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Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Regulation (EU) No 834/2011 of 19 August 2011 amending Annex I to Regulation (EC) No 689/2008 of the European Parliament and of the Council concerning the export and import of dangerous chemicals** 1
- ★ **Commission Regulation (EU) No 835/2011 of 19 August 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs ⁽¹⁾** 4
- ★ **Commission Regulation (EU) No 836/2011 of 19 August 2011 amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs ⁽¹⁾** 9
- Commission Implementing Regulation (EU) No 837/2011 of 19 August 2011 establishing the standard import values for determining the entry price of certain fruit and vegetables 17
- Commission Implementing Regulation (EU) No 838/2011 of 19 August 2011 on the issue of import licences for applications submitted in the first seven days of August 2011 under the tariff quota for high-quality beef administered by Regulation (EC) No 620/2009 19

Price: EUR 3

(Continued overleaf)

⁽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.

DECISIONS

2011/513/EU:

★ Commission Implementing Decision of 19 August 2011 authorising the placing on the market of Phosphatidylserine from soya phospholipids as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (<i>notified under document C(2011) 5897</i>)	20
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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 834/2011

of 19 August 2011

amending Annex I to Regulation (EC) No 689/2008 of the European Parliament and of the Council concerning the export and import of dangerous chemicals

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals ⁽¹⁾, and in particular Article 22(4) thereof,

Whereas:

- (1) Regulation (EC) No 689/2008 implements the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade, signed on 11 September 1998 and approved, on behalf of the Community, by Council Decision 2003/106/EC ⁽²⁾.
- (2) Annex I to Regulation (EC) No 689/2008 should be amended to take into account regulatory action in respect of certain chemicals taken pursuant to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽³⁾, Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽⁴⁾ and Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽⁵⁾.

- (3) The substances ethalfluralin, indolyacetic acid and thio-bencarb have not been included as active substances in Annex I to Directive 91/414/EEC, with the effect that those active substances are banned for pesticide use and thus should be added to the lists of chemicals contained in Parts 1 and 2 of Annex I to Regulation (EC) No 689/2008.

- (4) The substance guazatine has not been included as an active substance in Annex I to Directive 91/414/EEC and guazatine, as referred to as guazatine triacetate, has not been included as an active substance in Annex I, IA or IB to Directive 98/8/EC, with the effect that guazatine is banned for pesticide use and thus should be added to the lists of chemicals contained in Parts 1 and 2 of Annex I to Regulation (EC) No 689/2008. The addition of guazatine to Annex I was suspended due to a new application for inclusion in Annex I to Directive 91/414/EEC submitted pursuant to Article 13 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽⁶⁾. This new application has been withdrawn by the applicant with the effect that the reason for suspending the addition to Annex I disappeared. Therefore, the substance guazatine should be added to the lists of chemicals contained in Parts 1 and 2 of Annex I to Regulation (EC) No 689/2008.

- (5) The substance 1,3-dichloropropene has not been included as an active substance in Annex I to Directive 91/414/EEC, with the effect that 1,3-dichloropropene is banned for pesticide use and thus should be added to the lists of chemicals contained in Parts 1 and 2 of Annex I to Regulation (EC) No 689/2008. The addition of 1,3-dichloropropene to Part 2 of Annex I was suspended due to a new application for inclusion in Annex I to Directive

⁽¹⁾ OJ L 204, 31.7.2008, p. 1.⁽²⁾ OJ L 63, 6.3.2003, p. 27.⁽³⁾ OJ L 230, 19.8.1991, p. 1.⁽⁴⁾ OJ L 123, 24.4.1998, p. 1.⁽⁵⁾ OJ L 396, 30.12.2006, p. 1.⁽⁶⁾ OJ L 15, 18.1.2008, p. 5.

91/414/EEC submitted pursuant to Article 13 of Regulation (EC) No 33/2008. This new application resulted again in the decision not to include the substance 1,3-dichloropropene as an active substance in Annex I to Directive 91/414/EEC with the effect that 1,3-dichloropropene remains banned for pesticide use and that the reason for suspending the addition to Part 2 of Annex I disappeared. Therefore, the substance 1,3-dichloropropene should be added to the list of chemicals contained in Part 2 of Annex I to Regulation (EC) No 689/2008.

- (6) The substance haloxyfop-P has been included as an active substance in Annex I to Directive 91/414/EEC, with the effect that haloxyfop-P is no longer banned for pesticide use. Consequently the active substance, as referred to as haloxyfop-R, should be deleted from Part 1 of Annex I to Regulation (EC) No 689/2008.
- (7) Annex I to Regulation (EC) No 689/2008 should therefore be amended accordingly.

- (8) In order to allow enough time for Member States and industry to take the measures necessary for the implementation of this Regulation, its application should be deferred.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 689/2008 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 October 2011.

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

Done at Brussels, 19 August 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex I to Regulation (EC) No 689/2008 is amended as follows:

(1) Part 1 is amended as follows:

(a) the following entries are added:

Chemical	CAS No	Einecs No	CN code	Subcategory (*)	Use limitation (**)	Countries for which no notification is required
Ethalfuralin +	55283-68-6	259-564-3	2921 43 00	p(1)	b	
Guazatine +	108173-90-6 115044-19-4	236-855-3	3808 99 90	p(1)-p(2)	b-b	
Indolylacetic acid +	87-51-4	201-748-2	2933 99 80	p(1)	b	
Thiobencarb +	28249-77-6	248-924-5	2930 20 00	p(1)	b'	

(b) the following entry is deleted:

Chemical	CAS No	Einecs No	CN code	Subcategory (*)	Use limitation (**)	Countries for which no notification is required
'Haloxyp-R + (Haloxyp-P-methyl ester)	95977-29-0 (72619-32-0)	n.a. (406-250-0)	2933 39 99 (2933 39 99)	p(1)	b'	

(2) in Part 2 the following entries are added:

Chemical	CAS RN	Einecs No	CN code	Category (*)	Use limitation (**)
'1,3-dichloropropene	542-75-6	208-826-5	2903 29 00	p	b
Ethalfuralin	55283-68-6	259-564-3	2921 43 00	p	b
Guazatine	108173-90-6 115044-19-4	236-855-3	3808 99 90	p	b
Indolylacetic acid	87-51-4	201-748-2	2933 99 80	p	b
Thiobencarb	28249-77-6	248-924-5	2930 20 00	p	b'

COMMISSION REGULATION (EU) No 835/2011**of 19 August 2011****amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs ⁽²⁾ sets maximum levels for benzo(a)pyrene in a range of foodstuffs.

(2) Benzo(a)pyrene belongs to the group of polycyclic aromatic hydrocarbons (PAH) and is used as a marker for the occurrence and effect of carcinogenic PAH in food based on a scientific opinion of the former Scientific Committee on Food (SCF) ⁽³⁾. In its opinion of December 2002, the SCF recommended that further analyses of the relative proportions of these PAH in foods would be necessary for a future review of the suitability of maintaining benzo(a)pyrene as a marker.

(3) New data on occurrence of carcinogenic PAH in foodstuffs have been collected by the Member States in the framework of Commission Recommendation 2005/108/EC ⁽⁴⁾. The Commission asked the European Food Safety Authority (EFSA) to review the SCF opinion taking into account the new occurrence data, other relevant new scientific information as well as the Margin of Exposure (MOE) approach. Within this review, EFSA was asked to re-assess the suitability of maintaining benzo(a)pyrene as a marker.

(4) The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of EFSA adopted an opinion on Poly-

cyclic Aromatic Hydrocarbons in Food on 9 June 2008 ⁽⁵⁾. In this opinion EFSA concluded that benzo(a)pyrene is not a suitable marker for the occurrence of polycyclic aromatic hydrocarbons in food and that a system of four specific substances (PAH4 ⁽⁶⁾) or eight specific substances (PAH8 ⁽⁷⁾) would be the most suitable indicators of PAH in food. EFSA also concluded that a system of eight substances (PAH8) would not provide much added value compared to a system of four substances (PAH4).

(5) Furthermore, the CONTAM Panel concluded, using the Margin of Exposure (MOE) approach, that there is low concern for consumer health at the average estimated dietary exposures. However, for high level consumers the MOEs were close to or less than 10 000, which indicates a potential concern for consumer health.

(6) Based on the conclusions of EFSA, the current system of using benzo(a)pyrene as the only marker for the group of polycyclic aromatic hydrocarbons, can not be maintained. An amendment of Regulation (EC) No 1881/2006 is therefore necessary.

(7) New maximum levels for the sum of four substances (PAH4) (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) should be introduced, whilst maintaining a separate maximum level for benzo(a)pyrene.

(8) Such system would ensure that PAH levels in food are kept at levels that do not cause health concern and that the amount of PAH can also be controlled in those samples in which benzo(a)pyrene is not detectable, but where other PAH are present.

(9) The separate maximum level for benzo(a)pyrene is maintained to ensure comparability of previous and future data. After a certain time of implementation of this amendment and on basis of new data that will be generated in future, the need for retaining a separate maximum level for benzo(a) pyrene should be re-assessed.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ OJ L 364, 20.12.2006, p. 5.

⁽³⁾ Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food (expressed on 4 December 2002).

http://ec.europa.eu/food/fs/sc/scf/out153_en.pdf

⁽⁴⁾ OJ L 34, 8.2.2005, p. 43.

⁽⁵⁾ *The EFSA Journal* (2008) 724, 1-114.

⁽⁶⁾ Benzo(a)pyrene, Chrysene, Benz(a)anthracene, benzo(b)fluoranthene.

⁽⁷⁾ Benzo(a)pyrene, Chrysene, Benz(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(g,h,i)perylene, dibenz(a,h)anthracene and indeno(1,2,3-c,d)pyrene.

- (10) As regards the sum of the four substances (PAH4), lower bound concentrations should be used as the basis for compliance decisions.
- (11) Maximum levels for polycyclic aromatic hydrocarbons must be safe and as low as reasonably achievable (ALARA) based upon good manufacturing and agricultural/fishery practices. The new PAH occurrence data show that background levels of PAH are lower than previously thought in some food commodities. Benzo(a)pyrene maximum levels have therefore been adapted to reflect more realistic lower background levels in fresh and smoked bivalve molluscs.
- (12) Data for smoked fish and smoked meat have also shown that lower maximum levels are achievable. Nevertheless, adaptations of current smoking technology may be necessary in some cases. Therefore, a two step procedure should be established for smoked meat and smoked fish which grants a transition of two years from the date of application of this Regulation before lower maximum levels become applicable.
- (13) Smoked sprats and canned smoked sprats have been found to contain higher levels of PAH than other smoked fish. Specific maximum levels should be established for smoked sprats and canned smoked sprats in order to reflect what is achievable in these foodstuffs.
- (14) Previously a maximum level for benzo(a)pyrene in "muscle meat of fish other than smoked fish" was established as an indicator for potential environmental pollution. Nevertheless, it has been shown that PAH are quickly metabolised in fresh fish and do not accumulate in the muscle meat. Therefore, maintaining a maximum level for PAH in fresh fish is no longer appropriate.
- (15) High levels of PAH have been found in some types of heat treated meat and heat treated meat products sold to the final consumer. These levels are avoidable if appropriate processing conditions and equipment are used. It is therefore appropriate to establish maximum levels for PAH in meat and meat products that have undergone a heat treatment process known to potentially result in formation of PAH, i.e. only grilling and barbecuing.
- (16) Cocoa butter was temporarily exempted from the existing maximum level for benzo(a)pyrene in oils and fats under Regulation (EC) No 1881/2006 and a review of the appropriateness of setting a maximum level for PAH in cocoa butter was foreseen by 1 April 2007. The review was then postponed pending the result of the then ongoing scientific re-assessment of PAH by EFSA.
- (17) Cocoa butter contains higher levels of PAH than other oils and fats. This is mainly due to inappropriate drying practices of the cocoa beans and the fact that cocoa butter can not be refined as other vegetable oils and fats. Cocoa butter is a main constituent of cocoa raw products (e.g. cocoa beans, cocoa mass, cocoa nibs or cocoa liquor) and is present in chocolate and other cocoa products often consumed by children. It thereby contributes to human exposure, in particular to exposure of children. It is therefore necessary to establish maximum levels for PAH in cocoa beans and derived products, thereby also including cocoa butter.
- (18) Maximum levels for PAH in cocoa beans should be established at levels as low as reasonably achievable and taking into account the current technological possibilities of producing countries. They should be established on a fat basis since PAH concentrate in the fat fraction, the cocoa butter. To allow producing countries to make technological improvements in order to adapt to these maximum levels, the date of application of the maximum levels for cocoa beans and derived products should be deferred. Furthermore, initially a higher maximum level for the sum of the four substances should apply to these products. After a transition period of two years a lower maximum level should apply. The levels of PAH in cocoa beans and derived products should be regularly monitored with a view to assessing the possibility for further decreasing the maximum levels in future.
- (19) Data have shown that coconut oil can contain higher amounts of PAH4 than other vegetable oils and fats. This is due to the proportionally higher presence of benz(a)anthracene and chrysene which can not be easily removed during refinement of coconut oil. Specific maximum levels for coconut oil should therefore be set at levels as low as reasonably achievable and taking into account the current technological possibilities of producing countries. As technological improvements in producing countries are expected, the levels of PAH in coconut oil should be regularly monitored with a view to assessing the possibility for setting lower levels in future.
- (20) Current occurrence data on PAH in cereals and vegetables are limited. The available data indicate that cereals and vegetables contain rather low levels of PAH. The low levels seen in the currently available occurrence data do not justify the immediate setting of maximum levels. Nevertheless, EFSA identified cereals and vegetables as being important contributors to human exposure due to their high consumption. Therefore, PAH levels in these two product groups should be further monitored. On the basis of further data, the need for setting maximum levels will be evaluated.

- (21) High levels of PAH have been found in some food supplements. Nevertheless, the levels are variable and depend on the specific type of food supplements. Further data on food supplements are needed and should be collected. Once these data become available, the need for setting maximum levels for PAH in food supplements will be evaluated.
- (22) Member States and food business operators should be allowed time to adapt to the maximum levels established by this Regulation. The date of application of this Regulation should therefore be deferred. A transitional period should be provided for the products already placed on the market before the date of application of the amendments introduced by this Regulation.
- (23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

1. Foodstuffs not complying with the maximum levels applicable from 1 September 2012 pursuant to Section 6 "Polycyclic aromatic hydrocarbons" of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are

lawfully placed on the market prior to 1 September 2012, may continue to be marketed after that date until their date of minimum durability or use-by-date.

2. Foodstuffs not complying with the maximum levels applicable from 1 September 2014 pursuant to points 6.1.4 and 6.1.5 of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are lawfully placed on the market prior to 1 September 2014, may continue to be marketed after that date until their date of minimum durability or use-by-date.

3. Foodstuffs not complying with the maximum levels applicable from 1 April 2013 pursuant to point 6.1.2 of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are lawfully placed on the market prior to 1 April 2013, may continue to be marketed after that date until their date of minimum durability or use-by-date.

4. Foodstuffs not complying with the maximum level applicable from 1 April 2015 pursuant to point 6.1.2 of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are lawfully placed on the market prior to 1 April 2015, may continue to be marketed after that date until their date of minimum durability or use-by-date.

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 1 September 2012.

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

Done at Brussels, 19 August 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

The Annex to Regulation (EC) No 1881/2006 is amended as follows:

(1) Section 6: *Polycyclic aromatic hydrocarbons* is replaced by the following:

"Section 6: *Polycyclic aromatic hydrocarbons*

Foodstuffs		Maximum levels (µg/kg)	
6.1	Benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene	Benzo(a)pyrene	Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene ⁽⁴⁵⁾
6.1.1	Oils and fats (excluding cocoa butter and coconut oil) intended for direct human consumption or use as an ingredient in food	2,0	10,0
6.1.2	Cocoa beans and derived products	5,0 µg/kg fat as from 1.4.2013	35,0 µg/kg fat as from 1.4.2013 until 31.3.2015 30,0 µg/kg fat as from 1.4.2015
6.1.3	Coconut oil intended for direct human consumption or use as an ingredient in food	2,0	20,0
6.1.4	Smoked meat and smoked meat products	5,0 until 31.8.2014 2,0 as from 1.9.2014	30,0 as from 1.9.2012 until 31.8.2014 12,0 as from 1.9.2014
6.1.5	Muscle meat of smoked fish and smoked fishery products ⁽²⁵⁾⁽³⁶⁾ , excluding fishery products listed in points 6.1.6 and 6.1.7. The maximum level for smoked crustaceans applies to muscle meat from appendages and abdomen ⁽⁴⁴⁾ . In case of smoked crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) it applies to muscle meat from appendages.	5,0 until 31.8.2014 2,0 as from 1.9.2014	30,0 as from 1.9.2012 until 31.8.2014 12,0 as from 1.9.2014
6.1.6	Smoked sprats and canned smoked sprats ⁽²⁵⁾⁽⁴⁷⁾ (<i>sprattus sprattus</i>); bivalve molluscs (fresh, chilled or frozen) ⁽²⁶⁾ ; heat treated meat and heat treated meat products ⁽⁴⁶⁾ sold to the final consumer	5,0	30,0
6.1.7	Bivalve molluscs ⁽³⁶⁾ (smoked)	6,0	35,0
6.1.8	Processed cereal-based foods and baby foods for infants and young children ⁽³⁾⁽²⁹⁾	1,0	1,0
6.1.9	Infant formulae and follow-on formulae, including infant milk and follow-on milk ⁽⁸⁾⁽²⁹⁾	1,0	1,0

Foodstuffs		Maximum levels ($\mu\text{g/kg}$)	
6.1.10	Dietary foods for special medical purposes (⁹)(²⁹) intended specifically for infants	1,0	1,0

(⁴⁵) Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.

(⁴⁶) Meat and meat products that have undergone a heat treatment potentially resulting in formation of PAH, i.e. only grilling and barbecuing.

(⁴⁷) For the canned product the analysis shall be carried out on the whole content of the can. As regards the maximum level for the whole composite product Art. 2(1)(c) and 2(2) shall apply."

(2) Endnote (³⁵) is deleted.

COMMISSION REGULATION (EU) No 836/2011**of 19 August 2011****amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs****(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 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽¹⁾, in particular Article 11(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs ⁽²⁾ established, inter alia, maximum levels for the contaminant benzo(a)pyrene.
- (2) The Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted an opinion on Polycyclic Aromatic Hydrocarbons in Food on 9 June 2008 ⁽³⁾. The EFSA concluded that benzo(a)pyrene is not a suitable marker for the occurrence of polycyclic aromatic hydrocarbons (PAH) in food and that a system of four specific substances or eight specific substances would be the most suitable markers of PAH in food. The EFSA also concluded that a system of eight substances would not provide much added value compared to a system of four substances.
- (3) As a consequence Commission Regulation (EU) No 835/2011 ⁽⁴⁾ amended Regulation (EC) No 1881/2006 in order to set maximum levels for the sum of four polycyclic aromatic hydrocarbons (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene).
- (4) Commission Regulation (EC) No 333/2007 ⁽⁵⁾ lays down analytical performance criteria only for benzo(a)pyrene. It is therefore necessary to lay down analytical performance criteria for the other three substances for which maximum levels are now set out in Regulation (EC) No 1881/2006.

(5) The European Union Reference Laboratory for Polycyclic Aromatic Hydrocarbons (EU-RL PAH) in collaboration with the national reference laboratories carried out a survey among official control laboratories to assess which analytical performance criteria would be achievable for benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene in relevant food matrices. The outcome of this survey was summarised by the EU-RL PAH in the Report on 'Performance characteristics of analysis methods for the determination of 4 polycyclic aromatic hydrocarbons in food' ⁽⁶⁾. The results of the survey show that the analytical performance criteria currently applicable to benzo(a)pyrene are also suitable for the other three substances.

(6) Experience acquired while implementing Regulation (EC) No 333/2007 revealed that in some cases the current sampling provisions may be impracticable or may lead to unacceptable economic damage to the sampled lot. For such cases, departure from the sampling procedures should be allowed, provided that sampling remains sufficiently representative of the sampled lot or subplot and that the procedure used is fully documented. For sampling at the retail stage, flexibility to depart from the sampling procedures existed already. The provisions for sampling at retail stage should be aligned with the general sampling procedures.

(7) More detailed provisions are needed as regards the material of sampling containers when samples are taken for PAH analysis. Plastic containers are widely used by enforcement authorities, but they are not suitable when sampling is carried out for PAH analysis, as the PAH content of the sample can be altered by these materials.

(8) Clarification is needed for some aspects of the specific requirements for analytical methods, in particular the requirements regarding the use of the performance criteria and the 'fitness-for-purpose' approach. Furthermore, the presentation of the tables with the performance criteria should be modified to appear more uniform across all analytes.

(9) Regulation (EC) No 333/2007 should therefore be amended accordingly. Since Regulation (EU) No 835/2011 and this Regulation are inter-linked, both Regulations should become applicable on the same date.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1.

⁽²⁾ OJ L 364, 20.12.2006, p. 5.

⁽³⁾ The EFSA Journal (2008) 724, p. 1.

⁽⁴⁾ See page 4 of this Official Journal.

⁽⁵⁾ OJ L 88, 29.3.2007, p. 29.

⁽⁶⁾ JRC Report 59046, 2010.

- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 333/2007 is amended as follows:

- (1) the title is replaced by the following:

'Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs';

- (2) in Article 1, paragraph 1 is replaced by the following:

'1. Sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons ("PAH") listed in Sections 3, 4 and 6 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the Annex to this Regulation.';

- (3) the Annex is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 September 2012.

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

Done at Brussels, 19 August 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

The Annex to Regulation (EC) No 333/2007 is amended as follows:

- (1) in point B.1.7 'Packaging and transmission of samples', the following second paragraph is added:

'In case of sampling for PAH analysis plastic containers shall be avoided if possible as they could alter the PAH content of the sample. Inert, PAH-free glass containers, adequately protecting the sample from light, shall be used wherever possible. Where this is practically impossible, at least direct contact of the sample with plastics shall be avoided, e.g. in case of solid samples by wrapping the sample in aluminium foil before placing it in the sampling container.';

- (2) points B.2 and B.3 are replaced by the following:

B.2. SAMPLING PLANS

B.2.1. Division of lots into sublots

Large lots shall be divided into sublots on condition that the subplot may be separated physically. For products traded in bulk consignments (e.g. cereals) Table 1 shall apply. For other products Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20 %.

B.2.2. Number of incremental samples

The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible, e.g. when the sample consists of 1 package or unit.

The minimum number of incremental samples to be taken from the lot or subplot shall be as given in Table 3.

In the case of bulk liquid products the lot or subplot shall be thoroughly mixed in so far as possible and in so far it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or subplot. It is therefore sufficient to take three incremental samples from a lot or subplot to form the aggregate sample.

The incremental samples shall be of similar weight/volume. The weight/volume of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kg or 1 litre. Departure from this method shall be recorded in the record provided for under point B.1.8 of this Annex.

Table 1

Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

Table 2

Subdivision of lots into sublots for other products

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

Table 3

Minimum number of incremental samples to be taken from the lot or subplot

Weight or volume of lot/sublot (in kg or litre)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

If the lot or subplot consists of individual packages or units, then the number of packages or units which shall be taken to form the aggregate sample is given in Table 4.

Table 4

Number of packages or units (incremental samples) which shall be taken to form the aggregate sample if the lot or subplot consists of individual packages or units

Number of packages or units in the lot/sublot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5 %, at least 2 packages or units
> 100	about 5 %, at maximum 10 packages or units

The maximum levels for inorganic tin apply to the contents of each can, but for practical reasons it is necessary to use an aggregate sampling approach. If the result of the test for an aggregate sample of cans is less than but close to the maximum level of inorganic tin and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations.

Where it is not possible to carry out the method of sampling set out in this chapter because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or subplot and is fully documented.

B.2.3. Specific provisions for the sampling of large fish arriving in large lots

In case the lot or subplot to be sampled contains large fishes (individual fishes weighing more than about 1 kg) and the lot or subplot weighs more than 500 kg, the incremental sample shall consist of the middle part of the fish. Each incremental sample shall weigh at least 100 g.

B.3. SAMPLING AT RETAIL STAGE

Sampling of foodstuffs at retail stage shall be done where possible in accordance with the sampling provisions set out in point B.2.2 of this Annex.

Where it is not possible to carry out the method of sampling set out in point B.2.2 because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or subplot and is fully documented.;

- (3) in the first paragraph of point C.1 'Laboratory Quality Standards', footnote 1 is deleted;
- (4) in point C.2.2.1 'Specific procedures for lead, cadmium, mercury and inorganic tin', the second paragraph is replaced by the following:

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. For those aspects not specifically covered by this Regulation, the CEN Standard "Foodstuffs - Determination of trace elements – Performance criteria, general considerations and sample preparation"⁽¹⁾ has been found to be satisfactory but other sample preparation methods may be equally valid.;

- (5) point C.2.2.2 is replaced by the following:

'C.2.2.2. Specific procedures for polycyclic aromatic hydrocarbons

The analyst shall ensure that samples do not become contaminated during sample preparation. Containers shall be rinsed with high purity acetone or hexane before use to minimise the risk of contamination. Wherever possible, apparatus and equipment coming into contact with the sample shall be made of inert materials such as aluminium, glass or polished stainless steel. Plastics such as polypropylene or PTFE shall be avoided because the analytes can adsorb onto these materials.;

(6) point C.3.1 'Definitions' is amended as follows:

(a) the definition for 'HORRAT_r' is replaced by the following:

'HORRAT (*)_r = The observed RSD_r divided by the RSD_r value estimated from the (modified) Horwitz equation (**) (cf. point C.3.3.1 ("Notes to the performance criteria")) using the assumption $r = 0,66 R$.

(*) Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.

(**) M. Thompson, Analyst, 2000, p. 125 and 385-386.'

(b) the definition for 'HORRAT_R' is replaced by the following:

'HORRAT (*)_R = The observed RSD_R divided by the RSD_R value estimated from the (modified) Horwitz equation (**) (cf. point C.3.3.1 ("Notes to the performance criteria")).

(*) Horwitz W. and Albert, R., 2006, The Horwitz Ratio (HorRat): A useful Index of Method Performance with respect to Precision, Journal of AOAC International, Vol. 89, 1095-1109.

(**) M. Thompson, Analyst, 2000, p. 125 and 385-386.'

(c) the definition for 'u' is replaced by the following:

'u = Combined standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model (*)

(*) International vocabulary of metrology – Basic and general concepts and associated terms (VIM), JCGM 200:2008.;

(7) point C.3.2 is replaced by the following:

'C.3.2 General requirements

Methods of analysis used for food control purposes shall comply with the provisions of Annex III to Regulation (EC) No 882/2004.

Methods for analysis for total tin are appropriate for official control on inorganic tin levels.

For the analysis of lead in wine, the methods and rules established by the OIV (*) apply in accordance with Article 31 of Council Regulation (EC) No 479/2008 (**).

(*) Organisation internationale de la vigne et du vin.

(**) Council Regulation (EC) No 479/2008 of 29 April 2008 on the common organisation of the market in wine amending Regulations (EC) No 1493/1999, (EC) No 1782/2003, (EC) No 1290/2005, (EC) No 3/2008 and repealing Regulations (EEC) No 2392/86 and (EC) No 1493/1999 (OJ L 148, 6.6.2008, p. 1).;

(8) point C.3.3.1 is replaced by the following:

'C.3.3.1. Performance criteria

Where no specific methods for the determination of contaminants in foodstuffs are prescribed at European Union level, laboratories may select any validated method of analysis for the respective matrix provided that the selected method meets the specific performance criteria set out in Tables 5, 6 and 7.

It is recommended that fully validated methods (i.e. methods validated by collaborative trial for the respective matrix) are used where appropriate and available. Other suitable validated methods (e.g. in-house validated methods for the respective matrix) may also be used provided that they fulfil the performance criteria set out in Tables 5, 6 and 7.

Where possible, the validation of in-house validated methods shall include a certified reference material.

- (a) Performance criteria for methods of analysis for lead, cadmium, mercury and inorganic tin:

Table 5

Parameter	Criterion		
Applicability	Foods specified in Regulation (EC) No 1881/2006		
Specificity	Free from matrix or spectral interferences		
Repeatability (RSD _r)	HORRAT _r less than 2		
Reproducibility (RSD _R)	HORRAT _R less than 2		
Recovery	The provisions of point D.1.2 apply		
	Inorganic tin	Lead, cadmium, mercury	
		ML is < 0,100 mg/kg	ML is ≥ 0,100 mg/kg
LOD	≤ 5 mg/kg	≤ one fifth of the ML	≤ one tenth of the ML
LOQ	≤ 10 mg/kg	≤ two fifths of the ML	≤ one fifth of the ML

- (b) Performance criteria for methods of analysis for 3-MCPD:

Table 6

Parameter	Criterion
Applicability	Foods specified in Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences
Field blanks	Less than LOD
Repeatability (RSD _r)	0,66 times RSD _R as derived from (modified) Horwitz equation
Reproducibility (RSD _R)	as derived from (modified) Horwitz equation
Recovery	75-110 %
LOD	≤ 5 µg/kg (on dry matter basis)
LOQ	≤ 10 µg/kg (on dry matter basis)

- (c) Performance criteria for methods of analysis for polycyclic aromatic hydrocarbons:

The four polycyclic aromatic hydrocarbons to which these criteria apply are benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene.

Table 7

Parameter	Criterion
Applicability	Foods specified in Regulation (EC) No 1881/2006
Specificity	Free from matrix or spectral interferences, verification of positive detection
Repeatability (RSD _r)	HORRAT _r less than 2
Reproducibility (RSD _R)	HORRAT _R less than 2

Parameter	Criterion
Recovery	50-120 %
LOD	$\leq 0,30 \mu\text{g/kg}$ for each of the four substances
LOQ	$\leq 0,90 \mu\text{g/kg}$ for each of the four substances

(d) Notes to the performance criteria:

The Horwitz equation (*) (for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$) and the modified Horwitz equation (**) (for concentrations $C < 1,2 \times 10^{-7}$) are generalised precision equations which are independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Modified Horwitz equation for concentrations $C < 1,2 \times 10^{-7}$:

$$\text{RSD}_R = 22 \%$$

where:

- RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$
- C is the concentration ratio (i.e. $1 = 100 \text{ g}/100 \text{ g}$, $0,001 = 1 \text{ 000 mg/kg}$). The modified Horwitz equation applies to concentrations $C < 1,2 \times 10^{-7}$.

Horwitz equation for concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$:

$$\text{RSD}_R = 2C^{(-0,15)}$$

where:

- RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$
- C is the concentration ratio (i.e. $1 = 100 \text{ g}/100 \text{ g}$, $0,001 = 1 \text{ 000 mg/kg}$). The Horwitz equation applies to concentrations $1,2 \times 10^{-7} \leq C \leq 0,138$.

(*) W. Horwitz, L.R. Kamps, K.W. Boyer, J.Assoc.Off.Analy.Chem.,1980, 63, 1344.

(**) M. Thompson, Analyst, 2000, p. 125 and 385-386.;

(9) point C.3.3.2 is replaced by the following:

‘C.3.3.2. “Fitness-for-purpose” approach

For in-house validated methods, as an alternative a “fitness-for-purpose” approach (*) may be used to assess their suitability for official control. Methods suitable for official control must produce results with a combined standard measurement uncertainty (u) less than the maximum standard measurement uncertainty calculated using the formula below:

$$U_f = \sqrt{(\text{LOD}/2)^2 + (\alpha C)^2}$$

where:

- U_f is the maximum standard measurement uncertainty ($\mu\text{g/kg}$).
- LOD is the limit of detection of the method ($\mu\text{g/kg}$). The LOD must meet the performance criteria set in point C.3.3.1 for the concentration of interest.
- C is the concentration of interest ($\mu\text{g/kg}$);
- α is a numeric factor to be used depending on the value of C . The values to be used are given in Table 8.

Table 8

Numeric values to be used for α as constant in formula set out in this point, depending on the concentration of interest

C ($\mu\text{g/kg}$)	α
≤ 50	0,2
51-500	0,18

C (µg/kg)	α
501-1 000	0,15
1 001-10 000	0,12
> 10 000	0,1

The analyst shall note the "Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation" (**).

(*) M. Thompson and R. Wood, Accred. Qual. Assur., 2006, p. 10 and 471-478.

(**) http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf;

(10) in point D.1.2 'Recovery calculations', the second paragraph is replaced by the following:

'In case no extraction step is applied in the analytical method (e.g. in case of metals), the result may be reported uncorrected for recovery if evidence is provided by ideally making use of suitable certified reference material that the certified concentration allowing for the measurement uncertainty is achieved (i.e. high accuracy of the measurement), and thus that the method is not biased. In case the result is reported uncorrected for recovery this shall be mentioned.';

(11) in point D.1.3 'Measurement uncertainty', the second paragraph is replaced by the following:

'The analyst shall note the "Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation" (*).

(*) http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf.

COMMISSION IMPLEMENTING REGULATION (EU) No 837/2011**of 19 August 2011****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:

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,

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 hereto.

Article 2

This Regulation shall enter into force on 20 August 2011.

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

Done at Brussels, 19 August 2011.

*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	AR	38,5
	MK	29,3
	ZZ	33,9
0707 00 05	TR	74,4
	ZZ	74,4
0709 90 70	EC	45,6
	TR	125,7
	ZZ	85,7
0805 50 10	AR	60,9
	BR	45,3
	TR	64,0
	UY	60,8
	ZA	79,4
	ZZ	62,1
0806 10 10	EG	67,8
	MK	41,0
	TR	155,5
	ZZ	88,1
0808 10 80	AR	85,5
	BR	43,8
	CL	112,6
	CN	64,4
	NZ	103,0
	US	209,5
	ZA	91,1
	ZZ	101,4
0808 20 50	AR	161,3
	CL	156,9
	CN	52,2
	TR	148,9
	ZA	116,2
	ZZ	127,1
0809 30	TR	125,4
	ZZ	125,4
0809 40 05	BA	46,2
	ZZ	46,2

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

COMMISSION IMPLEMENTING REGULATION (EU) No 838/2011**of 19 August 2011****on the issue of import licences for applications submitted in the first seven days of August 2011
under the tariff quota for high-quality beef administered by Regulation (EC) No 620/2009**

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences ⁽²⁾, and in particular Article 7(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 620/2009 of 13 July 2009 providing for the administration of an import tariff quota for high-quality beef ⁽³⁾ sets out detailed rules for the submission and issue of import licences.
- (2) Article 7(2) of Regulation (EC) No 1301/2006 provides that in cases where quantities covered by licence appli-

cations exceed the quantities available for the quota period, allocation coefficients should be fixed for the quantities covered by each licence application. The applications for import licences submitted pursuant to Article 3 of Regulation (EC) No 620/2009 between 1 and 7 August 2011 exceed the quantities available. Therefore, the extent to which import licences may be issued and the allocation coefficient should be determined,

HAS ADOPTED THIS REGULATION:

Article 1

Import licence applications covered by the quota with order number 09.4449 and submitted between 1 and 7 August 2011 in accordance with Article 3 of Regulation (EC) No 620/2009, shall be multiplied by an allocation coefficient of 0,490234 %.

Article 2

This Regulation shall enter into force on the day following 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, 19 August 2011.

*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 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 182, 15.7.2009, p. 25.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 19 August 2011

authorising the placing on the market of Phosphatidylserine from soya phospholipids as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2011) 5897)

(2011/513/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 28 September 2009 the company Cantox Health Science International on behalf of the company Enzymotec Ltd made a request to the competent authorities of Finland to place Phosphatidylserine from soya phospholipids on the market as novel food ingredient.
- (2) On 14 April 2010 the competent food assessment body of Finland issued its initial assessment report. In that report it came to the conclusion that the company Enzymotec has provided sufficient information to authorise the placing on the market of Phosphatidylserine from soya phospholipids as a novel food ingredient.
- (3) The Commission forwarded the initial assessment report to all Member States on 21 April 2010.
- (4) Within the 60 days-period laid down in Article 6(4) of Regulation (EC) No 258/97, one reasoned objection to the marketing of the product, which concerns the maximum daily intake, was raised in accordance with that provision. In accordance with the provisions of Article 6(4) a Commission implementing Decision is required that takes into account the reasoned objection raised.

(5) Phosphatidylserine from soya phospholipids complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(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

Phosphatidylserine from soya phospholipids as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses specified in Annex II.

Article 2

The designation of Phosphatidylserine from soya phospholipids authorised by this Decision on the labelling of the foodstuff containing it shall be 'Soya phosphatidylserine'.

Article 3

This Decision is addressed to Enzymotec Ltd, P.O. Box 6, Migdal HaEmeq, 23106 Israel.

Done at Brussels, 19 August 2011.

For the Commission

John DALLI

Member of the Commission

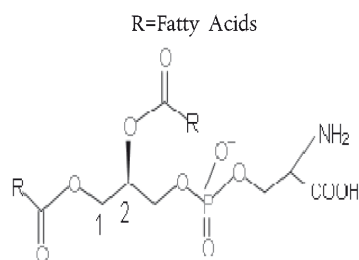
⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

ANNEX I

Specifications of Phosphatidylserine from soya phospholipids*Description:*

The novel food ingredient is an off-white to light yellow powder. It is also available in liquid form with a clear brown to orange colour. The liquid form contains medium chain triacylglycerides (MCT) as a carrier. It contains lower levels of Phosphatidylserine due to the fact that it includes significant amounts of oil (MCT).

Phosphatidylserine from soya phospholipids is obtained through enzymatic transphosphatidylation of high-phosphatidylcholine soybean lecithin with the amino acid L-serine. Phosphatidylserine consists of a glycerophosphate skeleton conjugated with two fatty acids and L-serine via a phosphodiester linkage.

Structural Formula:

Characteristics of Phosphatidylserine from soya phospholipids

Parameter	Powder Form	Liquid Form
Moisture	less than 2 %	less than 2 %
Phospholipids	not less than 85 %	not less than 25 %
Phosphatidylserine	not less than 61 %	not less than 20 %
Glycerides	less than 2 %	not applicable
free L-serine	less than 1 %	less than 1 %
Tocopherols	less than 0,3 %	less than 0,3 %
Phytosterols	less than 0,2 %	less than 0,2 %

ANNEX II

Use-Level (mg) of Phosphatidylserine from soya phospholipids	
Beverages based on yoghurt	50 mg/100 ml
Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready to drink)
Foods based on yoghurt	80 mg/100 g
Cereal bars	350 mg/100 g
Chocolate based confectionary	200 mg/100 g

Phosphatidylserine from soya phospholipids may be used in food for special medical purposes only in compliance with Commission Directive 1999/21/EC ⁽¹⁾.

⁽¹⁾ OJ L 91, 7.4.1999, p. 29.

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