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Price: EUR 3

(Continued overleaf)

⁽¹⁾ Text with EEA relevance

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) No 305/2013

of 26 November 2012

supplementing Directive 2010/40/EU of the European Parliament and of the Council with regard to the harmonised provision for an interoperable EU-wide eCall**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2010/40/EU of the European Parliament and of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport ⁽¹⁾, and in particular Article 7 thereof,

After consulting the European Data Protection Supervisor,

Whereas:

- (1) Directive 2010/40/EU requires the Commission to adopt delegated acts as regards specifications necessary to ensure the compatibility, interoperability and continuity for the deployment and operational use of intelligent transport systems (ITS).
- (2) According to Article 3(d) of Directive 2010/40/EU, the harmonised provision for an interoperable EU-wide eCall service shall constitute a priority action. The Commission should, therefore, adopt the necessary specifications in this field.
- (3) Article 26 of Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive) ⁽²⁾ requires that calls to the single European emergency call number 112 are answered appropriately and handled in a manner that is best suited to the national organisation of emergency systems, including the emergency call response centres (public safety answering points).

- (4) The Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'eCall: Time for deployment' ⁽³⁾, envisages new regulatory measures to speed up the deployment of an in-vehicle emergency call service in the Union. One of the proposed measures is to make the necessary upgrading of the public safety answering point (PSAP) infrastructure required for proper receipt and handling of eCalls mandatory.
- (5) Commission Recommendation 2011/750/EU ⁽⁴⁾ on support for an EU-wide eCall service in electronic communication networks for the transmission of in-vehicle emergency calls based on 112 ('eCalls') advises Member States to indicate the eCall PSAP to route eCalls and to ensure that mobile network operators handle eCalls properly.
- (6) It is expected that, by reducing the response time of the emergency services, the interoperable EU-wide eCall will reduce the number of fatalities in the Union as well as the severity of injuries caused by road accidents.
- (7) The interoperable EU-wide eCall is also expected to bring savings to society by improving incident management and by reducing road congestion and secondary accidents.
- (8) The processing of personal data in the context of the handling of eCalls by the PSAPs, the emergency services and service partners is performed in accordance with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽⁵⁾ and Directive 2002/58/EC of the European Parliament and of the

⁽¹⁾ OJ L 207, 6.8.2010, p. 1.⁽²⁾ OJ L 108, 24.4.2002, p. 51.⁽³⁾ COM(2009) 434 final.⁽⁴⁾ OJ L 303, 22.11.2011, p. 46.⁽⁵⁾ OJ L 281, 23.11.1995, p. 31.

Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) ⁽¹⁾. Member States shall ensure that this compliance is demonstrated, with national data protection authorities, either during a priori control procedures, such as prior notifications or a posteriori checks, such as in the course of complaints and investigations.

- (9) The interoperable EU-wide eCall service follows the recommendations made by the Article 29 Data Protection Working Party and contained in the 'Working document on data protection and privacy implications in eCall initiative', adopted on 26 September 2006 (1609/06/EN — WP 125). Vehicles equipped with eCall in-vehicle equipment shall not be traceable in their normal operational status. The minimum set of data sent by the eCall in-vehicle equipment (i.e. when triggered) shall include the minimum information required for the appropriate handling of emergency calls.
- (10) Without prejudice to Directive 95/46/EC, Member States shall take into account, when deploying the eCall PSAPs infrastructure, the 'Working document on data protection and privacy implications in eCall initiative' adopted by the Article 29 Working Party on 26 September 2006 (1609/06/EN — WP 125).
- (11) It is important that all Member States should develop common technical solutions and practices for the provision of emergency call services. The development of common technical solutions should be pursued in particular through the European standardisation organisations, in order to facilitate the introduction of the eCall service, ensure the interoperability and continuity of the service throughout the Union, and reduce the costs of implementation for the Union as a whole.
- (12) The European Standardisation Organisations, ETSI and CEN, have developed common standards for the deployment of a pan-European eCall service, which the present Regulation makes the reference to.
- (13) Infrastructures already deployed should be granted sufficient time to upgrade, therefore the Regulation should apply to them 12 months after entry into force,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation establishes the specifications for the upgrading of the Public Safety Answering Point (PSAP) infrastructure required for the proper receipt and handling of eCalls, in

order to ensure the compatibility, interoperability and continuity of the harmonised EU-wide eCall service.

Article 2

Definitions

The following definitions shall apply for the purposes of this Regulation:

- (a) 'emergency service' means a service, recognised as such by the Member State, that provides immediate and rapid assistance in situations where there is, in particular, a direct risk to life or limb, to individual or public health or safety, to private or public property, or to the environment, in accordance with national legislation;
- (b) 'public safety answering point' (PSAP) means a physical location where emergency calls are first received under the responsibility of a public authority or a private organisation recognised by the Member State;
- (c) 'most appropriate PSAP' means a PSAP defined beforehand by responsible authorities to cover emergency calls from a certain area or for emergency calls of a certain type;
- (d) 'eCall PSAP' means a most appropriate PSAP defined beforehand by the authorities to first receive and handle the eCalls;
- (e) 'eCall PSAP operator' means a person in the eCall PSAP receiving and/or handling the emergency calls;
- (f) 'service partner' means a public or private organisation recognised by national authorities, that has a role in the handling of incidents related to an eCall (e.g. road operator, assistance service);
- (g) 'in-vehicle equipment' means equipment within the vehicle that provides or has access to the in-vehicle data required to perform the eCall transaction via a public mobile wireless communications network;
- (h) 'eCall' (referred to in Directive 2010/40/EU as 'interoperable EU-wide eCall') means an in-vehicle emergency call to 112, made either automatically by means of the activation of in-vehicle sensors or manually, which carries a standardised minimum set of data and establishes an audio channel between the vehicle and the eCall PSAP via public mobile wireless communications networks;

⁽¹⁾ OJ L 201, 31.7.2002, p. 37.

- (i) 'eCall transaction' means the establishment of a mobile wireless communications session across a public wireless communications network and the transmission of a minimum set of data from a vehicle to an eCall PSAP and the establishment of an audio channel between the vehicle and the same eCall PSAP;
- (j) 'minimum set of data' (MSD) means the information defined by the standard 'Road transport and traffic telematics — eSafety — eCall minimum set of data (MSD)' (EN 15722) which is sent to the eCall PSAP;
- (k) 'Vehicle Identification Number (VIN)' means the alphanumeric code assigned to a vehicle by the manufacturer in order to ensure proper identification of every vehicle, as described in ISO standard 3779;
- (l) 'mobile wireless communications network' means wireless communications network with homogeneous handover between network access points;
- (m) 'public mobile wireless communications network' means mobile wireless communications network available to the public in accordance with Directive 2002/22/EC and with Directive 2002/21/EC of the European Parliament and of the Council ⁽¹⁾;
- (n) 'emergency control centre' means a facility used by one or more emergency services to handle emergency calls;
- (o) 'raw MSD' means a representation of the transmitted minimum set of data before being presented in an intelligible way to the eCall PSAP operator.

Article 3

eCall PSAP requirements

1. Member States shall ensure that any eCall PSAP is equipped to handle eCalls and receive the MSD originating from the in-vehicle equipment according to the standards 'Intelligent transport system — eSafety — PanEuropean eCall-Operating requirements' (EN 16072) and 'Intelligent transport systems — eSafety — eCall High Level Application Requirements (HLAP)' (EN 16062).

2. The eCall PSAP shall handle eCalls as expeditiously and effectively as any other call made to the single European

emergency number 112. The eCall PSAP shall process eCalls in line with the requirements of national regulations for emergency call processing.

3. The eCall PSAP shall be able to receive the data contents of the MSD and present them to the eCall PSAP operator clearly and understandably.

4. The eCall PSAP shall have access to an appropriate Geographical Information System (GIS) or an equivalent system allowing the eCall PSAP operator to identify the position and heading of the vehicle to a minimum degree of accuracy as defined in EN 15722 for the MSD coordinates.

5. The abovementioned requirements shall enable the eCall PSAP to provide location, type of eCall activation (manual or automatic) and other relevant data to the appropriate emergency service(s) or service partner(s).

6. The eCall PSAP (initially receiving the eCall) shall establish audio communication with the vehicle and handle the eCall data; if necessary, the eCall PSAP may reroute the call and MSD data to another PSAP, emergency control centre or service partner according to national procedures determined by the national authority. Rerouting may be done via data or audio connection, or, preferably, both.

7. When appropriate, and depending on national procedures and legislation, the eCall PSAP and appropriate emergency service(s) or service partner(s) may be granted access to the characteristics of the vehicle contained in national databases and/or other relevant resources, in order to obtain information that is necessary for dealing with an eCall, notably to allow the interpretation of the Vehicle Identification Number (VIN) and the presentation of additional relevant information, particularly vehicle type and model.

Article 4

Conformity assessment

Member States shall designate the authorities that are competent for assessing the conformity of the operations of the eCall PSAPs with the requirements listed in Article 3 and shall notify them to the Commission. Conformity assessment shall be based on the part of the standard 'Intelligent transport systems — eSafety — eCall end to end conformance testing' (EN 16454) that relates to PSAPs conformance to pan-European eCall.

⁽¹⁾ OJ L 108, 24.4.2002, p. 33.

*Article 5***Obligations linked to the deployment of the eCall PSAPs infrastructure**

Member States shall ensure that this Regulation is applied when the eCall PSAPs infrastructure for the handling of the interoperable EU-wide eCall is deployed, in accordance with the principles for specifications and deployment laid down in Annex II to Directive 2010/40/EU. This is without prejudice to the right of each Member State to decide on the deployment of the eCall PSAPs infrastructure for the handling of the interoperable EU-wide eCall on its territory. This right is without prejudice to any legislative act adopted under the second subparagraph of Article 6(2) of Directive 2010/40/EU.

*Article 6***Rules on privacy and data protection**

1. The PSAPs, including eCall PSAPs, shall be regarded as data controllers within the meaning of Article 2(d) of Directive 95/46/EC. Where the eCall data is to be sent to other emergency control centres or service partners pursuant to Article 3(5), the latter shall also be considered as data controllers. Member States shall ensure that the processing of personal data in the context of the handling of the eCalls by the PSAPs, the emergency services and service partners is carried out in accordance with Directives 95/46/EC and 2002/58/EC, and that this compliance is demonstrated to the national data protection authorities.

2. In particular, Member States shall ensure that personal data are protected against misuse, including unlawful access, alteration or loss, and that protocols concerning personal data storage, retention duration, processing and protection are established at the appropriate level and properly observed.

*Article 7***Rules on liability**

1. The eCall PSAPs must be able to demonstrate to the competent authorities that they meet all specified conformance

requirements of the eCall standards listed in Article 3(1) in respect of the part(s) of the system under their design and/or control. They shall be liable only for that part of the eCalls for which they are responsible, which starts at the time the eCalls reach the eCall PSAP, in accordance with national procedures.

2. To that end, and in addition to other existing measures related to the handling of 112 calls in particular, both the raw MSD received with the eCall and the MSD contents presented to the eCall operator shall be retained for a determined period of time, in accordance with national regulations. Such data shall be stored in accordance with Articles 6, 13 and 17 of Directive 95/46/EC.

*Article 8***Reporting**

Member States shall report to the Commission by 23 October 2013 on the state of implementation of this Regulation. This report shall include at least the list of competent authorities for assessing the conformity of the operations of the eCall PSAPs, the list and geographical coverage of the eCall PSAPs, a schedule of deployment during the ensuing two years, the description of the conformance tests and the description of the privacy and data protection protocols.

*Article 9***Entry into force and application**

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

It shall apply to infrastructures deployed from the date of entry into force of this Regulation. It shall apply from 23 April 2014 to infrastructures already deployed at the date of entry into force of this Regulation.

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

Done at Brussels, 26 November 2012.

For the Commission
The President
José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 306/2013

of 2 April 2013

concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) for weaned piglets and weaned Suidae other than *Sus scrofa domesticus* (holder of authorisation Kemin Europa N.V.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of a preparation of *Bacillus subtilis* (ATCC PTA-6737). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a new use of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for weaned piglets and weaned Suidae other than *Sus scrofa domesticus*, to be classified in the additive category 'zoo-technical additives'.
- (4) The use of a preparation of *Bacillus subtilis* (ATCC PTA-6737) was authorised for 10 years for chickens for fattening by Commission Regulation (EU) No 107/2010⁽²⁾ and chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches by Commission Implementing Regulation (EU) No 885/2011⁽³⁾.
- (5) The European Food Safety Authority ('the Authority') in its opinion of 25 April 2012⁽⁴⁾ confirmed its previous

conclusions that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (ATCC PTA-6737) is presumed safe for all animal species, consumers of the products of any animals given the additive and the environment. Although three trials performed by the applicant showed at least one significantly improved parameter in comparison with control groups, the Authority was unable to establish a minimum effective dose as proposed by the applicant, because of conflicting results at different dose levels tested. Two trials showed significant improvements with a dose of 1×10^7 CFU/kg but not at 5×10^7 CFU/kg feed. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of the preparation of *Bacillus subtilis* (ATCC PTA-6737) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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

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*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 36, 9.2.2010, p. 1.

⁽³⁾ OJ L 229, 6.9.2011, p. 3.

⁽⁴⁾ EFSA Journal 2012; 10(5):2671.

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

Done at Brussels, 2 April 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1823	Kemin Europa N.V.	Bacillus subtilis (ATCC PTA-6737)	<i>Additive composition</i> Preparation of <i>Bacillus subtilis</i> (ATCC PTA-6737) containing a minimum of 1×10^{10} CFU/g additive <i>Characterisation of the active substance</i> Viable spores of <i>Bacillus subtilis</i> (ATCC PTA-6737) <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using tryptone soya agar with pre heat-treatment of feed samples. Identification: pulsed-field gel electrophoresis (PFGE) method.	(Weaned) piglets and (weaned) Suidae other than <i>Sus scrofa domestica</i>	—	1×10^7	—	(1) In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. (2) For use in (weaned) piglets up to approximately 35 kg.	23 April 2023

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 307/2013**of 2 April 2013****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

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

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 2 April 2013.

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

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

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

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MA	69,7
	TN	99,6
	TR	126,7
	ZZ	98,7
0707 00 05	JO	194,1
	TR	145,4
	ZZ	169,8
0709 93 10	MA	46,3
	TR	107,4
	ZZ	76,9
0805 10 20	EG	54,1
	IL	65,2
	MA	57,6
	TN	58,7
	TR	69,0
	ZZ	60,9
0805 50 10	TR	71,9
	ZZ	71,9
0808 10 80	AR	108,9
	BR	93,3
	CL	131,0
	CN	78,7
	MK	27,7
	US	180,6
	ZA	111,6
0808 30 90	ZZ	104,5
	AR	117,1
	CL	145,2
	TR	208,9
	US	158,2
	ZA	129,2
	ZZ	151,7

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

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 27 March 2013

repealing Decisions 2003/135/EC, 2004/832/EC and 2005/59/EC approving plans for the eradication of classical swine fever and the emergency vaccination of feral pigs in Germany, France and Slovakia

*(notified under document C(2013) 1741)***(Only the French, German and Slovakian texts are authentic)**

(2013/164/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever ⁽¹⁾, and in particular Article 16(1), Article 20(2), Article 25(3) and Article 29(2) thereof,

Whereas:

(1) Commission Decision 2003/135/EC of 27 February 2003 on the approval of the plans for the eradication of classical swine fever and the emergency vaccination of feral pigs against classical swine fever in Germany, in the federal states of Lower Saxony, North Rhine-Westphalia, Rhineland-Palatinate and Saarland ⁽²⁾, Commission Decision 2004/832/EC of 3 December 2004 approving the plans for the eradication of classical swine fever in feral pigs and the emergency vaccination of such pigs in the Northern Vosges, France ⁽³⁾ and Commission Decision 2005/59/EC of 26 January 2005 approving the plans for the eradication of classical swine fever in feral pigs and the emergency vaccination of such pigs in Slovakia ⁽⁴⁾ were adopted following the confirmation of classical swine fever in feral pigs in certain regions of France, Germany and Slovakia, respectively. By those Decisions, the plans for the eradication of classical swine fever and the emergency vaccination of feral pigs against that disease were approved for those Member States.

(2) Commission Implementing Decision 2012/761/EU of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the

Member States for 2013 ⁽⁵⁾ approves, inter alia, the programmes for the control and monitoring of classical swine fever submitted by Germany and Slovakia.

(3) In 2011 France and Slovakia informed the Commission and the Member States of the favourable classical swine fever situation in their territory. The information provided indicated that classical swine fever had been successfully eradicated from the feral pigs in the affected areas of those Member States. In addition, in 2012, Germany informed the Commission and the Member States that classical swine fever was successfully eradicated from the feral pigs in the affected areas of that Member State.

(4) According to the information submitted by France, Germany and Slovakia, the emergency vaccination of feral pigs was stopped. In addition, a high level of surveillance in the areas previously affected by the disease is maintained as part of the programmes approved by Implementing Decision 2012/761/EU. The measures provided for in the plans for the eradication of classical swine fever and the emergency vaccination of feral pigs against classical swine fever approved for those Member States are therefore no longer necessary.

(5) For reasons of clarity and consistency of Union legislation, Decisions 2003/135/EC, 2004/832/EC and 2005/59/EC should therefore be repealed.

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

HAS ADOPTED THIS DECISION:

Article 1

Decisions 2003/135/EC, 2004/832/EC and 2005/59/EC are repealed.

⁽¹⁾ OJ L 316, 1.12.2001, p. 5.

⁽²⁾ OJ L 53, 28.2.2003, p. 47.

⁽³⁾ OJ L 359, 4.12.2004, p. 62.

⁽⁴⁾ OJ L 24, 27.1.2005, p. 46.

⁽⁵⁾ OJ L 336, 8.12.2012, p. 83.

Article 2

This Decision is addressed to the Federal Republic of Germany, the French Republic and the Slovak Republic.

Done at Brussels, 27 March 2013.

For the Commission

Tonio BORG

Member of the Commission

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 27 March 2013

on the presence of T-2 and HT-2 toxin in cereals and cereal products

(Text with EEA relevance)

(2013/165/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) T-2 toxin and HT-2 toxin are mycotoxins produced by various *Fusarium* species. T-2 toxin is rapidly metabolised to a large number of products, HT-2 toxin being a major metabolite.
- (2) The Scientific Panel on Contaminants in the Food Chain (CONTAM panel) of the European Food Safety Authority (EFSA) adopted an opinion on a request from the Commission related on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed ⁽¹⁾.
- (3) The CONTAM Panel established a group tolerable daily intake (TDI) of 100 ng/kg b.w. for the sum of T-2 and HT-2 toxins. Estimates of chronic human dietary exposure to the sum of T-2 and HT-2 toxins based on the available occurrence data are below the TDI for populations of all age groups, and thus not an immediate health concern.
- (4) As regards the animal health risk, the CONTAM Panel concluded that for ruminants, rabbits and fish, the current estimated exposure to T-2 and HT-2 toxin is considered unlikely to be a health concern. For pigs, poultry, horses and dogs, the estimates of exposure to T-2 and HT-2 toxin indicate that the risk of adverse health effects is low. Cats are amongst the most

sensitive animal species. Due to the limited data and the severe adverse health effects at low dose levels, no NOAEL or LOAEL could be established. Therefore this Recommendation is not of application for feed for cats, for which stricter measures will be established.

- (5) The CONTAM Panel further concluded that the carry-over of T-2 and HT-2 toxins from feed to food products of animal origin is limited and hence contributes only to a negligible extent to human exposure.
- (6) Taking into account the conclusions of the scientific opinion, together with the large year to year variation in occurrence of T-2 and HT-2 toxin, it is appropriate to collect more data on T-2 and HT-2 in cereals and cereal products and more information on the effects of food processing (i.e. cooking) and agronomic factors on the presence of T-2 and HT-2 toxin. Furthermore, it is necessary to obtain more information on the different factors which lead to relative high levels of T-2 and HT-2 toxin in cereals and cereal products in order to be able to identify the measures to be taken to avoid or to reduce the presence of T-2 and HT-2 toxin in cereals and cereal products. Investigations have to be undertaken in order to collect information on the factors resulting in relative high levels of T-2 and HT-2 toxin in cereals and cereal products and on the effects of feed and food processing. Based on the available data, T-2 and HT-2 do not occur or only in very low levels in rice and rice products and therefore it is appropriate to exclude these products from the scope of this Recommendation.
- (7) The results of monitoring of cereals and cereal products will be used to assess changes and trends in human and animal exposure to T-2 and HT-2 toxin. It is therefore appropriate to use methods of analysis with a sufficient sensitivity.
- (8) To provide orientation in which cases it would be appropriate to perform such investigations, it is appropriate to provide indicative values above which such investigations would be appropriate. To determine these indicative

⁽¹⁾ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. *EFSA Journal* 2011; 9(12):2481. [187 pp.] doi:10.2903/j.efsa.2011.2481. Available online: www.efsa.europa.eu/efsajournal

values the occurrence data available in the EFSA database have been used. To perform the investigations traceability is of major importance.

- (9) In 2015 an assessment of the gathered information in the frame of this Recommendation should be undertaken. The monitoring data obtained as a result of this Recommendation will also enable a better understanding of the year-to-year variance and the presence of T-2 and HT-2 toxin in the wide range of cereal products the factors resulting in higher levels and the measures which could be taken to prevent the presence or mitigate the presence of T-2 and HT-2 toxins, including through agronomic factors and through processing.

HAS ADOPTED THIS RECOMMENDATION:

- (1) Member States should, with the active involvement of feed and food business operators, perform monitoring for the presence of T-2 and HT-2 toxin in cereals and cereal products. For the purpose of this Recommendation rice is not included in cereals and rice products are not included in cereal products.
- (2) Member States should encourage that samples are simultaneously analysed for the presence of T-2 and HT-2 and other *Fusarium*-toxins such as deoxynivalenol, zearalenone and fumonisin B1 + B2 to allow the extent of co-occurrence to be assessed.

In case the used method of analysis enables it, it would be appropriate to analyse also the masked mycotoxins in particular the mono- and di-glycosylated conjugates of T-2 and HT-2 toxin.

- (3) The sampling and analysis for cereals and cereal products intended for human consumption should be performed in accordance with the provisions provided for in Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs⁽¹⁾ in particular:

- Annex I Part B for the sampling of cereals and cereal products,
- Annex II, point 4.3.1(g) Performance criteria for the analysis of T-2 and HT-2 toxin. The Limit of Quantification (LOQ) should preferably not be higher than

5 µg/kg for T-2 and HT-2 toxin individually, except for unprocessed cereals for which the LOQ should preferably not be higher than 10 µg/kg for T-2 and HT-2 toxin individually. In the case of the use of an analytical screening technique, the limit of detection should preferably not be higher than 25 µg/kg for the sum of T-2 and HT-2 toxin.

The sampling procedure applied by the food business operator might deviate from the provisions of Regulation (EC) No 401/2006 but should be representative for the lot sampled.

- (4) The sampling and analysis for cereals and cereal products intended for feed and compound feed should be performed in accordance with the provisions provided for in Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed⁽²⁾. The Limit of Quantification (LOQ) should preferably not be higher than 10 µg/kg for T-2 and HT-2 toxin individually. In the case of the use of an analytical screening technique, the limit of detection should preferably not be higher than 25 µg/kg for the sum of T-2 and HT-2 toxin.

The sampling procedure applied by the feed business operator might deviate from the provisions of Regulation (EC) No 152/2009 but should be representative for the lot sampled.

- (5) Member States, with the active involvement of the feed and food business operators, should perform investigations to identify the factors resulting in these levels above the indicative level and determine the measures to be taken to avoid or reduce such presence in future. These investigations should certainly be performed in case of repetitive findings within a certain period of time of levels above the indicative levels of T-2 and HT-2 toxin in cereals and cereal products mentioned in Annex to this Recommendation. The sampling and analysis with the objective to obtain more information on the different factors, including agronomic factors, which lead to relative high levels of T-2 and HT-2 toxin in cereals and cereal products, should be targeted on cereals and cereal products from primary processing.

- (6) Member States, with the active involvement of the feed and food business operators, should perform investigations on the effects of feed and food processing on the presence of T-2 and HT-2 toxin. These investigations should certainly be performed in case of repetitive findings within a certain period of time of levels above the indicative level of T-2 and HT-2 toxin in cereal products.

⁽¹⁾ OJ L 70, 9.3.2006, p. 12.

⁽²⁾ OJ L 54, 26.2.2009, p. 1.

- (7) Member States should ensure that the analytical results are provided on a regular basis to EFSA for compilation into a single database and that the outcome of the investigations is provided to the European Commission every year, the first time by December 2013. A guidance note will be elaborated to ensure uniform application of this Recommendation and to ensure comparable reporting of results of investigations.

Done at Brussels, 27 March 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX

Indicative levels for cereals and cereals products (*) ()**

	Indicative levels for the sum of T-2 and HT-2 (µg/kg) from which onwards/above which investigations should be performed, certainly in case of repetitive findings (*)
1. Unprocessed cereals (***)	
1.1. barley (including malting barley) and maize	200
1.2. oats (with husk)	1 000
1.3. wheat, rye and other cereals	100
2. Cereal grains for direct human consumption (****)	
2.1. oats	200
2.2. maize	100
2.3. other cereals	50
3. Cereal products for human consumption	
3.1. oat bran and flaked oats	200
3.2. cereal bran except oat bran, oat milling products other than oat bran and flaked oats, and maize milling products	100
3.3. other cereal milling products	50
3.4. breakfast cereals including formed cereal flakes	75
3.5. bread (including small bakery wares), pastries, biscuits, cereal snacks, pasta	25
3.6. cereal-based foods for infants and young children	15
4. Cereal products for feed and compound feed (*****)	
4.1. oat milling products (husks)	2 000
4.2. other cereal products	500
4.3. compound feed, with the exception of feed for cats	250

(*) The levels referred to in this Annex are indicative levels above which, certainly in the case of repetitive findings, investigations should be performed on the factors leading to the presence of T-2 and HT-2 toxin or on the effects of feed and food processing. The indicative levels are based on the occurrence data available in the EFSA database as presented in the EFSA opinion. The indicative levels are not feed and food safety levels.

(**) For the purpose of this Recommendation rice is not included in cereals and rice products are not included in cereal products.

(***) Unprocessed cereals are cereals which have not undergone any physical or thermal treatment other than drying, cleaning and sorting.

(****) Cereal grains for direct human consumption are cereal grains which have undergone drying, cleaning, de-husking and sorting processes and on which no further cleaning and sorting processes will be performed before their further processing in the food chain.

(*****) The indicative levels for cereals and cereal products intended for feed and compound feed are relative to a feed with a moisture content of 12 %.

CORRIGENDA

Corrigendum to Commission Directive 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(Official Journal of the European Union L 77 of 20 March 2013)

On page 21, Article 3(1), the second subparagraph is replaced as follows:

'They shall apply those provisions from 19 June 2014 as regards aerosol dispensers containing a substance.'

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