orders for notifiable diseases. Council Directive 2009/156/EC ([2]) provides for animal health conditions governing amongst others the movement of equidae, including conditions for the identification of equidae. Only dead equidae which comply with that Directive may be individually cremated in low-capacity incinerators. Chapter III of Annex III to Regulation (EU) No 142/2011 should be amended accordingly.

(9) Article 13(g) of Regulation (EC) No 1069/2009 provides that animal by-products originating from aquatic animals of Category 2 material may be ensiled, composted or transformed into biogas. The European Food Safety Authority ('EFSA') published a Scientific Opinion on the evaluation of a new processing method for animal by-products of Category 2 materials of fish origin ([3]). According to EFSA's opinion, risks arising from Category 2 materials of fish origin are adequately reduced by the processing method, and derived products may therefore be used for the production of organic fertilisers, composted, transformed into biogas or used for the manufacture of feed for fur animals or other animals not intended for human consumption. EFSA's opinion concludes that there is no increase in risk, if the processing method is also applied for the processing of by-products originating from aquatic animals of Category 3 materials. Category 3 material obtained from aquatic animals may therefore be destined for purposes listed in Article 14 of Regulation (EC) No 1069/2009.

(10) Following the successful outcome of EFSA's risk assessment, the ensilage of fish material should be added to the list of alternative processing methods in Chapter IV of Annex IV to Regulation (EU) No 142/2011. Annex IV to Regulation (EU) No 142/2011 should be amended accordingly.

([1]) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169).

([2]) Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (codified version) (OJ L 192, 23.7.2010, p. 1).

([3]) *EFSA Journal* 2011; 9(9):2389 (11 pp.).

(11) Digestion residues and compost of animal origin may in practice be mixed with materials of non-animal origin. Operators should know which rules apply for the disposal of such digestion residues and compost. In addition, it is necessary to clarify in which cases compost and digestion residues derived from catering waste may be disposed of in an authorised landfill. Chapter III of Annex V to Regulation (EU) No 142/2011 should be amended accordingly.

(12) Croatia notified a list of species of wild necrophagous birds which should be subject to the derogation on special feeding purposes laid down in Article 18 of Regulation (EC) No 1069/2009. The list of species of necrophagous birds in Annex VI to Regulation (EU) No 142/2011 should be amended accordingly.

(13) EFSA assessed the risk posed by composting containment and subsequent incineration of dead-on-farm porcine animals ([1]) and concluded that the composting containment as referred to in the alternative parameters laid down in Section 2 of Chapter III of Annex V to Regulation (EU) No 142/2011 is not a sufficient treatment for the safe disposal of Category 2 material and can therefore not be described as an alternative processing method in Chapter IV of Annex IV to that Regulation. Following the aforementioned EFSA's assessment the 'aerobic maturation and storage of dead-on-farm pigs with subsequent incineration or co-incineration' should be seen as a specific containment method for the storage of animal by-products pending their subsequent disposal in accordance with Regulation (EC) No 1069/2009. In order to differentiate that method from the approved methods of composting and to avoid the approval procedure required for composting plants laid down in Annex V to Regulation (EU) No 142/2011, it is appropriate to include that method in a new Chapter in Annex IX to that Regulation together with the method 'Hydrolysis with subsequent disposal', currently referred to in point H of Section II of Chapter IV of Annex IV, which is based on the same principles. Furthermore the reference to Annex IV in Section 11 of Chapter II of Annex XVI should be adapted accordingly. Annexes IV, IX and XVI to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(14) Rendered fats from Category 3 material are subject to specific requirements under Section 3 of Chapter II of Annex X to Regulation (EU) No 142/2011. However, there are no animal health grounds to prohibit the processing of Category 3 material from aquatic animals and animal by-products from aquatic animals as referred to in Article 10(i) and (j) of Regulation (EC) No 1069/2009 together with Category 3 animal by-products obtained from terrestrial animals into mixed rendered fats. Therefore it should be possible to use Category 3 materials from aquatic animals and animal by-products from aquatic animals as referred to in Article 10(i) and (j) of Regulation (EC) No 1069/2009 for the production of rendered fat. Point A(1) of Section 3 of Chapter II of Annex X to Regulation (EU) No 142/2011 should be amended accordingly.

(15) Requirements for the heat treatment of centrifuge or separator sludge which may be later used as or in the production of organic fertilisers and placed on the market are set out in Part III of Section 4 of Chapter II in Annex X to Regulation (EU) No 142/2011. It is opportune to introduce a derogation that the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within the Member States, provided that the operators can demonstrate that the heat treatment carried out according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the already established parameters applicable for placing on the market. Part III of Section 4 of Chapter II of Annex X to Regulation (EU) No 142/2011 should be amended accordingly.

(16) Intermediate products may be used, inter alia, for the production of laboratory reagents or *in vitro* diagnostic for animal purposes. After checks at the border inspection post in accordance with Article 4 of Council Directive 97/78/EC ([2]) the product has to be transported directly to the registered establishment or plant of destination. In order to clarify the requirements for the importation of intermediate products, Annex XII to Regulation (EU) No 142/2011 should be amended accordingly.

(17) Blood products intended for the production of feed for farmed animals, including spray dried blood and blood plasma of porcine animals, must have been produced in accordance with Section 2 of Chapter II of Annex X to Commission Regulation (EU) No 142/2011. With reference to point B of that Section, blood products are to be submitted to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV to that Regulation, or another method which ensures that the blood products comply with the microbiological standards for derived products set out in Chapter I of Annex X to Commission Regulation (EU) No 142/2011. Regulation (EU) No 142/2011 also provides, in particular in column 6 of row 2 in Table 1 of Section 1 of Chapter I of Annex XIV, that blood products not intended for human consumption that could be used as feed are to be accompanied by a health certificate in accordance with the model health certificate set out in Chapter 4(B) of Annex XV when they are intended for dispatch to or transit through the Union.

([1]) *EFSA Journal* 2012; 10(2):2559 (11 pp.).
([2]) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

(18) Porcine epidemic diarrhoea, including infection of pigs with the porcine epidemic diarrhoea virus (PEDv) and swine delta coronavirus (SDCv), has been reported in Asia, North America, the Caribbean, Central and South America. SDCv has never been detected in the Union. Inappropriate heat treatment or contamination after heat treatment of spray dried blood and blood plasma of porcine animals, a traditional ingredient for feed for piglets, is incriminated in the spread of the virus.

(19) The Commission, acting on its own initiative, adopted Commission Implementing Regulation (EU) No 483/2014 [1] as an interim safeguard measure in respect of the safety of spray dried blood and blood plasma of porcine animals intended for the production of feed for animals of the porcine species. Since the risk for animal health will remain, it is necessary to review the requirements for imports of spray dried blood and blood plasma of porcine animals intended for the production of feed for animals of the porcine species and implement the interim measures as a permanent requirement.

(20) Scientific observation indicates that porcine coronaviruses are inactivated in swine faeces if heated to and held at a temperature of 71 °C for 10 minutes or left at room temperature of 20 °C for 7 days. The virus did not survive in experimentally infected dry feed stored at room temperature of 24 °C for at least two weeks. In the Union and in third countries the commonly applied temperature for spray drying of blood and blood plasma is 80 °C throughout the substance.

(21) Based on the available information, it appears opportune to require that spray dried blood and blood plasma of porcine origin introduced from third countries and intended for feeding of porcine animals has been subjected to a high temperature treatment followed by subsequent storage for a certain time at room temperature in order to mitigate the risk of contamination after the treatment.

(22) Imports of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for uses other than as feed material, organic fertilisers or soil improvers should also be authorised where those materials are transported by plane, provided they comply with requirements laid down in Article 41 of Regulation (EC) No 1069/2009. Annex XIV to Regulation (EU) No 142/2011 should be amended accordingly.

(23) Following the amendments of the definition of 'intermediate products' and the additional requirements for imports of blood products, the model of declaration to be used for imports from third countries of intermediate products and the model of health certificate for imports of blood products intended as feed material should be modified accordingly. Chapter 4(B) and Chapter 20 of Annex XV to Regulation (EU) No 142/2011 should be amended accordingly.

(24) In order to avoid disruptions of trade, a transitional period should be laid down during which imports of the intermediate products to which the provisions of Regulation (EU) No 142/2011 apply, as amended by this Regulation, should be accepted by Member States in accordance with the rules in force prior to the entry into force of this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 142/2011 is amended as follows:

(1) In Article 15, the following paragraph is added:

'By way of derogation from Article 14 of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of small quantities of Category 3 materials as referred to in Article 10(f) of that Regulation by means referred to in Article 19(1)(d) of that Regulation, subject to compliance with the requirements for disposal by other means set out in Chapter IV of Annex VI hereto.'

[1] Commission Implementing Regulation (EU) No 483/2014 of 8 May 2014 on protection measures in relation to porcine diarrhoea caused by a deltacoronavirus as regards the animal health requirements for the introduction into the Union of spray dried blood and blood plasma of porcine origin intended for the production of feed for farmed porcine animals (OJ L 138, 13.5.2014, p. 52).

(2) In Article 19, point (c) is replaced by the following:

'(c) Chapter III, where they store derived products for certain intended purposes as referred to in Article 24(1)(j) of that Regulation;

(d) Chapter V, where they store on the farm animal by-products intended for subsequent disposal as referred to in Article 4 of that Regulation.'

(3) Article 20(4) is amended as follows:

(a) point (d) is replaced by the following:

'(d) operators using small quantities of Categories 2 and 3 materials referred to in Articles 9 and 10 of Regulation (EC) No 1069/2009 or of products derived therefrom, for the purpose of direct supply of the products within the region to the final user, on the local market or to local retail establishments, if the competent authority does not consider such activity to present a risk of spreading any serious transmissible disease to humans or animals; this point shall not apply where those materials are used as feed for farmed animals other than fur animals;'

(b) the following points (e) and (f) are added:

'(e) users of organic fertilisers or soil improvers at premises where farmed animals are not kept;

(f) operators handling and distributing organic fertilisers or soil improvers exclusively in ready-to-sell retail packaging of not more than 50 kg in weight for uses outside the feed and food chain.'

(4) In Article 22, paragraph 2 is replaced by the following:

'2. The placing on the market of the following is not subject to any animal health conditions:

(a) guano from wild sea birds, collected in the Union or imported from third countries;

(b) ready-to-sell growing media, other than that imported, with a content of less than:

(i) 5 % in volume of derived products of Category 3 material or of Category 2 material other than processed manure;

(ii) 50 % in volume of processed manure.'

(5) In Article 23, paragraph 3 is replaced by the following:

'3. The operator or owner of the establishment or plant of destination of intermediate products or his representative shall use and/or dispatch the intermediate products exclusively for use in manufacturing according to the definition of intermediate products under Point 35 of Annex I.'

(6) In Article 36, paragraph 3 is deleted.

(7) Annexes I, III, IV, V, VI, IX, X, XI, XII, XIV, XV and XVI are amended in accordance with the Annex to this Regulation.

Article 2

For a transitional period until 27 September 2015, consignments of animal by-products and of derived products accompanied by a model declaration, which has been completed and signed in accordance with the model set out in Chapter 20 of Annex XV to Regulation (EU) No 142/2011 in its version before the date of entry into force of this Regulation, shall continue to be accepted for importation into the Union, provided that such model declarations were completed and signed before 27 July 2015.

Article 3

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

It shall apply from 23 February 2015.

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

Done at Brussels, 6 January 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annexes I, III, IV, V, VI, IX, X, XI, XII, XIV, XV and XVI to Regulation (EU) No 142/2011 are amended as follows:

(1) Annex I is amended as follows:

(a) point 35 is replaced by the following:

'35. "**intermediate product**" means a derived product:

(a) which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, *in vitro* diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products as follows:

(i) as material in a manufacturing process or in the final production of a finished product;

(ii) in validation or verification during a manufacturing process; or

(iii) in quality control of a finished product;

(b) whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a);

(c) which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, *in vitro* diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products;'

(b) point 39 is replaced by the following:

'39. "**trade samples**" means animal by-products or derived products intended for particular studies or analyses authorised by the competent authority in accordance with Article 17(1) of Regulation (EC) No 1069/2009 with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment;'

(c) point 58 is replaced by the following:

'58. "**processing plant**" means premises or facilities for the processing of animal by-products as referred to in Article 24(1)(a) of Regulation (EC) No 1069/2009, in which animal by-products are processed in accordance with Annex IV and/or Annex X;'

(d) the following point 59 is added:

'59. "**growing media**" means materials, including potting soil, other than soil *in situ*, in which plants are grown and which is used independently from soil *in situ*.'

(2) In Annex III, Chapter III, point (a) is replaced by the following:

'(a) only be used for the disposal of:

(i) dead pet animals referred to in Article 8(a)(iii) of Regulation (EC) No 1069/2009;

(ii) Category 1 materials referred to in Article 8(b), (e) and (f), Category 2 materials referred to in Article 9 or Category 3 materials referred to in Article 10 of that Regulation; and

(iii) dead individually identified equine animals from holdings not subject to health restrictions in accordance with Article 4(5) or 5 of Directive 2009/156/EC, if authorised by the Member State;'

(3) In Annex IV, Chapter IV is amended as follows:

(a) Section 2 is amended as follows:

(i) point H is deleted;

(ii) the following point is added:

'K. Ensilage of fish material

1. Starting materials

For this process, only the following by-products obtained from aquatic animals may be used:

(a) Category 2 materials referred to in Article 9(f)(i) and (iii) of Regulation (EC) No 1069/2009;

(b) Category 3 materials.

2. Processing method

2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.

2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.

2.3. Before authorisation is given, the operator's permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be assessed by the competent authority.'

(b) In Section 3, point 2(d) is replaced by the following:

'(d) the lime-treated mixture of pig and poultry manure may be applied to land as processed manure;'

(c) In Section 3, the following point 2(e) is added:

'(e) The final product derived from the ensilaging of fish material may:

(i) for Category 2 materials, be used for purposes referred to in Article 13(a) to (d) and (g) to (i) of Regulation (EC) No 1069/2009 without further processing or as feed for animals referred to in Article 18 or Article 36(a)(ii) of that Regulation; or

(ii) for Category 3 materials, be used for purposes referred to in Article 14 of Regulation (EC) No 1069/2009.'

(4) In Annex V, Chapter III, Section 2 is amended as follows:

(a) in point 2(b), point (x) is replaced by the following:

'(x) animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004;'

(b) in point 2(b), the following point (xi) is added:

'(xi) mixture of animal by-products referred to in point 2(b) with non-animal by-product materials.'

(c) in point 3, point (b) is replaced by the following:

'(b) considers that the digestion residues or compost are unprocessed material and obliges operators to handle them in accordance with Regulation (EC) No 1069/2009, with this Regulation or, in the case of compost or digestion residues derived from catering waste, to recover or dispose of in accordance with the environmental legislation.'

(5) Annex VI is amended as follows:

(a) in Chapter II, Section 2, point 1(a)(i) is replaced by the following:

'(i) one of the following species of necrophagous birds in the following Member States:

Country code	Member State	Animal species	
		Local name	Latin name
BG	Bulgaria	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle imperial eagle white-tailed eagle black kite red kite	*Gypaetus barbatus* *Aegypius monachus* *Neophron percnopterus* *Gyps fulvus* *Aquila chrysaetos* *Aquila heliaca* *Haliaeetus albicilla* *Milvus migrans* *Milvus milvus*
EL	Greece	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle imperial eagle white-tailed eagle black kite	*Gypaetus barbatus* *Aegypius monachus* *Neophron percnopterus* *Gyps fulvus* *Aquila chrysaetos* *Aquila heliaca* *Haliaeetus albicilla* *Milvus migrans*
ES	Spain	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle Spanish imperial eagle black kite red kite	*Gypaetus barbatus* *Aegypius monachus* *Neophron percnopterus* *Gyps fulvus* *Aquila chrysaetos* *Aquila adalberti* *Milvus migrans* *Milvus milvus*
FR	France	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle white-tailed eagle black kite red kite	*Gypaetus barbatus* *Aegypius monachus* *Neophron percnopterus* *Gyps fulvus* *Aquila chrysaetos* *Haliaeetus albicilla* *Milvus migrans* *Milvus milvus*
HR	Croatia	bearded vulture black vulture Egyptian vulture griffon vulture	*Gypaetus barbatus* *Aegypius monachus* *Neophron percnopterus* *Gyps fulvus*

Country code	Member State	Animal species	
		Local name	Latin name
IT	Italy	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle black kite red kite	*Gypaetus barbatus* *Aegypius monachus* *Neophron percnopterus* *Gyps fulvus* *Aquila chrysaetos* *Milvus migrans* *Milvus milvus*
CY	Cyprus	black vulture griffon vulture	*Aegypius monachus* *Gyps fulvus*
PT	Portugal	black vulture Egyptian vulture griffon vulture golden eagle	*Aegypius monachus* *Neophron percnopterus* *Gyps fulvus* *Aquila chrysaetos*
SK	Slovakia	golden eagle imperial eagle white-tailed eagle black kite red kite	*Aquila chrysaetos* *Aquila heliaca* *Haliaeetus albicilla* *Milvus migrans* *Milvus milvus*'

(b) In Chapter IV, the second paragraph is deleted.

(6) In Annex IX, the following Chapter V is added:

'CHAPTER V

CONTAINMENT METHODS

Section 1

General provisions

1. Materials resulting from a containment method may be used or disposed of only within the Member State where that containment method is authorised by the competent authority.

2. The competent authority of a Member State shall make the results of official controls available to the competent authority of another Member State upon request, where a containment method is used for the first time in that Member State, in order to facilitate the introduction of the new containment method.

Section 2

Methodology

A. Aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration.

1. Member States concerned

The process of aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration may be used in France, Ireland, Latvia, Portugal and the United Kingdom.

Following aerobic maturation and storage of material, the competent authority of the Member State concerned must ensure that the materials are collected and disposed of within the territory of that Member State.

2. Starting materials

For this process, only the following materials of animals of the porcine species may be used:

(a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;

(b) Category 3 materials referred to in Article 10(h) of Regulation (EC) No 1069/2009.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding, provided this holding is not subject to restrictions due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species. This method may not be used for animals which have died due to those diseases or have been killed for diseases control purposes, or parts of those animals.

3. Methodology

3.1. General principles

The method is a process authorised by the competent authority.

The site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.

The operator must:

(a) take preventive measures against access of animals and put in place a documented pest control programme;

(b) put in place procedures to prevent the spreading of diseases;

(c) put in place procedures to prevent the spreading of used sawdust outside the closed system.

The process must be carried out in a closed system which consist of several cells, with a waterproof floor and delimited by solid walls. Any waste water must be collected; the cells must be connected with a drainpipe fitted with a 6 mm grid to capture solids.

Size and number of the cells must be adapted to the mortality level defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 with sufficient capacity for farm mortalities occurring during an eight-month period at least.

3.2. Phases

3.2.1. Filling and storage phase

The fallen pigs and other porcine material must be individually covered in sawdust and piled up until the cell is full. First a layer of at least 30 centimetres of sawdust must be placed on the ground. The carcasses and other porcine material must then be placed on this first layer of sawdust and each layer of carcasses and other porcine material must be covered with a layer of sawdust at least 30 cm thick.

Personnel must not walk on the stored material.

3.2.2. Maturing phase

When the cell is full and a rise in temperature allows the degradation of all the soft tissues, the maturation period starts and must last at least 3 months.

At the end of the filling and storage phase and during all of the maturation phase, the operator must monitor the temperature in each cell with a temperature sensor placed between 40 cm and 60 cm beneath the pile surface of the latest built layer.

The electronic reading and monitoring of the temperature must be recorded by the operator.

At the end of the filling and storage phase, the temperature monitoring is an indicator of a satisfactory pile layout. The temperature must be measured by an automatic recording device. The aim is to reach 55 °C during 3 consecutive days, revealing that the maturing process is active and that the pile layout is effective and that the maturing phase has started.

The operator must monitor the temperature once a day and the following measures shall be taken depending on the outcome of these measurements:

(a) where the temperature of 55 °C or more is maintained during 3 consecutive days, the pile may be removed after a 3 consecutive months maturing phase, or may remain stored on the premises awaiting a later removal;

(b) where the temperature of 55 °C is not reached during 3 consecutive days, measures defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be set by the operator; if needed, the competent authority may stop the processing method and the material must be disposed of in compliance with Article 13 of the aforementioned Regulation.

A time limit for the storage phase may be determined by the competent authority.

3.2.3. Transport and incineration or co-incineration

The transport of the resulted material after the maturation phase to the approved incineration or co-incineration plant is subject to controls referred to in Regulation (EC) No 1069/2009 or Directive 2008/98/EC.

B. Hydrolysis with subsequent disposal

1. Member States concerned

The process of hydrolysis with subsequent disposal may be used in Ireland, Spain, Latvia, Portugal and the United Kingdom.

Following hydrolysis, the authorising competent authority must ensure that the materials are collected and disposed of within the same Member State referred to above.

2. Starting materials

For this process, only the following materials of porcine origin may be used:

(a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;

(b) Category 3 materials referred to in Article 10(h) of that Regulation.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding and provided this holding is not subject to prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species, or animals that have been killed for disease control purposes.

3. Methodology

Hydrolysis with subsequent disposal is a temporary storage on the spot. It shall be carried out according to the following standards:

(a) Following their collection on a holding for which the competent authority has authorised the use of the processing method, based on an assessment of the animal density of the holding, the likely mortality rate and the potential risks for public and animal health which may arise, the animal by-products must be placed into a container which has been constructed in accordance with point (b) ("the container") and which has been placed at a dedicated site in accordance with points (c) and (d) ("the dedicated site").

(b) The container must:

(i) have a device to close it;

(ii) be waterproof, leak-proof and hermetically sealed;

(iii) be coated in a way which prevents corrosion;

(iv) be equipped with a device for controlling emissions in accordance with point (e).

(c) The container must be placed in a dedicated site which is physically separate from the holding.

That site must have dedicated access routes for the movement of materials and for collection vehicles.

(d) The container and the site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.

(e) The container must be linked to a pipe for gaseous emissions, which must be equipped with appropriate filters to prevent the transmission of diseases communicable to humans and animals.

(f) The container must be closed for the process of hydrolysis for a period of at least three months, in such a way that any unauthorised opening is prevented.

(g) The operator must put in place procedures to prevent the transmission of diseases communicable to humans or animals by movements of personnel.

(h) The operator must:

(i) take preventive measures against birds, rodents, insects and other vermin;

(ii) put in place a documented pest control programme.

(i) The operator must keep records of:

(i) any placing of material into the container;

(ii) any collection of hydrolysed material from the container.

(j) The operator must empty the container at regular intervals for a check:

(i) for the absence of corrosion;

(ii) to detect and prevent possible leakage of liquid materials into the ground.

(k) Following hydrolysis, the materials must be collected, used and disposed of in accordance with Article 13(a), (b), (c) or Article 13(e)(i) of Regulation (EC) No 1069/2009 or Article 14 of that Regulation for Category 3 materials.

(l) The process must be carried out in a batch mode.

(m) Any other handling or use of the hydrolysed materials, including their application to land, shall be prohibited.'

(7) In Annex X, Chapter II is amended as follows:

(a) in Section 3, point A, point 1 is replaced by the following:

'1. Rendered fats

Only Category 3 material, other than Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of rendered fat.'

(b) in Section 4, Part III, the following paragraph is added:

'By way of derogation from the first paragraph, the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within Member States which have authorised those alternative parameters, provided operators can demonstrate that the heat treatment according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the parameters set out in the first paragraph.'

(8) In Annex XI, Chapter II, a new Section 3 is added:

'Section 3

Requirements for approval of establishments or plants

In order to be approved in accordance with Article 24(1)(f) of Regulation (EC) No 1069/2009, operators shall ensure that establishments or plants carrying out the activities referred to in point 1 of Section 1 meet the requirements laid down in Article 8 of this Regulation and:

(a) have adequate facilities for storage of incoming ingredients to prevent cross-contamination and avoid contamination during storage;

(b) dispose of unused animal by-products or derived products in accordance with Articles 13 and 14 of Regulation (EC) No 1069/2009.'

(9) In Annex XII, point 3(a) is replaced by the following:

'3. The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:

(a) a registered establishment or plant for the production of laboratory reagents, medical devices and *in vitro* diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;'.

(10) Annex XIV is amended as follows:

(a) Chapter I is amended as follows:

(i) In Section 1, in row 2 of Table 1, the text in the fourth column is replaced by the following:

'The blood products must have been produced in accordance with Section 2 of Chapter II of Annex X and Section 5 of Chapter I of Annex XIV.'

(ii) a new Section 5 is added:

'Section 5

Imports of blood products for the feeding of farmed animals

The following requirements shall apply to the importation of blood products, including spray dried blood and blood plasma which have been derived from porcine animals intended for the feeding of porcine animals:

These derived products must be:

(a) subjected to a heat treatment at a temperature of at least 80 °C throughout the substance and the dry blood and blood plasma is of not more than 8 % moisture with a water activity (Aw) of less than 0,60;

(b) stored in dry warehouse conditions under room temperature for at least 6 weeks.'

(b) in Chapter II, Section 7, point 1(b) is replaced by the following:

'(b) the products are conveyed from the third country of origin directly to a border inspection post of entry into the Union and are not transhipped at any port or place outside the Union;'

(11) Annex XV is amended as follows:

(a) Chapter 4(B) is replaced by the following:

'CHAPTER 4(B)

Health certificate

For blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through (2) the European Union

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postcode Tel.		I.6. Person responsible for the load in EU Name Address Postcode Tel.	
I.7. Country of origin / ISO code	I.8. Region of origin / Code	I.9. Country of destination / ISO code	I.10. Region of destination / Code
I.11. Place of origin Name / Approval number Address Name / Approval number Address Name / Approval number Address		I.12. Place of destination Custom warehouse ☐ Name / Approval number Address Postcode	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
			I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Seal/Container No			I.24. Type of packaging
I.25. Commodities certified for: Animal feedingstuff ☐ Technical use ☐			

I.26. For transit through EU to third country ☐		I.27. For import or admission into EU ☐	
Third country	ISO code		

I.28. Identification of the commodities			
		Approval number of establishments	
Species (Scientific name)	Nature of commodity	Manufacturing plant	Batch number

Blood products not intended for human consumption that could be used as feed material

COUNTRY

II. **Health information**	II.a. Certificate reference No	II.b.

Part II: Certification

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([1a]) and Commission Regulation (EU) No 142/2011 ([1b]) and certify that the blood products described above:

II.1. consist of blood products that satisfy the health requirements below;

II.2. consist exclusively of blood products not intended for human consumption;

II.3. have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;

II.4. have been prepared exclusively with the following animal by-products:

([2]) *either* [blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;]

([2]) *and/or* [blood of slaughtered animals, which is rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of diseases communicable to humans or animals, derived from carcases that have been slaughtered in a slaughterhouse and were considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation;]

II.5. in order to inactivate pathogenic agents, have been submitted

([2]) *either* [to processing in accordance with processing method ..... ([3]) as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011;]

([2]) *or* [to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I of Annex X to Regulation (EU) No 142/2011;]

([2]) *or* [in the case of blood products, including spray dried blood and blood plasma, of porcine origin intended for the feeding of porcine animals, to a heat treatment at a temperature of at least 80 °C throughout the substance and the dry blood and blood plasma is of not more than 8 % moisture with a water activity (Aw) of less than 0,60.]

II.6. have been examined under the responsibility of the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards[(4)]:

Salmonella: absence in 25g: n = 5, c = 0, m = 0, M = 0,

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.7. the end product was:

([2]) *either* [packed in new or sterilised bags;]

([2]) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating 'NOT FOR HUMAN CONSUMPTION';

II.8. the end product was stored in enclosed storage;

II.9. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment;

([2]) *and* [in the case of blood products, including spray dried blood and blood plasma of porcine origin intended for the feeding of porcine animals, has been stored in dry warehouse conditions under room temperature for at least 6 weeks.]

II.10. does not contain and is not derived from:

([2]) *either* [specified risk material or mechanically separated meat obtained from bones of bovine, ovine or caprine animals and, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ([5]), the animals from which this animal by-product or derived product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod- shaped instrument introduced into the cranial cavity.]

([2]) *or* [bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001.]

COUNTRY

Blood products not intended for human consumption that could be used as feed material

II. **Health information**	II.a. Certificate reference No	II.b.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11.99.

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

— Box reference I.25: technical use: any use other than for animal consumption.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia, PESCA, Reptilia.

Part II:

([1a]) OJ L 300, 14.11.2009, p. 1.

([1b]) OJ L 54, 26.2.2011, p. 1.

([2]) Delete as appropriate.

([3]) Insert method 1 to 5 or 7 as applicable.

([4]) Where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

([5]) OJ L 147, 31.5.2001, p. 1.

— The signature and the stamp must be in a different colour to that of the printing.

— Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

(b) Chapter 20 is replaced by the following:

'CHAPTER 20

Model declaration

Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postcode Tel.		I.6. Person responsible for the load in EU Name Address Postcode Tel.	
I.7. Country of origin	ISO code I.8. Region of origin Code	I.9. Country of destination	ISO code I.10. Region of destination Code
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postcode	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Seal/Container No		I.24. Type of packaging	
I.25. Commodities certified for: Technical use ☐			

I.26. For transit through EU to third country ☐		I.27. For import or admission into EU ☐	
Third country	ISO code		

I.28. Identification of the commodities			
	Approval number of establishments		
Species (Scientific name)	Manufacturing plant	Net weight	Batch number

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

COUNTRY

II. **Health information**	II.a. Certificate reference No	II.b.

Part II: Certification

DECLARATION

I, the undersigned, declare that the intermediate product referred to above is intended to be imported by me into the Union and satisfies the definition provided for in point 35 of Annex I of Commission Regulation (EU) No 142/2011 ([1a]), and in particular that:

(1) it is intended for the manufacture of:

([2]) *either* [— medicinal products,]

([2]) *and/or* [— veterinary medicinal products,]

([2]) *and/or* [— medical devices for medical and veterinary purposes,]

([2]) *and/or* [— active implantable medical devices,]

([2]) *and/or* [— in vitro diagnostic medical devices for medical and veterinary purposes,]

([2]) *and/or* [— laboratory reagents,]

([2]) *and/or* [— cosmetic products;]

(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the material directly or as a component of a product intended for that purpose, except for the fact that it requires further manufacturing or transformation such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service as medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes or cosmetic products in accordance with the Union legislation ([1b]) applicable to those products or as laboratory reagents;

(3) it has been derived from:

([2]) *either* [— material which may have originated from animals submitted to illegal treatment as defined in Article 1(2)(d) of Council Directive 96/22/EC or Article 2(b) of Council Directive 96/23/EC;]

([2]) *and/or* [— carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

([2]) *and/or* [— carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;

(ii) heads of poultry;

(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;

(iv) pig bristles;

(v) feathers;]

([2]) *and/or* [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

([2]) *and/or* [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

COUNTRY

II. **Health information**	II.a. Certificate reference No	II.b.

([2]) *and/or* [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

([2]) *and/or* [— pet food and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

([2]) *and/or* [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

([2]) *and/or* [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

([2]) *and/or* [— animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

([2]) *and/or* [— the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

— hatchery by-products,

— eggs,

— egg by-products, including egg shells;

(iii) day-old chicks killed for commercial reasons;]

([2]) *and/or* [— animal by-products from aquatic or terrestrial invertebrates other than species pathogenic to humans or animals;]

([2]) *and/or* [— animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]

([2]) *and/or* [— products derived from or generated by:

— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals,

— aquatic or terrestrial invertebrates other than species pathogenic to humans or animals,

— animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]

([2]) and/or [— animals and parts of animals, other than those referred to in Article 8 or Article 10 of Regulation (EC) No 1069/2009,

(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;

(ii) foetuses;

(iii) oocytes, embryos and semen which are not destined for breeding purposes; and

(iv) dead-in-shell poultry;]

([2]) *and/or* [— animal by-products other than Category 1 material or Category 3 material;]

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

COUNTRY

II. **Health information**	II.a. Certificate reference No	II.b.

(4) its outer packaging is labelled 'FOR MEDICINAL PRODUCTS/VETERINARY MEDICINAL PRODUCTS/MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES/ACTIVE IMPLANTABLE MEDICAL DEVICES/IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES/LABORATORY REAGENTS/COSMETIC PRODUCTS ONLY' and it is not intended to be diverted at any stage within the Union for any other use;

(5) the consignment will be transported directly to the place of destination as indicated under point I.12 of this declaration, that is:

— an establishment or plant for the production of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products, which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009,

— an establishment or plant which has been approved in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they shall only be dispatched to an establishment or plant referred to in the preceding indent of this point.

Notes

— Box reference I.19: use appropriate Harmonised System (HS) code under the following headings: 02.06; 04.07; 04.08; 05.06; 05.07; 05.11; 12.12; 21.06; 30.01; 30.02; 31.01; 51.01, 51.02 or 15.05.00.

— Box reference I.25: technical use: any use other than for animal consumption.

([1a]) OJ L 54, 26.2.2011, p. 1.

([1b]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1) and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169), as appropriate.

([2]) Delete as appropriate.

The importer

Name (in capital letters): Address:

Date: Signature:'

(12) In Annex XVI, Chapter III, Section 11 is replaced by the following:

'Section 11

Official controls regarding hydrolysis with subsequent disposal

The competent authority shall carry out controls at sites where hydrolysis with subsequent disposal is carried out in accordance with point B of Section 2 of Chapter V of Annex IX.

Such controls shall, for the purpose of reconciliation of the quantities of hydrolysed materials dispatched and disposed of, include documentary checks:

(a) of the amount of materials which are hydrolysed at the site;

(b) in the establishments or plants where the hydrolysed materials are disposed of.

Controls shall be carried out regularly on the basis of a risk assessment.

During the period of the first 12 months of operation, a control visit to a site, where a container for the hydrolysis is located, shall be carried out every time hydrolysed material is collected from the container.

Following the period of the first 12 months of operation, a control visit to such sites shall be carried out every time the container is emptied and checked for the absence of corrosion and leaking in accordance with point B(3)(j) of Section 2 of Chapter V of Annex IX.'

COMMISSION IMPLEMENTING REGULATION (EU) 2015/10

of 6 January 2015

on criteria for applicants for rail infrastructure capacity and repealing Implementing Regulation (EU) No 870/2014

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area [1], and in particular Article 41(3) thereof,

Whereas:

(1) Article 41(2) of Directive 2012/34/EU provides for the possibility for infrastructure managers to set requirements with regard to applicants to ensure that their legitimate expectations about future revenues and utilisation of the infrastructure are safeguarded.

(2) Those requirements should be appropriate, transparent and non-discriminatory. They can only include the provision of a financial guarantee that should not exceed an appropriate level proportional to the contemplated level of activity, and assurance of the capability of the applicant to prepare compliant bids for infrastructure capacity.

(3) Financial guarantees could take the form of advance payments or guarantees provided by financial institutions

(4) The appropriateness of the requirements referred to in Article 41(2) of Directive 2012/34/EU should take account of the fact that the infrastructure of competing transport modes, such as road and air transport, sea ships and inland waterways, is often free of user charges and hence also free of financial guarantees thereon. In order to ensure fair competition between transport modes, financial guarantees should be limited to the strict minimum in terms of level and duration.

(5) Those financial guarantees are only appropriate if they are necessary for the purpose of reassuring the infrastructure manager about the future revenues and utilisation of the infrastructure. Considering that infrastructure managers are able to rely on the checks and surveillance of the financial fitness of railway undertakings under the licensing procedure in accordance with Chapter III of Directive 2012/34/EU, and in particular Article 20 of that Directive, the need for financial guarantees is further reduced.

(6) The principle of non-discrimination applies to those guarantees, therefore there should be no distinction between the guarantee requirements for privately and publicly owned applicants.

(7) Guarantees should be commensurate with the level of risk posed by the applicant for the infrastructure manager at different stages of capacity allocation. The risk is considered generally to be low as long as the capacity can be re-allocated to other railway undertakings.

(8) A guarantee which is requested in relation to the preparation of compliant bids can only be considered as appropriate, transparent and non-discriminatory if the infrastructure manager sets out clear and transparent rules for preparing a capacity request in the network statement, and offers the necessary support tools to applicants. Since it is not possible to objectively determine the capability of preparing compliant bids before the application procedure, any lack of capability can only be determined after that procedure, on the basis of a repeated failure to put forward those bids or provide the necessary information to the infrastructure manager. The applicant should be responsible for that failure which carries a sanction involving the exclusion of the applicant from the application for a specific train path.

[1] OJ L 343, 14.12.2012, p. 32.

(9) Commission Implementing Regulation (EU) No 870/2014 ([1]) was mistakenly adopted in a version other than that which had received the positive opinion of the Committee. Implementing Regulation (EU) No 870/2014 should accordingly be repealed.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 62(1) of Directive 2012/34/EU,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation sets out the requirements for financial guarantees that an infrastructure manager may request to ensure that its legitimate expectations about future revenues are met without exceeding a level proportional to the level of activities contemplated by the applicant. The requirements include in particular the conditions when a guarantee or an advance payment may be requested and the level and duration of a financial guarantee. In addition, this Regulation sets out certain details as regards the criteria to assess the capability of an applicant to prepare compliant bids for infrastructure capacity.

Article 2

Definitions

For the purpose of this Regulation, the following definition applies:

'financial guarantee' means (a) advance payments to reduce and anticipate future obligations to pay infrastructure charges or (b) contractual arrangements by which a financial institution such as bank commits to ensure that such payments are effected once they are due.

Article 3

Conditions for financial guarantees

1. The applicant may choose to meet a request for financial guarantee by means of either advance payment or contractual arrangement in the meaning of Article 2. If an applicant provides an advance payment for infrastructure charges, the infrastructure manager shall not at the same time request other financial guarantees for the same contemplated activities.

2. The infrastructure manager may request applicants to provide financial guarantees where the credit rating of the applicant suggests that he might have difficulties in effecting regular payments for infrastructure charges. The infrastructure manager shall mention such credit ratings in the section on charging principles of its network statement, if applicable. The infrastructure manager shall base his request for a financial guarantee on ratings not older than two years provided by a credit rating agency or another professional rating or credit scoring entity.

3. The infrastructure manager shall not request a financial guarantee:

(a) from the designated railway undertaking if a financial guarantee has already been granted or paid by the applicant, which is not a railway undertaking, to cover future payments for the same contemplated activities;

(b) if the infrastructure charge is to be paid directly to the infrastructure manager by a competent authority pursuant to Regulation (EC) No 1370/2007 of the European Parliament and of the Council ([2]).

([1]) Commission Implementing Regulation (EU) No 870/2014 of 11 August 2014 on criteria for applicants for rail infrastructure capacity (OJ L 239, 12.8.2014, p. 11).

([2]) Regulation (EC) No 1370/2007 of the European Parliament and of the Council of 23 October 2007 on public passenger transport services by rail and by road and repealing Council Regulations (EEC) Nos 1191/69 and 1107/70 (OJ L 315, 3.12.2007, p. 1).

Article 4

Level and duration of financial guarantees

1. The level of financial guarantees regarding one applicant shall not exceed the estimated amount of charges incurred during two months of train operations requested.

2. An infrastructure manager shall not require that a financial guarantee takes effect or is paid more than 10 days before the first of the month in which the railway undertaking starts the train operations in relation to the infrastructure charges which this financial guarantee is to cover. If the capacity is allocated after this point in time, the infrastructure manager may request the financial guarantee at short notice.

Article 5

Capability to prepare compliant bids for infrastructure capacity

The infrastructure manager shall not reject an application for a specific train path on grounds of failing to provide assurance of the capability to prepare a compliant bid for infrastructure capacity, within the meaning of Article 41(2) of Directive 2012/34/EU, unless:

(a) the applicant has failed to answer two subsequent requests requiring the provision of the missing information or has repeatedly responded in a way that does not satisfy the conditions set out in the network statement referred to in Article 27 of Directive 2012/34/EU and in Annex IV to that Directive regarding the application procedures for train paths and

(b) the infrastructure manager is able to demonstrate at the request of and to the satisfaction of the regulatory body that it has taken all reasonable steps to support the correct and timely submission of applications.

Article 6

Transitional provision

Where necessary, infrastructure managers shall align their network statements to the provisions of this Regulation for the first time table period following the entry into force of this Regulation.

Article 7

Implementing Regulation (EU) No 870/2014 is repealed.

Article 8

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

It shall apply from 16 June 2015, with the exception of Article 7, which shall apply from the date of entry into force.

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

Done at Brussels, 6 January 2015.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2015/11

of 6 January 2015

entering a name in the register of protected designations of origin and protected geographical indications (Kranjska klobasa (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Articles 15(2) and 52(3)(b) thereof,

Whereas:

(1) Regulation (EU) No 1151/2012 entered into force on 3 January 2013. It repealed and replaced Council Regulation (EC) No 510/2006 ([2]).

(2) Pursuant to the first subparagraph of Article 6(2), the Slovenian application to register the name 'Kranjska klobasa' was published in the *Official Journal of the European Union* ([3]).

(3) Germany on 3 July 2012, Croatia on 16 August 2012 and Austria on 17 August 2012, submitted oppositions to the registration under Article 7(1) of Regulation (EC) No 510/2006. ([4]) The oppositions were deemed admissible.

(4) By letters dated 24 October 2012, the Commission invited the interested parties to engage in appropriate consultations to seek agreement among themselves within six months in accordance with their internal procedures.

(5) Slovenia and Germany on one side, and Slovenia and Austria on the other side, reached an agreement. In contrast no agreement was reached between Slovenia and Croatia.

(6) Given that no agreement was reached between Slovenia and Croatia, the Commission should adopt a decision in accordance with the procedure referred to in Article 52(3)(b) of Regulation (EU) No 1151/2012.

(7) Concerning the alleged failure of compliance with Article 2(1)(b) of Regulation (EC) No 510/2006, replaced by Article 5(2) of Regulation (EU) No 1151/2012, in respect of the delimitation of the geographical area, i.e. that the product does not originate in a specific place, region or country or that the consumer is misled, no obvious error was identified. With regard to the alleged failure concerning use of the name of a country which was allowed in exceptional cases, 'Kranjska' is not the name of a country but of a (former) region. Moreover, Regulation (EU) No 1151/2012 does not foresee for protected geographical indications the use of the name of a country in exceptional cases only. Concerning the allegation that the geographical area has no natural characteristics distinguishing it from neighbouring areas, there is no need to assess the substance of this allegation as this is not required by Regulation (EU) No 1151/2012.

(8) The terms'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer' and 'Bauernkrainer' on the one hand, and the terms 'Kranjska' and 'Kranjska kobasica' on the other hand were found to be the names of similar sausages in German and Croatian language respectively and have common historic origins referring to the former Land of 'Kranjska' which no longer exists administratively today. As the names have common origins and given the visual similarities between the products, the application of the protection envisaged by Article 13 of Regulation (EU) No 1151/2012, and in particular point (b) of paragraph (1) thereof, could have the result that 'Kranjska klobasa', if registered, would prevent producers not complying with the product specification of 'Kranjska klobasa' from using the terms 'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer', 'Bauernkrainer', 'Kranjska' and 'Kranjska kobasica'.

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OJ L 93, 31.3.2006, p. 12).
([3]) OJ C 48, 18.2.2012, p. 23.
([4]) Meanwhile replaced by points (a), (c) and (d) of Article 10 of Regulation (EU) No 1151/2012.

(9) The evidence shows that the use of the terms 'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer', 'Bauernkrainer', 'Kranjska' and 'Kranjska kobasica' referred to products having a common origin with 'Kranjska klobasa', was not meant to exploit the reputation of the latter name and that the consumer has not been or couldn't have been misled as to the true origin of the products. In addition, it was shown that these designations have been in legal use consistently and fairly for at least 25 years before the application for registration of the name 'Kranjska klobasa' was submitted to the Commission.

(10) However, it is to be noted that in German language, in two centuries time, the name 'Krainer', and its compound names have definitively lost the geographical link to the Carniola Region. This is confirmed by the fact that both in the agreements reached with Germany and Austria respectively Slovenia acknowledged that the use of the terms 'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer' and 'Bauernkrainer' should not be understood as an abuse of the name 'Kranjska klobasa'.

(11) For all the reasons above, in the interests of fairness and traditional usage, irrespectively of whether 'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer', 'Bauernkrainer', 'Kranjska' and 'Kranjska kobasica' can be considered as generic under Article 41 of Regulation (EU) No 1151/2012 and provided that principles and rules applicable in the Union's legal order are respected, the free use of the terms 'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer' and 'Bauernkrainer' should be maintained without time restrictions, and the use of the terms 'Kranjska' and 'Kranjska kobasica' should be allowed for the maximum transitional period foreseen by Article 15(2) of Regulation (EU) No 1151/2012.

(12) Article 6(1) of Regulation (EU) No 1151/2012 prohibits the registration of names that have become generic. The oppositions claimed that consumers in Austria, Croatia and Germany do not associate the names used on their market terms such as 'Krainer', 'Krainer Wurst', 'Kranjska' and 'Kranjska kobasica' with a particular origin. While the name proposed for registration is 'Kranjska klobasa', the evidence provided in the statements of opposition referred to the alleged general use of the term 'Krainer', 'Krainer Wurst', 'Kranjska' and 'Kranjska kobasica' in Austria, Croatia and Germany, and not to that of 'Kranjska klobasa'. The oppositions do not take into consideration the situation in Slovenia. No evidence has been provided in the statements of oppositions to show general usage comprising or including the name proposed for registration. Therefore, on the basis of information provided, the name 'Kranjska klobasa' cannot be considered to be generic and there is accordingly no failure of compliance with Article 6(1) of Regulation (EU) No 1151/2012.

(13) Whereas protection is granted for the term 'Kranjska klobasa' as a whole, the non-geographical component of that term may be used, and used in translation, throughout the Union, provided the principles and rules applicable in the Union's legal order are respected.

(14) In the light of the above, the name 'Kranjska klobasa' should be entered in the Register of protected designations of origin and protected geographical indications.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Kranjska klobasa' (PGI) is registered.

The name in the first alinea identifies a product from class 1.2. Meat products (cooked, salted, smoked, etc.) of Annex XI of Commission Implementing Regulation (EU) No 668/2014 ([1]).

([1]) Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

Article 2

The terms 'Krainer', 'Käsekrainer', 'Schweinskrainer', 'Osterkrainer' and 'Bauernkrainer' may continue to be used within the territory of the Union, provided the principles and rules applicable in its legal order are respected.

The terms 'Kranjska' and 'Kranjska kobasica' may be used to designate sausages not complying with the specification for 'Kranjska klobasa' for a period of 15 years from the date of entry into force of this Regulation.

Article 3

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

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

Done at Brussels, 6 January 2015.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2015/12

of 6 January 2015

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 Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([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, 6 January 2015.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([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	AL	70,5
	IL	102,8
	MA	89,8
	TR	103,2
	ZZ	91,6
0707 00 05	TR	159,9
	ZZ	159,9
0709 93 10	MA	89,1
	SN	80,8
	TR	156,9
	ZZ	108,9
0805 10 20	EG	41,2
	MA	68,6
	TR	61,7
	ZA	36,4
	ZW	32,9
	ZZ	48,2
0805 20 10	MA	57,5
	ZZ	57,5
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	85,5
	JM	105,9
	TR	76,3
	ZZ	89,2
0805 50 10	TR	59,7
	ZZ	59,7
0808 10 80	AR	164,5
	BR	62,9
	CL	82,5
	MK	39,8
	US	145,8
	ZA	147,0
	ZZ	107,1
0808 30 90	US	171,4
	ZZ	171,4

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2015/13

of 31 October 2014

amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments ([1]), and in particular Article 47 (b) thereof,

Whereas:

(1) Directive 2014/32/EU sets out the requirements that certain measuring instruments have to satisfy with a view to their being placed on the market and/or put to use for specific measuring tasks prescribed by the Member States.

(2) The first of the specific requirements for water meters (Requirement 1) included in Annex III to Directive 2014/32/EU refers to the rated operating condition for the flowrate range $Q_3/Q_1 \geq 10$.

(3) On 31 October 2011 an update of the standard EN 14154 which included the flowrate range $Q_3/Q_1 \geq 40$ entered into force. The revised EN 14154 standard reflects the international standard. It is more exigent in relation to the flowrate range than the specific requirements set out in Annex III to Directive 2014/32/EU and results in more precise measurements.

(4) Prior to the introduction of the flowrate range $Q_3/Q_1 \geq 10$ by means of Directive 2004/22/EC of the European Parliament and of the Council ([2]) on measuring instruments, the international OIML standard which already contained a requirement for the flowrate range of $Q_3/Q_1 \geq 40$ was applied in all Member States. As a result of the transitional provisions provided for in Article 50(2) of Directive 2014/32/EU, most of the water meters currently placed on the market are already in conformity with the requirement of $Q_3/Q_1 \geq 40$.

(5) Water meters with the flowrate range $Q_3/Q_1 \geq 10$ may be significantly cheaper than those meeting the requirements of the standard EN 14154 ($Q_3/Q_1 \geq 40$). Directive 2014/32/EU, in point 10 of Annex III thereto, gives discretion to the utility or the person legally designated for installing the water meter to determine, inter alia, what level of flowrate range is appropriate for the accurate measurement of consumption that is foreseen or foreseeable ([3]). Therefore, water meters not conforming to the standard EN 14154 for flowrate range but in line with the requirements set out in Annex III to Directive 2014/32/EU may be installed. This may, however, increase the possibility of customers having errors in bills resulting from the less precise measurement of the meter.

(6) The flowrate range of $Q_3/Q_1 \geq 40$ represents the state of the art embodied in the current international standard and manufacturing practice, as well as the minimum quality available at present on the Union market. It provides for more precise measurements thereby ensuring a higher level of protection of consumers. Given that the flowrate range of $Q_3/Q_1 \geq 40$ has for many years been and still is the minimum being installed by the market, compliance does not involve additional costs for users.

(7) Directive 2014/32/EU should be amended accordingly,

([1]) OJ L 96, 29.3.2014, p. 149.
([2]) Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments (OJ L 135, 30.4.2004, p. 1).
([3]) See point 10 of Annex III to Directive 2014/32/EU.

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Annex III to Directive 2014/32/EU, point 1 is replaced by the following:

'1. The flowrate range of the water.

The values for the flowrate range shall fulfil the following conditions:

$Q_3/Q_1 \geq 40$

$Q_2/Q_1 = 1{,}6$

$Q_4/Q_3 = 1{,}25$'.

Article 2

1. Member States shall adopt and publish, by 19 April 2016 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 20 April 2016.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 31 October 2014.

For the Commission
The President
José Manuel BARROSO

DECISIONS

COMMISSION DECISION (EU) 2015/14

of 5 January 2015

amending Decision 2012/88/EU on the technical specification for interoperability relating to the control-command and signalling subsystems of the trans-European rail system

(notified under document C(2014) 9909)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 [1], and in particular Article 6 thereof,

Whereas:

(1) With Decision C(2010) 2576 [2], the Commission gave the European Railway Agency (the Agency) a mandate to develop and review the technical specifications for interoperability (TSI) with a view to extending their scope to the entire rail system in the Union in accordance with Article 1(4) of Directive 2008/57/EC. On 10 January 2013 the Agency submitted its recommendation amending the TSI relating to the control-command and signalling subsystems of the trans-European rail system.

(2) According to Article 8(4) of Directive 2008/57/EC on TSI scope extension, a Member State should not apply the revised TSI in the case of projects at an advanced stage of development or subject to a contract in the course of performance, which was out of the scope of the previous TSI.

(3) The revised control-command and signalling TSI (CCS TSI) should apply to networks with 1 435 mm, 1 520 mm, 1 524 mm, 1 600 mm, and 1 668 mm nominal track gauge. This would provide interoperability within one-track-gauge systems and make it possible to develop and operate vehicles for multiple metric gauges. It would also make it possible to develop and use control-command and signalling subsystems and interoperability constituents independently of the track gauge. A high percentage of vehicles run both on the trans-European rail network and on the off-TEN rail network. The parameters of the on-board and the track-side control-command and signalling subsystems should therefore be the same for the whole network.

(4) Certain open points related to the compatibility of train detection systems may be closed, taking into account requirements for different track gauges (specification referenced as Index 77 in Annex A). The open point related to safety requirements for ETCS Driver-Machine Interface (DMI) function may be closed and progress have been made to clarify the open point on 'reliability/availability'.

(5) The provisions on assessment of interoperability constituents and subsystems, in the case where requirements are partially fulfilled, need to be clarified.

(6) In its role of system authority for the European Rail Traffic Management System (ERTMS), the Agency has prepared an update of the mandatory ERTMS specifications referenced in Annex A to the CCS TSI. Until the time the specifications related to train interface (FFFIS — Form Fit Functional Interface Specification) have reached, at both sides of the interface, a level of consensus among all stakeholders to be considered as mandatory, the Agency should refer to them in the application guide so that they can be used in call for tenders.

[1] OJ L 191, 18.7.2008, p. 1.
[2] Commission Decision C(2010) 2576 final of 29 April 2010 concerning a mandate to the European Railway Agency to develop and review Technical Specifications for Interoperability with a view to extending their scope to the whole rail system in the European Union.

(7) The Agency should publish tests specifications related to baseline 3 as soon as possible.

(8) Errors have been detected in the text of Commission Decision 2012/88/EU ([1]) and need to be corrected.

(9) The availability and quality of the GSM-R signals is essential for railway operations.

(10) GSM-R roaming to public networks is an optional function. If it is used in a Member State, its implementation should be indicated in line number 1.1.1.3.3.3 of the register of railway infrastructure in accordance with Commission Implementing Decision 2014/880/EU ([2]).

(11) The measures provided for in this Decision are in conformity with the opinion of the Committee established in accordance with Article 29(1) of Directive 2008/57/EC,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2012/88/EU is amended as follows:

(1) the title is replaced by the following: '**Commission Decision 2012/88/EU of 25 January 2012 on the technical specification for interoperability relating to the control-command and signalling subsystems**';

(2) Annex III is amended as follows:

(a) the following text is added at the end of section 1.1:

'This TSI is applicable to control-command and signalling track-side Subsystems of the rail network defined in the section 1.2 (Geographical scope) of this TSI and to the control-command and signalling on-board subsystems of vehicles which are (or are intended to be) operated on it. These vehicles are of one of the following types (as defined in Annex I sections 1.2 and 2.2 to Directive 2008/57/EC):

(1) self-propelling thermal or electric trains;

(2) thermal or electric traction units;

(3) passenger carriages, if equipped with a driving cab;

(4) mobile railway infrastructure construction and maintenance equipment, if equipped with a driving cab and intended to be used in transport mode on its own wheels.';

(b) the text of section 1.2 is replaced by the following:

'the geographical scope of this TSI is the network of the whole rail system, composed of:

(1) the trans-European conventional rail system network (TEN) as described in Annex I section 1.1 "Network" to Directive 2008/57/EC;

(2) the trans-European high-speed rail system network (TEN) as described in Annex I section 2.1 "Network" to Directive 2008/57/EC;

(3) other parts of the network of the whole rail system, following the extension of scope as described in Annex I section 4 to Directive 2008/57/EC;

and excludes the cases referred to in Article 1(3) of Directive 2008/57/EC.

The TSI shall apply to networks with 1 435 mm, 1 520 mm, 1 524 mm, 1 600 mm and 1 668 mm track gauges. However, it shall not apply to short border crossing lines with 1 520 mm track gauges that are connected to the network of third countries';

(c) the text of the fifth paragraph of section 2.2 is replaced by the following:

'Class B systems for the trans-European rail system network are a limited set of legacy control-command and signalling systems that were in use in the trans-European rail network before 20 April 2001.

([1]) Commission Decision 2012/88/EU of 25 January 2012 on the technical specification for interoperability relating to the control-command and signalling subsystems of the trans-European rail system (OJ L 51, 23.2.2012, p. 1).

([2]) Commission Implementing Decision 2014/880/EU of 26 November 2014 on the common specifications of the register of railway infrastructure and repealing Implementing Decision 2011/633/EU (OJ L 356, 12.12.2014, p. 489).

Class B systems for other parts of the network of the rail system in the European Union are a limited set of legacy control-command and signalling systems that were in use in that networks before 1 July 2015.

The list of Class B systems is established in the European Railway Agency technical documents "List of CCS Class B systems", ERA/TD/2011-11, version *2.0*';

(d) in the table of section 4.1, '4.2.1' is added to the basic parameters related to control-command and signalling track-side subsystem, part train protection and '4.2.1.2' is added to the basic parameters related to control-command and signalling on-board subsystem, part radio communication, and to control-command and signalling track-side subsystem, part radio communication;

(e) the text of section 4.2.1.2 is replaced by the following text:

'4.2.1.2. Availability/Reliability

This section refers to the occurrence of failure modes not causing safety hazards but creating degraded situations, the management of which could decrease the overall safety of the system.

In the context of this parameter, "failure" means the termination of the ability of an item to perform a required function with the required performance and "failure mode" means the effect by which the failure is observed.

To ensure that the relevant infrastructure managers and railway undertakings are given all the information they need to define appropriate procedures for managing degraded situations, the technical file accompanying the EC declaration of verification for an on-board or track-side CCS subsystem shall contain the calculated availability/reliability values related to failure modes having an impact on the capability of the CCS subsystem to supervise the safe movement of one or more vehicles or to establish radio voice communication between traffic control and the train drivers.

Compliance with the following calculated values shall be ensured:

(1) Mean time of hours of operation between failures of a CCS on-board subsystem requiring the isolation of the train protection functions: [open point];

(2) Mean time of hours of operation between failures of a CCS on-board subsystem preventing radio voice communication between traffic control and the train driver: [open point].

To allow the infrastructure managers and railway undertakings to monitor, during the life of the subsystems, the level of risk and the respect of the reliability/availability values used for the definition of procedures to manage degraded situations, the requirements for maintenance stated in Section 4.5 (Maintenance rules) shall be respected';

(f) the second row of the table in section '4.3.2 Interface to the rolling stock subsystem' is amended as follows:

'Electromagnetic compatibility between rolling stock and Control-Command and Signalling track-side equipment	4.2.11	Rolling stock characteristics to be compatible with train detection systems based on track circuits	HS RS TSI LOC & PAS TSI Wagon TSI	4.2.6.6.1 4.2.3.3.1.1 None
		Rolling stock characteristics to be compatible with train detection systems based on axle counters	HS RS TSI LOC & PAS TSI Wagon TSI	4.2.6.6.1 4.2.3.3.1.2 None'

(g) the following text is added at the end of section 6.1.1:

'With regard to checking if essential requirements are fulfilled through compliance with the basic parameters, and without prejudice to the obligations set out in Chapter 7 of this TSI, control-command and signalling interoperability constituents and subsystems that do not implement all functions, performance and interfaces as

specified in Chapter 4 (including the specifications referred to in Annex A), can obtain EC certificates of conformity or, respectively, EC certificates of verification, under the following conditions for issuing and using the certificates:

(1) the applicant for EC verification of a track-side control-command and signalling subsystem is responsible for deciding which functions, performance and interfaces need to be implemented to meet the objectives for the service and to ensure that no requirements contradicting or exceeding the TSIs are exported to the on-board control-command and signalling subsystems;

(2) the operation of an on-board control-command and signalling subsystem, that does not implement all functions, performance and interfaces specified in this TSI, may be subject to conditions or restrictions due to compatibility and/or safe integration with track-side control-command and signalling subsystems. Without prejudice to the tasks of a notified body described in respective EU legislation and related documents, the applicant for EC verification is responsible for ensuring that the technical file provides all the information that an operator needs to identify such conditions and restrictions;

(3) the Member State may refuse for duly justified reasons the authorisation for placing in service, or place conditions and restrictions on the operation, of control-command and signalling subsystems that do not implement all functions, performance and interfaces specified in this TSI.

If some essential requirements are fulfilled by national rules or if a control-command and signalling interoperability constituent or subsystem does not implement all functions, performance and interfaces specified in this TSI, the provisions of section 6.4.2 shall apply.';

(h) the text of the third paragraph of section 6.1.2 is amended as follows: in subparagraph 2 'See Annex A 4.2.2c' is deleted and in subparagraph 3 'unless otherwise specified in Annex A 4.2.2c' is deleted;

(i) the text of section 6.4 is replaced by the following:

'6.4 **Provisions in case of the partial fulfilment TSI requirements**

6.4.1. *Assessment of parts of control-command and signalling subsystems*

Pursuant to Article 18(5) of the Railway Interoperability Directive, the notified body may issue certificates of verification for certain parts of a subsystem, if allowed to do so under the relevant TSI.

As pointed out in section 2.2 (Scope) of this TSI, the track-side control-command and signalling subsystem contains three parts, while the on-board control-command and signalling subsystem contains two parts, specified in section 4.1 (Introduction).

A certificate of verification may be issued for each part specified in this TSI; the notified body only checks if that particular part fulfils the TSI requirements.

Regardless of which module is chosen, the notified body shall check that:

(1) the TSI requirements for the part in question have been fulfilled; and

(2) the TSI requirements already assessed for other parts of the same subsystem are still fulfilled.

6.4.2. *Control-command and signalling subsystems' partial fulfilment of the requirements due to limited application of the TSI*

If some essential requirements are fulfilled by national rules, the EC certificate of conformity for an interoperability constituent and the EC certificate of verification for a subsystem shall make precise reference to the parts of this TSI whose conformity has been assessed and the parts whose conformity has not been assessed.

If an interoperability constituent does not implement all functions, performance and interfaces specified in this TSI, an EC certificate of conformity may only be issued if the unimplemented functions, interfaces or performance are not required to integrate the interoperability constituent into a subsystem for the use indicated by the applicant, for example (*):

(a) the on-board ERTMS/ETCS interface to STM if the interoperability constituent is intended for installation on vehicles in which no external STM is needed;

(b) the RBC interface to other RBCs, if the RBC is intended for use in an application for which no neighbouring RBCs are planned.

The EC certificate of conformity (or accompanying documents) for the interoperability constituent shall fulfil all the following requirements:

(a) it indicates which functions, interfaces or performance are not implemented;

(b) it provides enough information to make it possible to identify the conditions under which the interoperability constituent can be used;

(c) it provides enough information to make it possible to identify the conditions of and restriction on the use that will apply to the interoperability of a subsystem incorporating it.

If a control-command and signalling subsystem does not implement all functions, performance and interfaces of this TSI (e.g. because they are not implemented by an interoperability constituent integrated into it), the EC certificate of verification shall indicate which requirements have been assessed and the corresponding conditions and restrictions on the use of the subsystem and its compatibility with other subsystems.

In any event, notified bodies shall coordinate with the Agency the way in which conditions and limits of use of interoperability constituents and subsystems are managed in the relevant certificates and technical files in the working group set up under Article 21a(5) of Regulation (EC) No 881/2004 of the European Parliament and of the Council (**).

6.4.3. *Intermediate Statement of Verification*

If conformity is assessed for parts of subsystems specified by the applicant and different from the parts allowed by section 4.1 (Introduction) of this TSI, or if only certain stages of the verification procedure have been performed, only an intermediate statement of verification may be issued.

(*) The procedures described in this Chapter do not prejudice the possibility of grouping constituents together.

(**) Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency (Agency Regulation) (OJ L 164, 30.4.2004, p. 1).';

(j) in section 7.2.9.3, the following rows are added at the end of the table:

'4.2.10 Track-side Train Detection Systems Index 77, Section 3.1.3.1: The minimum wheel rim width (B_R) for 1 600 mm track gauge network is 127 mm	T3	Applicable in North Ireland
4.2.10 Track-side Train Detection Systems Index 77, Section 3.1.3.3: The minimum flange thickness (S_d) for 1 600 mm track gauge network is 24 mm	T3	Applicable in North Ireland'

(k) the title of section 7.2.9.6 is replaced by 'Lithuania, Latvia and Estonia';

(l) the table in section 7.2.9.6 is replaced by:

'Specific case	Category	Notes
4.2.10 Track-side Train Detection Systems Index 77, Section 3.1.3.3: The minimum flange thickness (S_d) for 1 520 mm track gauge network is 20 mm	T3	This specific case is needed as long as ČME locomotives operate on 1 520 mm network

'Specific case	Category	Notes
4.2.10 Track-side Train Detection Systems Index 77, Section 3.1.3.4: The minimum flange height (S_h) for 1 520 mm track gauge network is 26,25 mm	T3	This specific case is needed as long as ČME locomotives operate on 1 520 mm network'

(m) in section 7.2.9.7, 'index 65' is replaced by 'index 33';

(n) the text of section 7.3.3 is replaced by the following:

'7.3.3. *ERTMS on-board implementation*

7.3.3.1. New vehicles

New vehicles authorised to be placed in service for the first time shall be equipped with ERTMS in line either with the set of specifications # 1 or the set of specifications # 2 listed in Table A2 of Annex A.

From 1 January 2018, new vehicles authorised to be placed in service for the first time shall be equipped with ERTMS only in line with the set of specifications # 2 listed in Table A2 of Annex A.

The requirement to be equipped with ERTMS does not apply to new mobile railway infrastructure construction and maintenance equipment, new shunting locomotives or other new vehicles not intended for high speed service, if they are intended exclusively for national service operated outside the corridors defined in section 7.3.4 and outside the lines ensuring the connections to the main European ports, marshalling yards, freight terminals and freight transport areas defined in section 7.3.5, or if they are intended for off-TEN cross-border service, i.e. service until the first station in the neighbouring country or to the first station where there are connections further in the neighbouring country.

7.3.3.2. Upgrading and renewal of existing vehicles

It is mandatory to fit ERTMS/ETCS on-board existing vehicles if installing any new train protection part of a control-command and signalling on-board subsystem on existing vehicles intended for high-speed service

7.3.3.3. Additional requirements

Member States may introduce additional requirements at national level, in particular with a view to

(1) allowing only ERTMS-equipped vehicles to access ERTMS-equipped lines, so that existing national systems can be decommissioned;

(2) requesting that new and upgraded or renewed mobile railway infrastructure construction and maintenance equipment, shunting locomotives and/or other vehicles, even if intended exclusively for national service, be equipped with ERTMS.';

(o) Annex A is amended in accordance with the Annex to this Decision;

(p) the table of Annex G is amended as follows:

(1) the line related to 'Vehicle metal mass' is deleted;

(2) the line related to 'DC and low frequency components of traction current' is deleted;

(3) the line related to 'safety requirements for ETCS DMI functions' is deleted.

Article 2

The following Article is added to Decision 2012/88/EU:

'Article 7a

1. By 1 July 2015 the European Railway Agency shall publish the mandatory specifications referred to in Table A2 of Annex A to this Decision, at Index 37b and 37c, column "Set of specifications # 2".

Before their publication, it shall send to the Commission a technical opinion on the insertion of these documents in Table A2 of Annex A to this Decision, with reference, name and version. The Commission shall inform accordingly the Committee established under Article 29 of Directive 2008/57/EC.

2. The European Railway Agency shall publish the specifications related to train interface (FFFIS — Form Fit Functional Interface Specification — Index 81 and 82 of Table A2 of Annex A to this Decision) when it considers that they are mature. The European Railway Agency shall regularly report on the assessment of this maturity to the Committee established under Article 29 of Directive 2008/57/EC. Before their publication, it shall send to the Commission a technical opinion on the insertion of these documents in Table A2 of Annex A to this Decision, with reference, name and version. The Commission shall inform accordingly the Committee established under Article 29 of Directive 2008/57/EC.'

Article 3

This Decision shall apply from 1 July 2015.

This Decision is addressed to the Member States and to the European Railway Agency.

Done at Brussels, 5 January 2015.

For the Commission
Violeta BULC
Member of the Commission

ANNEX

Annex A to Decision 2012/88/EU is amended as follows:

(1) the following line is deleted in Table A1:

'4.2.1 b	28'

(2) the following line in Table A1 is modified as follows:

'4.2.2.f	7, 81, 82'

(3) Table A2 is replaced by the following table and related notes:

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
1	ERA/ERTMS/003204	ERTMS/ETCS Functional requirement specification	5.0		Intentionally deleted			
2	Intentionally deleted				Intentionally deleted			
3	SUBSET-023	Glossary of Terms and Abbreviations	2.0.0		SUBSET-023	Glossary of Terms and Abbreviations	3.1.0	
4	SUBSET-026	System Requirements Specification	2.3.0		SUBSET-026	System Requirements Specification	3.4.0	
5	SUBSET-027	FFFIS Juridical recorder-downloading tool	2.3.0	Note 1	SUBSET-027	FIS Juridical Recording	3.1.0	
6	SUBSET-033	FIS for man-machine interface	2.0.0		ERA_ERTMS_015560	ETCS Driver Machine interface	3.4.0	
7	SUBSET-034	FIS for the train interface	2.0.0		SUBSET-034	Train Interface FIS	3.1.0	
8	SUBSET-035	Specific Transmission Module FFFIS	2.1.1		SUBSET-035	Specific Transmission Module FFFIS	3.1.0	
9	SUBSET-036	FFFIS for Eurobalise	2.4.1		SUBSET-036	FFFIS for Eurobalise	3.0.0	
10	SUBSET-037	EuroRadio FIS	2.3.0		SUBSET-037	EuroRadio FIS	3.1.0	
11	SUBSET-038	Offline key management FIS	2.3.0		SUBSET-038	Offline key management FIS	3.0.0	
12	SUBSET-039	FIS for the RBC/RBC handover	2.3.0		SUBSET-039	FIS for the RBC/RBC handover	3.1.0	

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
13	SUBSET-040	Dimensioning and Engineering rules	2.3.0		SUBSET-040	Dimensioning and Engineering rules	3.3.0	
14	SUBSET-041	Performance Requirements for Interoperability	2.1.0		SUBSET-041	Performance Requirements for Interoperability	3.1.0	
15	SUBSET-108	Interoperability related consolidation on TSI Annex A documents	1.2.0		Intentionally deleted			
16	SUBSET-044	FFFIS for Euroloop	2.3.0		SUBSET-044	FFFIS for Euroloop	2.4.0	
17	Intentionally deleted				Intentionally deleted			
18	SUBSET-046	Radio infill FFFS	2.0.0		Intentionally deleted			
19	SUBSET-047	Trackside-Trainborne FIS for Radio infill	2.0.0		SUBSET-047	Trackside-Trainborne FIS for Radio infill	3.0.0	
20	SUBSET-048	Trainborne FFFIS for Radio infill	2.0.0		SUBSET-048	Trainborne FFFIS for Radio infill	3.0.0	
21	SUBSET-049	Radio infill FIS with LEU/interlocking	2.0.0		Intentionally deleted			
22	Intentionally deleted				Intentionally deleted			
23	SUBSET-054	Responsibilities and rules for the assignment of values to ETCS variables	2.1.0		SUBSET-054	Responsibilities and rules for the assignment of values to ETCS variables	3.0.0	
24	Intentionally deleted				Intentionally deleted			
25	SUBSET-056	STM FFFIS Safe time layer	2.2.0		SUBSET-056	STM FFFIS Safe time layer	3.0.0	

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
26	SUBSET-057	STM FFFIS Safe link layer	2.2.0		SUBSET-057	STM FFFIS Safe link layer	3.0.0	
27	SUBSET-091	Safety Requirements for the Technical Interoperability of ETCS in Levels 1 and 2	2.5.0		SUBSET-091	Safety Requirements for the Technical Interoperability of ETCS in Levels 1 and 2	3.3.0	
28	Intentionally deleted			Note 8	Intentionally deleted			Note 8
29	SUBSET-102	Test specification for interface "K"	1.0.0		SUBSET-102	Test specification for interface "K"	2.0.0	
30	Intentionally deleted				Intentionally deleted			
31	SUBSET-094	Functional requirements for an onboard reference test facility	2.0.2		SUBSET-094	Functional requirements for an onboard reference test facility	3.0.0	
32	EIRENE FRS	GSM-R Functional requirements specification	7.4.0	Note 10	EIRENE FRS	GSM-R Functional requirements specification	7.4.0	Note 10
33	EIRENE SRS	GSM-R System requirements specification	15.4.0	Note 10	EIRENE SRS	GSM-R System requirements specification	15.4.0	Note 10
34	A11T6001	(MORANE) Radio Transmission FFFIS for EuroRadio	12.4		A11T6001	(MORANE) Radio Transmission FFFIS for EuroRadio	12.4	
35	Intentionally deleted				Intentionally deleted			
36 a	Intentionally deleted				Intentionally deleted			
36 b	Intentionally deleted				Intentionally deleted			
36 c	SUBSET-074-2	FFFIS STM Test cases document	1.0.0		SUBSET-074-2	FFFIS STM Test cases document	3.0.0	
37 a	Intentionally deleted				Intentionally deleted			

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
37 b	SUBSET-076-5-2	Test cases related to features	2.3.3		SUBSET-076-5-2	Test cases related to features		Note 11
37 c	SUBSET-076-6-3	Test sequences	2.3.3		Reserved	Test sequences generation: methodology and rules		Note 11
37 d	SUBSET-076-7	Scope of the test specifications	1.0.2		SUBSET-076-7	Scope of the test specifications	3.0.0	
37 e	Intentionally deleted				Intentionally deleted			
38	06E068	ETCS Markerboard definition	2.0		06E068	ETCS Markerboard definition	2.0	
39	SUBSET-092-1	ERTMS EuroRadio Conformance Requirements	2.3.0		SUBSET-092-1	ERTMS EuroRadio Conformance Requirements	3.0.0	
40	SUBSET-092-2	ERTMS EuroRadio test cases safety layer	2.3.0		SUBSET-092-2	ERTMS EuroRadio test cases safety layer	3.0.0	
41	Intentionally deleted				Intentionally deleted			
42	Intentionally deleted				Intentionally deleted			
43	SUBSET 085	Test specification for Eurobalise FFFIS	2.2.2		SUBSET 085	Test specification for Eurobalise FFFIS	3.0.0	
44	Intentionally deleted				Intentionally deleted			Note 9
45	SUBSET-101	Interface "K" Specification	1.0.0		SUBSET-101	Interface "K" Specification	2.0.0	
46	SUBSET-100	Interface "G" Specification	1.0.1		SUBSET-100	Interface "G" Specification	2.0.0	
47	Intentionally deleted				Intentionally deleted			
48	Reserved	Test specification for mobile equipment GSM-R		Note 4	Reserved	Test specification for mobile equipment GSM-R		Note 4
49	SUBSET-059	Performance requirements for STM	2.1.1		SUBSET-059	Performance requirements for STM	3.0.0	

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
50	SUBSET-103	Test specification for Euroloop	1.0.0		SUBSET-103	Test specification for Euroloop	1.1.0	
51	Reserved	Ergonomic aspects of the DMI			Intentionally deleted			
52	SUBSET-058	FFFIS STM Application layer	2.1.1		SUBSET-058	FFFIS STM Application layer	3.1.0	
53	Intentionally deleted				Intentionally deleted			
54	Intentionally deleted				Intentionally deleted			
55	Intentionally deleted				Intentionally deleted			
56	Intentionally deleted				Intentionally deleted			
57	Intentionally deleted				Intentionally deleted			
58	Intentionally deleted				Intentionally deleted			
59	Intentionally deleted				Intentionally deleted			
60	Intentionally deleted				SUBSET-104	ETCS System Version Management	3.2.0	
61	Intentionally deleted				Intentionally deleted			
62	Reserved	RBC-RBC Test specification for safe communication interface			Intentionally deleted			
63	SUBSET-098	RBC-RBC Safe Communication Interface	1.0.0		SUBSET-098	RBC-RBC Safe Communication Interface	3.0.0	
64	EN 301 515	Global System for Mobile Communication (GSM); Requirements for GSM operation on railways	2.3.0	Note 2	EN 301 515	Global System for Mobile Communication (GSM); Requirements for GSM operation on railways	2.3.0	Note 2
65	TS 102 281	Detailed requirements for GSM operation on railways	2.3.0	Note 3	TS 102 281	Detailed requirements for GSM operation on railways	2.3.0	Note 3

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
66	TS 103169	ASCI Options for Interoperability	1.1.1		TS 103169	ASCI Options for Interoperability	1.1.1	
67	(MORANE) P 38 T 9001	FFFIS for GSM-R SIM Cards	4.2		(MORANE) P 38 T 9001	FFFIS for GSM-R SIM Cards	4.2	
68	ETSI TS 102 610	Railway Telecommunication; GSM; Usage of the UUIE for GSM operation on railways	1.3.0		ETSI TS 102 610	Railway Telecommunication; GSM; Usage of the UUIE for GSM operation on railways	1.3.0	
69	(MORANE) F 10 T 6002	FFFS for Confirmation of High Priority Calls	5.0		(MORANE) F 10 T 6002	FFFS for Confirmation of High Priority Calls	5.0	
70	(MORANE) F 12 T 6002	FIS for Confirmation of High Priority Calls	5.0		(MORANE) F 12 T 6002	FIS for Confirmation of High Priority Calls	5.0	
71	(MORANE) E 10 T 6001	FFFS for Functional Addressing	4.1		(MORANE) E 10 T 6001	FFFS for Functional Addressing	4.1	
72	(MORANE) E 12 T 6001	FIS for Functional Addressing	5.1		(MORANE) E 12 T 6001	FIS for Functional Addressing	5.1	
73	(MORANE) F 10 T6001	FFFS for Location Dependent Addressing	4		(MORANE) F 10 T6001	FFFS for Location Dependent Addressing	4	
74	(MORANE) F 12 T6001	FIS for Location Dependent Addressing	3		(MORANE) F 12 T6001	FIS for Location Dependent Addressing	3	
75	(MORANE) F 10 T 6003	FFFS for Presentation of Functional Numbers to Called and Calling Parties	4		(MORANE) F 10 T 6003	FFFS for Presentation of Functional Numbers to Called and Calling Parties	4	
76	(MORANE) F 12 T 6003	FIS for Presentation of Functional Numbers to Called and Calling Parties	4		(MORANE) F 12 T 6003	FIS for Presentation of Functional Numbers to Called and Calling Parties	4	
77	ERA/ERTMS/ 033281	Interfaces between CCS track-side and other subsystems	2.0	Note 7	ERA/ERTMS/033281	Interfaces between CCS track-side and other subsystems	2.0	Note 7

'Index N	Set of specifications # 1 (ETCS baseline 2 and GSM-R baseline 0)				Set of specifications # 2 (ETCS baseline 3 and GSM-R baseline 0)			
	Reference	Name of Specification	Version	Notes	Reference	Name of Specification	Version	Notes
78	Reserved	Safety requirements for ETCS DMI functions			Intentionally deleted			Note 6
79	Not applicable	Not applicable			SUBSET-114	KMC-ETCS Entity Off-line KM FIS	1.0.0	
80	Not applicable	Not applicable			Intentionally deleted			Note 5
81	Not applicable	Not applicable			SUBSET-119	Train Interface FFFIS		Note 12
82	Not applicable	Not applicable			SUBSET-120	FFFIS TI — Safety Analysis		Note 12

Note 1: only the functional description of information to be recorded is mandatory, not the technical characteristics of the interface.
Note 2: the clauses of the specifications listed in section 2.1 of EN 301 515 which are referenced in Index 32 and Index 33 as "MI" are mandatory.
Note 3: the change requests (CRs) listed in table 1 and 2 of TS 102 281 which affect clauses referenced in Index 32 and Index 33 as "MI" are mandatory.
Note 4: Index 48 refers only to test cases for GSM-R mobile equipment. It is kept "reserved" for the time being. The application guide will contain a catalogue of available harmonised test cases for the assessment of mobile equipment and networks, according to the steps indicated in section 6.1.2 of this TSI.
Note 5: the products which are on the market are already tailored to the needs of the RU related to GSM-R Driver Machine Interface and fully interoperable so there is no need for a standard in the TSI CCS.
Note 6: information that was intended for Index 78 is now incorporated in Index 27 (SUBSET-091).
Note 7: this document is ETCS and GSM-R baseline independent.
Note 8: the requirements on reliability/availability are now in the TSI (section 4.2.1.2).
Note 9: ERA analysis showed there is no need for a mandatory specification for odometry interface.
Note 10: Only the (MI) requirements are mandated by TSI CCS.
Note 11: Specifications to be managed through a Technical opinion of the European Railway Agency
Note 12: Reference to these specifications will be published in the Application Guide, waiting for clarifications on the rolling stock side of the interface.';

(4) Table A 3 is replaced by the following table and a related note.

'No	Reference	Document name and comments	Version	Note
1	EN 50126	Railway applications — The specification and demonstration of reliability, availability, maintainability and safety (RAMS)	1999	1
2	EN 50128	Railway applications — Communication, signalling and processing systems — Software for railway control and protection systems	2011 or 2001	

'No	Reference	Document name and comments	Version	Note
3	EN 50129	Railway applications — Communication, signalling and processing systems — Safety related electronic systems for signalling	2003	1
4	EN 50159	Railway applications — Communication, signalling and processing systems — Safety-related communication in transmission systems	2010	1

Note 1: this standard is harmonised, see Commission Communication in the framework of the implementation of the 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 (OJ C 345, 26.11.2013, p. 3) where also published editorial corrigenda are indicated.'

COMMISSION DECISION (EU) 2015/15

of 5 January 2015

on a measure taken by Finland in accordance with Article 7 of Council Directive 89/686/EEC prohibiting the placing on the market of head protectors 'Ribcap'

(notified under document C(2014) 10114)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment [1], and in particular Article 7 thereof,

Whereas:

(1) In June 2014, the Finnish authorities notified to the Commission a measure of prohibition of placing on the market of head protectors manufactured by Ribcap AG, Berbegraben 4, CH-3110 Münsingen (Switzerland). The products, called 'Ribcap', bore CE marking, according to Directive 89/686/EEC on personal protective equipment.

(2) The products are marketed as head protectors PPE category I for, among other activities, ice-skating and skiing.

(3) Under Article 8(3) of Directive 89/686/EEC, EC type-examination shall not be required in the case of PPE models of simple design (Category I) where the designer assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

(4) The product is imported and distributed by Brandsense Oy/Classic Bike Finland, Mechelininkatu 15, FI-00100 Helsinki (Finland). According to its website, the company imports and markets bicycles.

(5) The web page of the importer contains links to the Ribcap brochure made by the manufacturer and to a Ribcap certificate based on tests on the product carried out by the University of Strasbourg, which would prove that Ribcap prevents head injuries; the words 'Certified Safety' are present in the packaging and marketing material. The words 'Certified Safety' can give the impression that the product has been EC type-examined by a notified body, while the University of Strasbourg is not a notified body.

(6) According to the claims made in the promotional brochure, Ribcap acts to protect the head during an impact. From the brochure, the consumer may get the impression that the products are suitable for use in various types of sports and as head protection — see, for instance, '*Ribcap is my comfortable, light and effective head protection for sports.*' Even if the words 'No protective effect like helmet' appear on the packaging of the product, the claims give a misleading image of the product's safety characteristics and can give the consumer the impression that the products protect against non-minimal risks.

(7) According to the categorisation guide included in the guidelines on the application of Directive 89/686/EEC, all helmets, including sports helmets are PPE Category II and therefore subject to an EC type examination by a notified body.

(8) The products are not accompanied by user instructions in Finnish and Swedish, which are the official languages of Finland.

(9) In the opinion of the Finnish authorities, as the products are not accompanied by user instructions describing in which situations they are intended to be used or which are the limits of use, the products can give a false feeling of security and mislead the consumer to believe that such products would have the same protective qualities as a helmet (PPE cat. II).

(10) The declaration of conformity drawn up by the manufacturer was sent by the distributor to Finnish authorities; such declaration is not drawn in accordance with the model given in Annex VI to Directive 89/686/EEC.

[1] OJ L 399, 30.12.1989, p. 18.

(11) The Commission wrote to the manufacturer and the distributor in Finland inviting them to communicate their observations on the measure taken by the Finnish authorities. In his reply, the manufacturer reaffirmed his view that Ribcap is not a helmet but rather a woollen hat with protectors, which should be categorised as PPE Category I under Directive 89/686/EEC. The manufacturer conceded that the use of the words 'certified safety' is perhaps confusing and unfortunate.

(12) The manufacturer attached to his reply a report issued by the Swiss Authorities. In the report a letter from the Swiss Authorities to Ribcap is mentioned, where they require, among other things, that 'the product could no longer be advertised in such a way as to give the impression of protecting the head from injury in the event of a fall experienced while moving using equipment (skis, snowboard, bicycle, etc.)'. The updated product description, together with an extensive warning, allowed Ribcap to market its products as 'hats with sewn-in protectors', PPE Category I.

(13) Neither the product description nor the warning for the marketing of the products in Finland appear to comply with the requirements needed to market the products as PPE Category I, as in the former the products are marketed as head protectors for ice-skating, skiing and other outdoor activities.

(14) In light of the documentation available and the comments expressed by the parties concerned, the Commission considers that the head protectors 'Ribcap' failed to comply with the basic health and safety requirements 1.1.2 *Level and classes of protection*, 1.4 *Information supplied by the manufacturers* and 3.1.1 *Impact caused by falling or projecting objects and collision of parts of the body with an obstacle*,

HAS ADOPTED THIS DECISION:

Article 1

The measure taken by the Finnish authorities, consisting of prohibition of placing on the market of head protectors 'Ribcap' manufactured by Ribcap AG, is justified.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 5 January 2015.

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2015/16

of 6 January 2015

on the publication with a restriction in the *Official Journal of the European Union* of the reference of standard EN 1870-17:2012 on manual horizontal cutting cross-cut sawing machines with one saw unit under Directive 2006/42/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to the Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC ([1]), and in particular Article 10 thereof,

Having regard to the opinion of the committee established by Article 22 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([2]),

Whereas:

(1) Where a national standard transposing a harmonised standard, the reference of which has been published in the *Official Journal of the European Union*, covers one or more essential health and safety requirements set out in Annex I to Directive 2006/42/EC, the machine built in accordance with this standard is presumed to meet the essential health and safety requirements concerned.

(2) In May 2013, France lodged a formal objection in accordance with Article 10 of Directive 2006/42/EC in respect of standard EN 1870-17:2012 'Safety of woodworking machines — Circular sawing machines — Part 17: Manual horizontal cutting cross-cut sawing machines with one saw unit (radial arm saws)', proposed by the European Committee for Standardization (CEN) to be harmonized under Directive 2006/42/EC.

(3) The formal objection is based on the failure of the provisions provided for in paragraph 3 of clause *5.3.6.1 Guarding of the saw blade* of the standard which states that the guard may be fixed or movable without indicating when each of them would be necessary, whereas these two categories of devices are different in nature, and offer different levels of safety which correspond to different risk analyses.

(4) Having examined the standard EN 1870-17:2012 together with the representatives of the committee established by Article 22 of Directive 2006/42/EC, the Commission concluded that the standard fails to meet the essential health and safety requirements provided for in point *1.4.2 'Special requirements for guards'* of Annex I to Directive 2006/42/EC, since it allows the designer to choose to install guards offering different levels of safety without referring to a risk analysis.

(5) The inclusion in a harmonised standard of options, one of which fails to comply with the relevant essential health and safety requirements of Directive 2006/42/EC, is liable to create confusion as to the presumption of conformity conferred by the application of the standard.

(6) Taking into consideration the need to improve the safety aspects of standard EN 1870-17:2012 and pending a suitable revision of that standard, the publication in the *Official Journal of the European Union* of the reference of the standard EN 1870-17:2012 should be accompanied by an appropriate warning,

([1]) OJ L 157, 9.6.2006, p. 24.
([2]) OJ L 316, 14.11.2012, p. 12.

HAS ADOPTED THIS DECISION:

Article 1

The reference of standard EN 1870-17:2012 'Safety of woodworking machines — Circular sawing machines — Part 17: Manual horizontal cutting cross-cut sawing machines with one saw unit (radial arm saws)' shall be published in the *Official Journal of the European Union* with restriciton as set out in the Annex.

Article 2

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

Done at Brussels, 6 January 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

COMMISSION COMMUNICATION IN THE FRAMEWORK OF THE IMPLEMENTATION OF THE DIRECTIVE 2006/42/EC

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

ESO ([1])	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 1870-17:2012 Safety of woodworking machines — Circular sawing machines — Part 17: Manual horizontal cutting cross-cut sawing machines with one saw unit (manual radial arm saws)	This is the first publication	EN 1870-17:2007 + A2:2009 Note 2	The date of this publication

Warning: With regards to the choice of guards of the saw blade, this publication does not concern paragraphs 3 of clauses 5.3.6.1 of this standard, the application of which does not confer a presumption of conformity to the essential health and safety requirements 1.4.2 of Annex I to Directive 2006/42/EC.

([1]) ESO: European Standardisation Organisation:
— CEN: Avenue Marnix 17, B-1000, Brussels, Tel.+32 2 5500811; fax + 32 2 5500819 (http://www.cen.eu)

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European standardisation organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 2: The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation.

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