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⁽¹⁾ Text with EEA relevance

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1096/2012

of 14 November 2012

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

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, Germany's application to register the name 'Aischgründer Karpfen' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 14 November 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 64, 3.3.2012, p. 16.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom

GERMANY

Aischgründer Karpfen (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1097/2012**of 23 November 2012**

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

(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 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 ⁽¹⁾, and in particular Article 21(5)(a) and Articles 23(3) and 48(2) thereof,

Whereas:

- (1) Regulation (EC) No 1069/2009 lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products. It also provides rules for placing on the market of animal by-products and derived products.
- (2) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive ⁽²⁾, lays down implementing rules for Regulation (EC) No 1069/2009, including rules on the registration of operators, the content of commercial documents which accompany consignments of animal by-products and derived products in trade between Member States and the layout of the notification form which must be provided for certain animal by-products and derived products pursuant to Article 48(1) of Regulation (EC) No 1069/2009.
- (3) Pursuant to Regulation (EC) No 1069/2009, operators are to ensure that animal by-products and derived products are traceable at all stages of the chain of collecting, manufacturing, use and disposal, so as to

avoid unnecessary disruptions of the internal market in the case of events which are linked to actual or potential risks to public or animal health.

- (4) Operators must ensure that activities covered by the scope of animal by-products legislation are registered or approved. However, handling of small quantities of Categories 2 and 3 materials may present negligible risk if they originate from areas where no transmissible disease to humans or animals has been notified. Member States should therefore be authorised to allow particular activities without registration as provided for in Article 23 of Regulation (EC) No 1069/2009. Such a derogation must be limited only to activities concerning the direct supply of the products within the region to the final user, on the local market or to local retail establishments.
- (5) Each consignment of animal by-products or derived products to be traded between Member States is to be accompanied by a commercial document. However, it is necessary to amend and extend current requirements on the commercial document to ensure that it includes all necessary information on the safe handling, treatment and intended use or disposal of the concerned material.
- (6) On the commercial document operators must specify certain information on the consignment, in particular the category of animal by-products or derived products, nature of commodity and type of treatment. According to Article 3 of Regulation (EU) No 142/2011 there is no need to issue a commercial document for derived products which have been declared as the end point in the manufacturing chain. Also a reference to processing standards in Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽³⁾ may be removed. Annex VIII to Regulation (EU) No 142/2011 should therefore be amended.
- (7) Several animal by-products and derived products referred to in Article 48(1) of Regulation (EC) No 1069/2009 must be authorised in advance by the competent authority of the Member State of destination upon application by the operator. Annex XVI to Regulation (EU) No 142/2011 sets out a standard format for the authorisation of the dispatch of animal by-products and derived products to another Member State. That format

⁽¹⁾ OJ L 300, 14.11.2009, p. 1.

⁽²⁾ OJ L 54, 26.2.2011, p. 1.

⁽³⁾ OJ L 139, 30.4.2004, p. 55.

should be amended to include information on the end date of validity of authorisations, the volume or mass of the consignment, the name and address of the consignor, the origin of the animal by-products and the place of destination of the consignment. Annex XVI to Regulation (EU) No 142/2011 should therefore be amended.

- (8) Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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

- (1) in Article 20, point (c) of paragraph 4 is replaced by the following:
- ‘(c) operators transporting dry untreated wool and hair, provided they are securely enclosed in packaging, and

directly dispatched to a plant producing derived products for uses outside the feed chain or to a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents;

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

- (2) Annexes VIII and XVI are amended in accordance with the text in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 23 November 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

The Annexes to Regulation (EU) No 142/2011 are amended as follows:

- (1) in Annex VIII, Chapter III, the model commercial document is replaced by the following:

'Commercial document'

For the transport of animal by-products and derived products not intended for human consumption in accordance with Regulation (EC) No 1069/2009 within the European Union

EUROPEAN UNION**Commercial document**

Part I: Details of dispatched consignment	I.1. Consignor Name Address Postcode				I.2. Document reference No		I.2.a. Local reference No									
					I.3. Central competent authority											
					I.4. Local competent authority											
	I.5. Consignee Name Address Postcode Tel.				I.6.											
					I.7.											
	I.8. Country of origin		ISO code		I.9. Region of origin		Code		I.10. Country of destination		ISO code		I.11. Region of destination		Code	
	I.12. Place of origin Establishment ☐ Name Address Postcode Approval number				I.13. Place of destination Establishment ☐ Other ☐ Name Address Postcode Approval number											
					I.14. Place of loading											
					I.15. Date of departure											
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification																
I.17. Transporter Name Address Postcode Approval number Member State				I.18. Description of commodity												
				I.19. Commodity code (CN code)				I.20. Quantity								
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐ Controlled temperature ☐				I.22. Number of packages												
I.23. Seal/Container No				I.24. Type of packaging												
I.25. Commodities certified for: Animal feedingstuff ☐ Technical use ☐																
I.26.				I.27. Transit through Member States ☐ Member State Member State Member State ISO Code ISO Code ISO Code												
I.28. Export ☐ Third country Exit point ISO Code Code				I.29.												
I.30.																
I.31. Identification of the commodities Species (scientific name) Nature of commodity Category Treatment type Approval number of establishments Manufacturing plant Batch number																

COUNTRY		Animal by-products/derived products not intended for human consumption	
II. Health information		II.a. Certificate reference number	II.b.
II.1. Declaration by the consignor			
I, the undersigned, declare that:			
II.1.1. the information in Part I is factually correct;			
II.1.2. all precautions have been taken to avoid contamination of the animal by-products or derived products with pathogenic agents and cross-contamination between various categories.			
Notes:			
Part I:			
— Box reference I.9 and I.11: if appropriate.			
— Box reference I.12, I.13 and I.17: approval number or registration number. In the case of processed manure indicate in Box I.13 the approval or registration number of plant or holding of destination.			
— Box reference I.14: complete if different from 'I.1. Consignor'.			
— Box reference I.25: technical use: any use other than for animal consumption.			
— Box reference I.31:			
Animal species:		For Category 3 material and products derived therefrom destined for use as feed material. Select from the following: Aves, Ruminants, Non-Ruminants, <i>Mammalia</i> , <i>Pesca</i> , <i>Mollusca</i> , <i>Crustacea</i> , Invertebrates.	
Nature of commodity:		Enter a commodity chosen from the following list: 'apiculture by-products', 'blood products', 'blood', 'bloodmeal', 'digestion residues', 'digestive tract content', 'dog-chews', 'fishmeal', 'flavouring innards', 'gelatine', 'greaves', 'hides and skins', 'hydrolysed proteins', 'organic fertilisers', 'pet food', 'processed animal protein', 'processed pet food', 'raw pet food', 'rendered fats', 'compost', 'processed manure', 'fish oil', 'milk products', 'centrifuge or separator sludge from milk processing', 'dicalciumphosphate', 'tricalciumphosphate', 'collagen', 'egg products', 'serum of equidae', 'game trophies', 'wool', 'hair', 'pig bristles', 'feathers', 'animal by-products for processing', 'derived products'.	
Category:		Specify Category 1, 2 or 3 materials. In case of Category 3 material, indicate the point of Article 10 of Regulation (EC) No 1069/2009 that refers to the animal by-product concerned (e.g. Article 10(a), Article 10(b), etc.). In the case of Category 3 material for use in raw petfood indicate '3a', '3b(i)' or '3b(ii)' depending on whether the animal by-products are referred to in Article 10(a) or in Article 10(b)(i) or (ii) of Regulation (EC) No 1069/2009. In the case of hides and skins and products derived therefrom, indicate '3b(iii)' or '3(n)' depending on whether the animal by-products or derived products are referred to in Article 10(b)(iii) or in Article 10(n) of Regulation (EC) No 1069/2009. Where the consignment is made of more than one category, indicate the quantity and if applicable the number of containers per category of materials.	
Treatment type:		For treated hides and skins indicate the treatment: '(a)' for dried; '(b)' for dry-salted or wet-salted for at least 14 days prior to dispatch; '(c)' for salted for seven days in sea salt with the addition of 2 % sodium carbonate. For Categories 1 and 2 materials describe the method of processing or transformation. Indicate the relevant processing method (choose a method from 1 to 5 referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011). For Category 3 materials and derived products from Category 3 material destined for use in feed: if appropriate describe the nature and the methods of the treatment. Indicate the relevant processing method (choose a method from 1 to 7 referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011).	
Batch number:		Enter batch number or ear tag number, if applicable.	
Part II:			
— The signature must be in a different colour to that of the printing.			
Signature			
Done at on			
(place)		(date)	
.....			
(signature of the responsible person/consignor (name, in capital letters)'			

(2) in Annex XVI, Chapter III, Section 10 is replaced by the following:

'Section 10

Standard format for applications for certain authorisations in intra-Union trade

Operators shall apply to the competent authority of the Member State of destination for the authorisation of the dispatch of animal by-products and derived products referred to in Article 48(1) of Regulation (EC) No 1069/2009 in accordance with the following format:

**APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL
BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE**

(ARTICLE 48 OF REGULATION (EC) No 1069/2009)

Name and address of place of origin	Approval or registration number, issued by (competent authority)
Name and address of consignor	Approval or registration number, issued by (competent authority)
Name and address of applicant	Approval or registration number, issued by (competent authority)
Name and address of place of destination	Approval or registration number, issued by (competent authority)
Animal by-products/derived products ⁽¹⁾ ☐ Category 1 material consisting of: (nature of the material) ☐ Category 2 material consisting of: (nature of the material) ☐ Meat-and-bone meal derived from Category 1 material ☐ Animal fat derived from Category 1 material ☐ Meat-and-bone meal derived from Category 2 material ☐ Animal fat derived from Category 2 material	Intended use ⁽¹⁾ ☐ Disposal ☐ Processing ☐ Combustion ☐ Application to land ☐ Transformation into biogas ☐ Composting ☐ Petfood ⁽²⁾ ☐ Production of biodiesel ☐ For feeding to ⁽³⁾ : ☐ For the manufacture of the following derived products ⁽⁴⁾ :
Indicate the quantity of animal by-products/derived products (volume or mass) ⁽⁴⁾ ⁽⁵⁾	

**(APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL
BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE**

(ARTICLE 48 OF REGULATION (EC) No 1069/2009)

In case of meat-and-bone meal and animal fat:

The materials have been processed according to the following
method ⁽⁶⁾:

Species of origin:

I, the undersigned, declare that the above information is factually correct.

.....
(Signature: name, date, contact details: telephone, fax (if applicable), e-mail)

Decision by the competent authority of the Member State of destination ⁽⁷⁾:

The dispatch of the consignment is:

☐ refused.

☐ accepted.

☐ accepted subject to the application of pressure sterilisation (method 1) to the materials.

☐ accepted subject to the following conditions for the dispatch ⁽⁴⁾:

.....
.....
.....
.....
.....
.....

This authorisation is valid until: ⁽⁸⁾

.....
(Date, stamp and signature of the competent authority)

Notes:

Complete the document in BLOCK capitals.

⁽¹⁾ Tick as appropriate.

⁽²⁾ In the case of petfood produced with Category 1 material comprising animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC.

⁽³⁾ Specify in accordance with Article 18 of Regulation (EC) No 1069/2009.

⁽⁴⁾ Fill in, if appropriate.

⁽⁵⁾ Specify.

⁽⁶⁾ Specify one of the processing methods referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011.

⁽⁷⁾ For the competent authority: tick as appropriate.

⁽⁸⁾ Insert date of expiration of authorisation.

COMMISSION IMPLEMENTING REGULATION (EU) No 1098/2012**of 23 November 2012****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, 23 November 2012.

*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	AL	41,5
	MA	46,2
	MK	32,3
	TN	73,5
	ZZ	48,4
0707 00 05	AL	63,5
	MK	58,4
	TR	88,7
	ZZ	70,2
0709 93 10	MA	102,5
	TR	110,9
	ZZ	106,7
0805 20 10	MA	137,8
	ZZ	137,8
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	65,5
	HR	37,0
	TR	84,6
	ZZ	62,4
0805 50 10	TR	83,0
	ZA	49,1
	ZZ	66,1
0808 10 80	CN	79,8
	MK	38,5
	NZ	138,3
	US	127,1
	ZA	145,8
	ZZ	105,9
0808 30 90	CN	69,9
	TR	113,2
	US	136,8
	ZZ	106,6

⁽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'.

DIRECTIVES

COMMISSION DIRECTIVE 2012/38/EU

of 23 November 2012

amending Directive 98/8/EC of the European Parliament and of the Council to include *cis*-Tricos-9-ene as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes *cis*-Tricos-9-ene.
- (2) Pursuant to Regulation (EC) No 1451/2007, *cis*-Tricos-9-ene has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 19, repellents and attractants, as defined in Annex V to that Directive.
- (3) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 11 November 2009 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 25 May 2012, in an assessment report.
- (5) It appears from the evaluations that biocidal products used as attractants and containing *cis*-Tricos-9-ene may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include *cis*-Tricos-9-ene in Annex I to that Directive.
- (6) Not all potential uses and exposure scenarios have been evaluated at Union level. For example, outdoor use and exposure of food or feeding stuff were not assessed. It is therefore appropriate to require that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.
- (7) In the light of the possible indirect human exposure via consumption of food as a result of those uses represented in the assessment, it is appropriate to require, where relevant, verification of the need to set new or to amend existing maximum residue levels according to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽³⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ⁽⁴⁾. Measures should be adopted ensuring that the applicable maximum residue levels are not exceeded.
- (8) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of product-type 19 containing the active substance *cis*-Tricos-9-ene and also to facilitate the proper operation of the biocidal products market in general.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.⁽²⁾ OJ L 325, 11.12.2007, p. 3.⁽³⁾ OJ L 152, 16.6.2009, p. 11.⁽⁴⁾ OJ L 70, 16.3.2005, p. 1.

- (9) A reasonable period should be allowed to elapse before an active substance is included in Annex I to Directive 98/8/EC, in order to permit Member States and interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (10) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.
- (11) Directive 98/8/EC should therefore be amended accordingly.
- (12) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011 ⁽¹⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 September 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2014.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 November 2012.

For the Commission
The President

José Manuel BARROSO

⁽¹⁾ OJ C 369, 17.12.2011, p. 14.

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
'59	<i>cis</i> -tricos-9-ene (Muscalure)	<i>cis</i> -Tricos-9-ene; (Z)-Tricos-9-ene EC No: 248-505-7 CAS No: 27519-02-4	801 g/kg	1 October 2014	30 September 2016	30 September 2024	19	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. For products containing <i>cis</i>-tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>

DECISIONS

COUNCIL DECISION

of 20 November 2012

appointing a Spanish member of the Committee of the Regions

(2012/717/EU)

THE COUNCIL OF THE EUROPEAN UNION,

HAS ADOPTED THIS DECISION:

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Spanish Government,

Whereas:

(1) On 22 December 2009 and on 18 January 2010, the Council adopted Decisions 2009/1014/EU ⁽¹⁾ and 2010/29/EU ⁽²⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2010 to 25 January 2015.

(2) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms Esperanza AGUIRRE GIL DE BIEDMA,

Article 1

The following is hereby appointed as member to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2015:

— Mr Ignacio GONZÁLEZ GONZÁLEZ, *Presidente de la Comunidad Autónoma de Madrid*.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 20 November 2012.

For the Council

The President

A. D. MAVROYIANNIS

⁽¹⁾ OJ L 348, 29.12.2009, p. 22.

⁽²⁾ OJ L 12, 19.1.2010, p. 11.

COMMISSION IMPLEMENTING DECISION

of 20 September 2012

amending Decision 2008/458/EC laying down rules for the implementation of Decision No 575/2007/EC of the European Parliament and of the Council establishing the European Return Fund for the period 2008 to 2013 as part of the General programme 'Solidarity and Management of Migration Flows' as regards Member States' management and control systems, the rules for administrative and financial management and the eligibility of expenditure on projects co-financed by the Fund

(notified under document C(2012) 6408)

(Only the Bulgarian, Czech, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish texts are authentic)

(2012/718/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Decision No 575/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing the European Return Fund for the period 2008 to 2013 as part of the General programme 'Solidarity and Management of Migration Flows' ⁽¹⁾, and in particular Article 35(4) thereof,

Whereas:

- (1) The general objective of the European Return Fund is to support the efforts made by the Member States to improve the management of return in all its dimensions taking into account Union legislation in this field and in full compliance with fundamental rights.
- (2) In accordance with the specific objectives indicated in Article 3(1)(c) of Decision No 575/2007/EC, the Return Fund shall contribute to 'the promotion of an effective and uniform application of common standards on return in line with policy developments in this field'.
- (3) In that context, the Return Fund provides support to Member States for the implementation of Directive 2008/115/EC of the European Parliament and of the Council of 16 December 2008 on common standards and procedures in Member States for returning illegally staying third-country nationals ⁽²⁾ (the Return Directive) by co-financing a wide range of measures.
- (4) In order to ensure the effective implementation of the Return Directive by Member States, it is appropriate to further reinforce the support of the Fund by extending the scope of eligible measures, in particular, to address the needs relating to Article 16 of the Return Directive requiring that detention take place as a rule in specialised detention facilities. Moreover, in the light of the experience gained since the launch of the European Return Fund and in order to reinforce the capacities of Member States to ensure effective transportation of returnees during return procedures and return operations,

it is appropriate to give the possibilities under the Fund to finance necessary means of transport, such as buses.

- (5) Considering that the 2011 and 2012 annual programmes of the Member States under the European Return Fund are still ongoing, it is appropriate that the modified rules apply from the 2011 annual programme onwards.
- (6) In accordance with Article 3 of the Protocol on the position of the United Kingdom and Ireland, annexed to the Treaty on European Union and to the Treaty establishing the European Community, the United Kingdom is bound by the basic act and, as a consequence, by this Decision.
- (7) In accordance with Article 3 of the Protocol on the position of the United Kingdom and Ireland, annexed to the Treaty on European Union and to the Treaty establishing the European Community, Ireland is bound by the basic act and, as a consequence, by this Decision.
- (8) In accordance with Article 2 of the Protocol on the position of Denmark, annexed to the Treaty on European Union and to the Treaty establishing the European Community, Denmark is not bound by this Decision or subject to the application thereof.
- (9) The measures provided for in this Decision are in accordance with the opinion of the common Committee 'Solidarity and Management of Migration Flows' established by Decision No 574/2007/EC of the European Parliament and of the Council ⁽³⁾.
- (10) Decision 2008/458/EC should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex XI to Decision 2008/458/EC is amended as follows:

- (1) in point II.1.3.3, paragraph 3 is replaced by the following:

⁽¹⁾ OJ L 144, 6.6.2007, p. 45.

⁽²⁾ OJ L 348, 24.12.2008, p. 98.

⁽³⁾ OJ L 144, 6.6.2007, p. 22.

'3. For individual items costing below EUR 20 000 the full purchase cost is eligible, provided, that, except in duly justified cases, the equipment is purchased before the last 3 months of the project. Individual items costing EUR 20 000 or more are only eligible on the basis of depreciation. By way of derogation from the above conditions, for means of transport costing below EUR 250 000 the full purchase cost is eligible.';

(2) point II.1.4.2 is replaced by the following:

II.1.4.2. Purchase, construction or renovation

1. Where the acquisition of real estate is essential for implementation of the project and is clearly linked with its objectives, the purchase of real estate, i.e. buildings already constructed, or construction of real estate, is eligible for co-financing on the basis of the full or partial cost, or on the basis of depreciation, under the conditions set out below, without prejudice to the application of stricter national rules:

- (a) a certificate is obtained from an independent qualified valuer or duly authorised official body establishing that the price does not exceed the market value, either attesting that the real estate is in conformity with national regulations or specifying the points which are not in conformity that the final beneficiary plans to rectify as part of the project;
- (b) the real estate has not been purchased through a Community grant at any time prior to the implementation of the project;
- (c) the real estate is to be used solely for the purpose stated in the project for a period of at least 10 years after the end date of the project unless the Commission specifically authorises otherwise in the case of co-financing of the full or partial costs; in the case of co-financing on the basis of depreciation this period is reduced to 5 years;
- (d) the purchase of the real estate respects the principles of value for money and cost-effectiveness and is being considered as

proportionate to the aim to be achieved through the implementation of the project;

- (e) in the case of co-financing on the basis of depreciation, only the portion of the depreciation of these assets corresponding to the duration of use for the project and the rate of actual use for the project is eligible; depreciation shall be calculated according to national accounting rules.

2. Expenses for renovation, refurbishment and modernisation of real estate are eligible for co-financing on the basis of the full or partial cost or on the basis of depreciation. In the case of renovation costs only conditions (c) and (e) in paragraph 1 apply.'

Article 2

1. Article 1 shall apply from the date of adoption of this Decision.

2. Member States may decide to apply the changes in respect of ongoing or future projects as from the 2011 annual programmes.

Article 3

This Decision is addressed to the Kingdom of Belgium, the Republic of Bulgaria, the Czech Republic, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Grand Duchy of Luxembourg, Hungary, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, Romania, the Republic of Slovenia, the Slovak Republic, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 20 September 2012.

For the Commission

Cecilia MALMSTRÖM

Member of the Commission

COMMISSION DECISION

of 17 October 2012

on the national provisions notified by the Kingdom of Sweden pursuant to Article 114(5) of the Treaty on the Functioning of the European Union concerning the maximum admissible content of cadmium in fertilisers

*(notified under document C(2012) 7177)***(Only the Swedish text is authentic)****(Text with EEA relevance)**

(2012/719/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(6) thereof,

Whereas:

I. FACTS

- (1) On 17 October 2011, the Kingdom of Sweden notified the Commission, pursuant to Article 114(5) of the Treaty on the Functioning of the European Union (TFEU), of its intention to introduce national provisions to lower the content of cadmium allowed in phosphorous fertilisers to a maximum level of 46 grams of cadmium per tonne of phosphorous (equivalent to 20 mg Cd/kg P₂O₅). Those measures would derogate from Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers ⁽¹⁾ and would lower the maximum level of 100 grams of cadmium per tonne of phosphorous (equivalent to 44 mg Cd/kg P₂O₅) for which a derogation has already been granted to the Kingdom of Sweden.

1. Article 114(5) and (6) TFEU

- (2) Article 114, paragraphs 5 and 6 TFEU provide:

‘5. [...] If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notification [...] approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs [...] 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.’

2. EU legislation

- (3) Council Directive 76/116/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to fertilisers ⁽²⁾, laid down the requirements that fertilisers must fulfil in order to be placed on the market with the designation ‘EC fertiliser’.
- (4) Annex I to Directive 76/116/EEC set out the type designation and the corresponding requirements, e.g. with respect to its composition, that each fertiliser had to fulfil to be eligible for designation as ‘EC fertiliser’. Type designations in this list were grouped into categories, depending on the content of the primary nutrients, i.e. the elements nitrogen, phosphorus and potassium.
- (5) According to Article 7 of Directive 76/116/EEC ⁽³⁾, Member States were not permitted on grounds of composition, identification, labelling or packaging, to prohibit, restrict or hinder the marketing of fertilisers marked ‘EC fertiliser’ which complied with the provisions of the Directive.
- (6) Commission Decision 2002/399/EC of 24 May 2002 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers ⁽⁴⁾, granted a derogation from Directive 76/116/EEC, by approving the Swedish provisions which prohibited the placing on the Swedish market of fertilisers containing in excess of 100 grams of cadmium per tonne of phosphorus. This derogation was applicable until 31 December 2005.
- (7) Directive 76/116/EEC has been replaced by Regulation (EC) No 2003/2003 relating to fertilisers.

⁽²⁾ OJ L 24, 30.1.1976, p. 21, replaced by Regulation (EC) No 2003/2003.

⁽³⁾ Replaced by Article 5 of Regulation (EC) No 2003/2003.

⁽⁴⁾ OJ L 138, 28.5.2002, p. 24.

⁽¹⁾ OJ L 304, 21.11.2003, p. 1.

- (8) Article 35(2) of Regulation (EC) No 2003/2003 states that derogations from Article 7 of Directive 76/116/EEC that were granted by the Commission under former Article 95(6) of the EC Treaty shall be construed as derogations from Article 5 of that Regulation and shall continue to produce their effects notwithstanding the entry into force of the Regulation.
- (9) Recital 15 of Regulation (EC) No 2003/2003 announces that the Commission will address the issue of unintentional cadmium content in mineral fertilisers and will, where appropriate, draw up a proposal for a Regulation and will present it to the European Parliament and the Council. The Commission has conducted extensive preparatory work but due to the complexity of the various factors to be taken into account has not yet adopted a proposal.
- (10) Since the Swedish derogation was granted only until 31 December 2005, Sweden requested in June 2005 an extension of the existing derogation. Commission Decision 2006/347/EC of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers⁽¹⁾ allows the Swedish authorities to maintain the national measures until harmonised measures on cadmium in fertilisers are applied at EU level.

3. National provisions

- (11) 'The Chemicals Products (Handling, Import and Export Prohibitions) Ordinance' (1998:944)⁽²⁾ contains provisions relating, *inter alia*, to the maximum permissible cadmium content in fertilisers, including EC-designated fertilisers. Section 3, paragraph 1, provides that fertilisers covered by customs tariffs numbers 25.10, 28.09, 28.35, 31.03 and 31.05 containing in excess of 100 grams of cadmium per tonne of phosphorous may not be offered for sale or transferred.
- (12) The envisaged national measure notified under Article 114(5) TFEU would lower the content of cadmium allowed in phosphorous fertilisers from the current maximum level of 100 grams of cadmium per tonne of phosphorous to a level of 46 grams of cadmium per tonne of phosphorous (46 mg Cd/kg P, equivalent to 20 mg Cd/kg P₂O₅).
- phosphorous fertilisers to a maximum concentration of 46 grams per tonne of phosphorous. The Swedish authorities thus request to lower the cadmium content allowed by the derogation provided by Decision 2006/347/EC.
- (14) By letter of 17 October 2011, the Swedish authorities sent additional information to the Commission to provide the text of the national legislation in force reflecting the amendments introduced by Ordinances 2008:255 and 2009:654⁽³⁾.
- (15) By letter of 14 November 2011, the Commission informed the Swedish authorities that the six-month period for its examination according to Article 114(6) started on 18 October 2011.
- (16) By letter of 17 October 2011, the Commission informed the other Member States about the request received from Sweden. The Commission also published a notice regarding the request in the *Official Journal of the European Union*⁽⁴⁾ in order to inform other interested parties of the national measures that Sweden intends to introduce as well as the grounds invoked to that effect. In reaction, Latvia supported the Swedish request. No other comments were received by the Commission.
- (17) In view of the complexity of the matter, the Commission requested the Scientific Committee on Health and Environmental Risks (SCHER) for an opinion on the overall quality of the Swedish risk assessment, any significant deficiencies, the appropriateness of the scenarios studied and the assumptions made, as well as the reliability and validity of the conclusions concerning the identified risks for the environment.
- (18) SCHER adopted its opinion on 27 February 2012⁽⁵⁾. SCHER concluded that the risk assessment report prepared by the Swedish authorities was of good scientific quality and that in general the scenarios studied were appropriate and most parameter values used in the scenarios acceptable. However, SCHER considered that a number of statements in the report were not supported by sufficient evidence.
- (19) Due to the remaining uncertainties identified by the SCHER regarding key assumptions used by the Swedish authorities to conclude that there is a risk to aquatic organisms in small brooks in Sweden, which is the only environmental risk identified by the Swedish authorities, and in the absence of evidence highlighting a danger for human health linked to a prolongation of the period for assessment of the Swedish request, the Commission deemed justified to extend the period referred to in Article 114(6), first subparagraph.

II. PROCEDURE

- (13) By letter of 17 May 2011 the Kingdom of Sweden notified the Commission that, pursuant to Article 114(5) TFEU, it requests approval to introduce national provisions to lower the content of cadmium allowed in

⁽¹⁾ OJ L 129, 17.5.2006, p. 19.

⁽²⁾ Swedish Code of Statutes (SFS Svensk Författningssamling) of 14 July 1998.

⁽³⁾ Swedish Code of Statutes (SFS Svensk Författningssamling) of 4 June 2009.

⁽⁴⁾ OJ C 309, 21.10.2011, p. 8 and OJ C 339, 19.11.2011, p. 24.

⁽⁵⁾ http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_156.pdf

- (20) On 18 April 2012, the Commission notified the Kingdom of Sweden of its Decision⁽¹⁾, pursuant to Article 114(6), third subparagraph, TFEU, to extend the period of six months referred to in its first subparagraph to approve or reject the notified national provisions for a further period expiring on 18 October 2012.
- (21) By letter of 27 April 2012, the Commission informed the Swedish authorities about the uncertainties identified in the SCHER opinion and invited them to provide further clarifications that would allow the Commission to take a final position.
- (22) By letter of 2 July 2012, the Swedish authorities replied to the Commission without addressing the uncertainties identified by SCHER and, instead, argued that the notion of 'protection of the environment' under Article 114(5) TFEU covers health aspects. Therefore, an examination of the Swedish notification should include arguments in the notification relating to human health aspects.
- (27) Concerns regarding adverse effects of cadmium in fertilisers on the environment (and human health) were already extensively raised during the negotiations for the accession of Austria, Finland and Sweden to the European Union. As indicated above, those three Member States were granted temporary derogations from Union legislation on fertilisers in order to allow a careful evaluation of the risks from cadmium in fertilisers at EU level.
- (28) In 2002, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) was asked by the Commission for its opinion⁽²⁾ on the likelihood for accumulation of cadmium in soils through the use of phosphate fertilisers. Based on risk assessment studies carried out by eight Member States and additional analysis, the SCTEE estimated that phosphate fertilisers containing 60 mg cadmium/kg P₂O₅ or more are expected to lead to cadmium accumulation in most EU soils whereas phosphate fertilisers containing 20 mg cadmium/kg P₂O₅ or less are not expected to cause long-term soil accumulation over 100 years, if other cadmium inputs are not considered.

III. ASSESSMENT

1. Consideration of admissibility

- (23) The Commission considered in Decision 2012/230/EU that the application submitted by the Kingdom of Sweden with a view to obtaining an authorisation to introduce stricter national measures concerning the maximum admissible content of cadmium in fertilisers is admissible.

2. Assessment of merits

- (24) In accordance with the provisions of Article 114 TFEU, the Commission has to assure that all conditions enabling a Member State to avail of the possibilities of derogation provided for in that Article are met.
- (25) Article 114(5) TFEU requires that when a Member State deems it necessary to introduce national provisions derogating from a harmonisation measure, those provisions have to be justified on the basis of new scientific evidence relating to the protection of the environment or the working environment, on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure.
- (26) In addition, pursuant to Article 114(6) TFEU, the Commission is either to approve or reject the draft national provisions in question after verifying whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States, and whether or not they shall constitute an obstacle to the functioning of the internal market.
- (29) In the framework of Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances⁽³⁾, cadmium and cadmium oxide were identified as priority substances for evaluation.
- (30) When Regulation (EC) No 2003/2003 was adopted, the Commission did not set a limit value for cadmium in fertilisers but recognised the need to address this specific concern once information from the EU risk assessment on cadmium and cadmium oxide would become available.
- (31) The EU Risk Assessment Report on cadmium and cadmium oxide was issued in December 2007⁽⁴⁾. Based on its conclusions, the Risk Reduction Strategy for cadmium and cadmium oxide recommended concrete measures to reduce cadmium content in food-stuffs, tobacco blends and for phosphate fertilisers taking into account the variety of conditions throughout the Union⁽⁵⁾.
- (32) Work is ongoing at EU level to set appropriate limit values for cadmium in fertilisers taking into account a range of factors including also the variety of conditions throughout the EU, as well as the availability, geographic origin and composition of phosphates for the production of fertilisers. The Commission intends to include appropriate limits for contaminants in fertilising materials (including cadmium) in the proposal for the revision of the Fertilisers Regulation which is planned for 2013.

⁽¹⁾ Commission Decision 2012/230/EU of 18 April 2012 extending the period referred to in Article 114(6) of the Treaty on the Functioning of the European Union in relation to national provisions concerning the maximum admissible content of cadmium in fertilisers notified by the Kingdom of Sweden pursuant to Article 114(5) of the TFEU (OJ L 116, 28.4.2012, p. 29).

⁽²⁾ http://ec.europa.eu/health/ph_risk/committees/sct/documents/out162_en.pdf

⁽³⁾ OJ L 84, 5.4.1993, p. 1.

⁽⁴⁾ http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/cdoxidereport302.pdf

⁽⁵⁾ OJ C 149, 14.6.2008, p. 6.

- (33) To support their request for lowering the existing limit value in Sweden, the Swedish authorities have conducted a new risk assessment of cadmium in the Swedish environment, which was finalised in January 2011. It compares the predicted no effect concentrations (PNECs) for organisms representative for various environmental compartments with the cadmium concentrations in the Swedish environment taking on the basis of various scenarios for cadmium input from fertilisers and other sources. In the notification, reference is also made to certain studies made available in the framework of the previous requests submitted to the Commission in accordance with Article 114(4) TFEU (which were already taken into account to justify the current derogation allowing Sweden to maintain a maximum level of 100 grams of cadmium per tonne of phosphorous) and to the EU risk assessment on cadmium and cadmium oxide.
- (34) The PNEC for fresh water is dependent on hardness. Since Sweden has very soft fresh waters, toxicity for aquatic organisms is expected to occur at lower cadmium concentration compared to other parts of Europe. It is, therefore, likely that aquatic organisms in Swedish waters are in general more sensitive to cadmium compared to waters in central and southern Europe.
- (35) Results of monitoring programmes in Swedish surface waters in 2006 and 2009 show that about 1 % of the lakes and 7 % of the coastal waters show higher cadmium concentrations than the PNEC values. A review conducted in 2008 concluded that emission reduction measures have for most metals led to significant decreased concentrations in aquatic organisms, but for cadmium the situation is less clear. A tendency of increasing effects on the immune system in fish (eelpout) during the last years seems to correlate with increasing concentrations of cadmium in fish. A further report has been produced in 2011 with the aim to describe future trends of cadmium in arable soils and crops to estimate concentrations in 100 years and results have been used in a worst case modelling to estimate the risk to aquatic organisms inhabiting waters close to fields fertilised during 100 years ahead.
- (36) The Swedish authorities conclude in their assessment that there might be an increased risk for aquatic organisms living in extremely soft waters (below hardness 5 mg CaCO₃/l) in the longer term. But this is only likely in small brooks with low dilution of the drainage water from the agricultural soil. No other risk to the environment resulting from the use of cadmium in fertilisers has been identified by the Swedish authorities.
- (37) Due to the complexity of the relations between soil cadmium inputs via phosphate fertilisers, possible soil accumulation and risks to the environment, the Commission requested the Scientific Committee on Health and Environmental Risks (SCHER) for an opinion on the overall quality of the Swedish risk assessment, any significant deficiencies, the appropriateness of the scenarios studied and the assumptions made, as well as the reliability and validity of the conclusions concerning the identified risks for the environment.
- (38) SCHER adopted its opinion on 27 February 2012 ⁽¹⁾. As already presented in Decision 2012/230/EU, SCHER concluded that the risk assessment report prepared by the Swedish authorities is of good scientific quality and that in general the scenarios studied are appropriate and most parameter values used in the scenarios are acceptable. However, SCHER considered that a number of statements and/or assumptions in the report were not supported by sufficient evidence and that for some scenarios rather worst case conditions were used. SCHER considered that the assumptions proposed by the Swedish authorities to predict cadmium concentration in soft water could lead to an over-estimation of the risks and, consequently, did not support the results presented by the Swedish authorities for brooks, which is the only environmental compartment for which the Swedish authorities had identified risks. Overall, SCHER did not consider the assumptions made in the Swedish report as appropriate for calculating risk in the Swedish environment.
- (39) None the less, SCHER recalled the earlier assessment of CSTEE in 2002, which estimated that cadmium concentrations in soil are expected not to increase in most European soils at a limit of 46 mg Cd/kg P. Although not being new scientific evidence, SCHER confirmed that such estimate is still defensible including for Swedish agricultural soils and noted that the derivation was based on a 'stand-still principle', not on a risk assessment as performed by the Swedish authorities in their current justification.
- (40) In their letter of 2 July 2012, the Swedish authorities have not provided further clarification that would address the weak points identified by SCHER with regard to the possible risks to the environment. Noting that the opinion of CSTEE in 2002 predates the adoption of Regulation (EC) No 2003/2003, the Commission, therefore, concludes that the Swedish authorities have not demonstrated that there is a risk to the environment based on new scientific evidence on grounds of a problem specific to Sweden arising after the adoption of Regulation (EC) No 2003/2003.
- (41) In their letter of 2 July 2012, the Swedish authorities argued that the notion of 'protection of the environment' in Article 114(5) TFEU covers health aspects and that an examination of the Swedish notification should, therefore, include arguments relating to the health aspects.

⁽¹⁾ http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_156.pdf

- (42) Without prejudice to the correct legal interpretation of Article 114(5), the Commission extended its analysis to the assessment of possible risks posed by cadmium in fertilisers to the Swedish population via the environment, i.e. notably through dietary intake.
- (43) In their justification, the Swedish authorities identify health-related grounds for further reducing cadmium exposure amongst the population in Sweden, such as a high frequency of osteoporosis, increased cases of brittle bones and bone fractures, impacts on the functioning of kidneys in parts of the population where cadmium content exceed 1 mg/g creatinine, as well as risks for sensitive groups of the population (diabetics and people suffering from iron deficiency, both groups being of high proportion in Sweden). According to the Swedish authorities, the lower pH level in Swedish soils may lead to higher uptake of cadmium in crops, which in turn can lead to higher exposure of the population, as exposure depends to a great extent on the intake of cadmium through food, above all food of plant origin.
- (44) The Commission requested a further opinion of SCHER on whether the risks to human health identified by the Swedish authorities are specific to Sweden and have arisen after the adoption of Regulation (EC) No 2003/2003 ⁽¹⁾.
- (45) With regard to the question whether the situation in Sweden is different compared to other parts of Europe, SCHER agreed that soil pH is on average lower in Sweden than in other parts of Europe. However, as cadmium removal from the soil by leaching is also increasing with lower soil pH value, the net cadmium soil accumulation is lower in Sweden than in most parts of Europe at comparable cadmium concentration and fertiliser application rates. SCHER notes that the Swedish report itself (summary of Annex IV) supports SCHER's conclusion as it states: 'It was difficult to unambiguously show whether there are specific conditions in Sweden that make Swedish soils more vulnerable to Cd input than those in central Europe. However, pH is a major factor that regulates the uptake of cadmium from soils to crops and pH in Swedish soil appears to be around one pH unit lower than the general average for Europe. This is probably related to the scarcity of lime-bearing bedrock in Sweden. Swedish wheat also contains cadmium in levels that are comparable to those in many other European countries, in spite of the fact that cadmium concentrations in Swedish soils are relatively low'. SCHER comments that while input data on atmospheric deposition have been updated in the Swedish report, the scenarios for mass balance calculation were already included in the scenarios considered in the opinion of the CSTEE of 2002, and there is no new information suggesting that these would not be applicable anymore.
- (46) SCHER agrees that the lower pH increases cadmium bioavailability and uptake by crops, hence that the soil cadmium availability to wheat is somewhat larger than in most European countries. However, SCHER notes that if that low pH is maintained, the future trends in crop cadmium concentrations are smaller (lower increase) in Sweden compared to most other trends in Europe because soil cadmium increases at a lower rate at equal input.
- (47) With regard to dietary exposure to cadmium, SCHER concludes that the Swedish report does not provide data suggesting that dietary cadmium exposure is larger in Sweden than in the rest of Europe neither at the mean nor at the upper percentiles of exposure. Recent trends do not suggest an increasing trend in dietary exposure, including body burden cadmium in the general population. Lastly, SCHER notes that the Swedish report provides evidence that effects of cadmium on human health in Sweden can be noted at a body burden of cadmium that is lower than that reported before, however it does not provide evidence that the Swedish population is more sensitive or became more sensitive to cadmium than those in other European countries.
- (48) Overall, SCHER concludes that the Swedish report contains a detailed and updated assessment of long-term effects of cadmium from fertilisers on human health via the food chain. SCHER notes that the report does not provide convincing arguments to show that the Swedish case is a unique one or that data which appeared after the adoption of Regulation (EC) No 2003/2003 suggest specific reasons for additional concern.
- (49) In conclusion, the Commission considers that the Kingdom of Sweden has not provided justification for the intended national measure with regard to the maximum content of cadmium in fertilisers on the basis of new scientific evidence relating to the protection of the environment on grounds of a specific problem in Sweden having arisen after the adoption of Regulation (EC) No 2003/2003.
- (50) The Commission notes that the Swedish notification does not refer to the protection of the working environment as a ground for introducing the notified measure.

IV. CONCLUSION

- (51) Article 114(5) TFEU requires that, if a Member State deems it necessary to introduce national provisions in derogation from Union harmonisation measures, the national provisions must be justified by new scientific evidence relating to the protection of the environment or the working environment, there must be a problem specific to the State making the request, and the problem must have arisen after the adoption of the harmonisation measure.

⁽¹⁾ Opinions of SCHER are available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/index_en.htm#id5

- (52) In this case, after having examined the Swedish request, the Commission considers that the Kingdom of Sweden has not provided new scientific evidence relating to the protection of the environment or working environment demonstrating that there is a specific problem within its territory which arose following the adoption of Regulation (EC) No 2003/2003 relating to fertilisers, and which makes it necessary to introduce the notified national measures.
- (53) Consequently, the request from the Kingdom of Sweden for introducing national measures to lower the content of cadmium allowed in phosphorous fertilisers to a maximum level of 46 grams of cadmium per tonne of phosphorous does not fulfil the conditions set out in Article 114(5).
- (54) Under Article 114(6) of the EC Treaty, the Commission is either to approve or reject the draft national provisions in question after verifying whether or not they are a means of arbitrary discrimination or a disguised restriction to trade between Member States, and whether or not they shall constitute an obstacle to the functioning of the internal market.
- (55) Since the request made by the Kingdom of Sweden does not fulfil the basic conditions set out in Article 114(5), there is no need for the Commission to verify the conditions in Article 114(6).
- (56) In the light of the foregoing, it can be concluded that the request of the Kingdom of Sweden for introducing national provisions derogating from Regulation (EC)

No 2003/2003 is admissible but does not fulfil the conditions set out in Article 114(5) TFEU, as Sweden did not provide new scientific evidence relating to the protection of the environment on grounds of a problem specific to their territory arising after the adoption of Regulation (EC) No 2003/2003.

- (57) The Commission therefore considers that the notified national provisions cannot be approved in accordance with Article 114(6) TFEU,

HAS ADOPTED THIS DECISION:

Article 1

The envisaged national provisions intended to lower the content of cadmium allowed in phosphorous fertilisers from the current maximum level of 100 grams of cadmium per tonne of phosphorus to a level of 46 grams, which the Kingdom of Sweden notified to the Commission on 17 October 2011, are rejected.

Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 17 October 2012.

For the Commission
Antonio TAJANI
Vice-President

COMMISSION DECISION**of 14 November 2012****establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents***(notified under document C(2012) 8054)***(Text with EEA relevance)***(2012/720/EU)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the European Union Eco-labelling Board,

Whereas:

- (1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.
- (2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.
- (3) The new criteria, as well as the related assessment and verification requirements, should be valid for four years from the date of adoption of this Decision.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Article 1

The product group 'Industrial and Institutional Automatic Dishwasher Detergents' shall comprise single and multi-component dishwasher detergents, rinse and pre-soaks, designed for use in professional dishwashers.

The following products are excluded from the scope of this product group: consumer automatic dishwasher detergents, detergents intended to be used in washers of medical devices

or in special machines for cleaning industrial equipment, including in special machines for the food industry.

Sprays not dosed via automatic pumps are excluded from this product group.

Article 2

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, an item of automatic dishwasher detergent shall fall within the product group 'Industrial and Institutional Automatic Dishwasher Detergents' as defined in Article 1 of this Decision and shall comply with the criteria as well as the related assessment and verification requirements set out in the Annex to this Decision.

Article 3

The criteria for the product group 'Industrial and Institutional Automatic Dishwasher Detergents', as well as the related assessment and verification requirements, shall be valid for four years from the date of adoption of this Decision.

Article 4

For administrative purposes the code number assigned to the product group 'Industrial and Institutional Automatic Dishwasher Detergents' shall be '038'.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 14 November 2012.

For the Commission

Janez POTOČNIK

Member of the Commission

⁽¹⁾ OJ L 27, 30.1.2010, p. 1.

ANNEX

FRAMEWORK

The aims of the criteria

The criteria aim, in particular, at promoting products that have a reduced impact on aquatic ecosystems, contain a limited amount of hazardous substances and whose performance has been tested.

CRITERIA

Criteria are set for each of the following aspects:

1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
2. Biodegradability
3. Excluded or limited substances and mixtures
4. Packaging requirements
5. Washing performance (fitness for use)
6. Automatic dosing systems
7. User information — Information appearing on the EU Ecolabel

(1) Assessment and verification**(a) Requirements**

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses test reports or other evidence to show compliance with the criteria, it is understood that these may originate from the applicant and/or his supplier(s) and/or their supplier(s) etc., as appropriate.

Where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Appendix I makes reference to the detergent ingredient database (DID list) which contains the most widely used ingoing substances used in detergent formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) and for the assessment of the biodegradability of the ingoing substances. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website or via the websites of the individual competent bodies.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

(b) Measurement thresholds

Compliance with the ecological criteria is required for substances intentionally added, as well as for by-products and impurities from raw materials, the concentration of which equals or exceeds 0,010 % by weight of final formulation.

For biocides and colouring agents compliance with the criteria is required regardless of their concentration.

Substances meeting the threshold limit as listed above are hereby referred to as 'Ingoing substances'.

(2) Functional unit

The functional unit for this product group shall be expressed in g/l washing solution (grams per litre washing solution).

Requirements relating to assessment and verification of the functional unit:

The full formulation indicating trade name, chemical name, CAS No, DID No (*), the ingoing quantity including and excluding water, the function and the form of all the ingoing substances (regardless of concentration) in the product must be submitted to the competent body. A sample of the artwork including dosage recommendations must be submitted to the competent body.

Safety data sheets for each ingoing substance shall be submitted to the competent body in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽¹⁾.

Parts A and B of the DID list can be found on the EU Ecolabel website:

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

EU ECOLABEL CRITERIA

Criterion 1 — Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

The Critical Dilution Volume (CDV_{chronic}) of a single or multi-component system must not exceed the following limits (at the highest recommended dose):

CDV at the highest recommended dosage	Soft	Medium	Hard
Product type	0-6 °dH	7-13 °dH	> 14 °dH
Pre-soaks	2 000	2 000	2 000
Dishwasher detergents	3 000	5 000	10 000
Multi-component system	3 000	4 000	7 000
Rinse aids	3 000	3 000	3 000

The Critical Dilution Volume (CDV_{chronic}) is calculated for all ingoing substances (i) in the product using the following equation:

$$CDV_{\text{chronic}} = \sum CDV_{(i)} = \sum \frac{\text{weight}_{(i)} \times DF_{(i)}}{TF_{\text{chronic}(i)}} \times 1\,000$$

Where:

weight = the weight of the ingoing substance per recommended dose

DF = the degradation factor

TF = the chronic toxicity factor of the substance as stated in the DID list.

Biocides and colouring agents present in the product shall also be included in the CDV calculation even if the concentration is lower than 0,010 % (100 ppm).

Because of the degradation of the substances in the wash process, separate rules apply to the following substances:

— Hydrogen Peroxide (H_2O_2) — not to be included in calculation of CDV,

— Peracetic acid — to be included in the calculation as acetic acid.

Assessment and verification: the applicant shall provide the calculation of the CDV_{chronic} of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website.

The values of the DF and TF parameters shall be as given in the Detergent Ingredient Database list (DID list). If the substance is not found on the DID list, the parameters shall be calculated using the guidelines in Part B of the DID list and attaching the associated documentation.

(*) DID No is the number of the ingoing substance on the DID list ('Detergent Ingredient Database' list), and is used in determining compliance with criteria 1 and 2.

(1) OJ L 396, 30.12.2006, p. 1.

Criterion 2 — Biodegradability

(a) Biodegradability of surfactants

All surfactants must be biodegradable under aerobic and anaerobic conditions.

(b) Biodegradability of organic substances

The content of all organic substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the following limits:

aNBO

Product type (g/l washing solution)	Soft	Medium	Hard
	0-6 °dH	7-13 °dH	> 14 °dH
Pre-soaks	0,4	0,4	0,4
Dishwasher detergents/Multi-component system	0,4	0,4	0,4
Rinse aids	0,04	0,04	0,04

anNBO

Product type (g/l washing solution)	Soft	Medium	Hard
	0-6 °dH	7-13 °dH	> 14 °dH
Pre-soaks	0,4	0,4	0,4
Dishwasher detergents/Multi-component system	0,6	1,0	1,5
Rinse aids	0,04	0,04	0,04

Assessment and verification: the applicant shall provide documentation for the degradability of surfactants as well as the calculation of aNBO and anNBO for the product. A spreadsheet for use in calculating aNBO and anNBO values is available on the EU Ecolabel website.

For both surfactants and aNBO and anNBO values reference should be done to the DID List. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided as described in Appendix I.

Note that TAED should be considered anaerobically biodegradable.

In the absence of documentation in accordance with the above requirements, a substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:

1. Readily degradable and has low adsorption ($A < 25\%$); or
2. Readily degradable and has high desorption ($D > 75\%$); or
3. Readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106.

Criterion 3 — Excluded or limited substances and mixtures

(a) Specified excluded ingoing substances

The following ingoing substances must not be included in the product, neither as part of the formulation nor as part of any mixture included in the formulation:

— EDTA (ethylenediamine tetraacetate),

- Fragrances,
- Reactive chlorine compounds,
- APEO (Alkyl phenol ethoxylates) and APD (Alkylphenols and derivatives thereof).

Assessment and verification: the applicant shall provide a completed and signed declaration of compliance.

(b) Hazardous substances and mixtures

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any component of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁾ or Council Directive 67/548/EEC ⁽²⁾ nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

List of hazard statements:

Hazard Statement ⁽¹⁾	Risk Phrase ⁽²⁾
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ OJ 196, 16.8.1967, p. 1.

Hazard Statement ⁽¹⁾	Risk Phrase ⁽²⁾
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

⁽¹⁾ Regulation (EC) No 1272/2008.

⁽²⁾ Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended.

Note that this criterion also applies to known degradation products such as formaldehyde from formaldehyde releasers.

Substances or mixtures which change their properties through processing (e.g. become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard) are exempted from the above requirement.

The final product must not be labelled according to the hazard statements above.

Derogations

The following substances are specifically exempted from this requirement:

Surfactants < 15 % in the final product	H400: Very toxic to aquatic life	R50
Biocides for preservation purpose (*) (only for liquids with pH between 2 and 12 and maximum 0,10 % w/w of active material)	H331: Toxic if inhaled	R23
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
	H400: Very toxic to aquatic life	R50

Enzymes (**)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
	H400: Very toxic to aquatic life	R50
NTA as in impurity in MGDA and GLDA (***)	H351: Suspected of causing cancer	R40

(*) Derogation is only for criterion 3(b). Biocides shall comply with criterion 3(d).

(**) Including stabilisers and other auxiliary substances in the preparations.

(***) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %.

Assessment and verification: the applicant shall demonstrate compliance with this criterion by providing a declaration on the non-classification of each ingoing substance into any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) No 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII to Regulation (EC) No 1907/2006. This declaration shall be supported by summarised information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in Sections 10, 11 and 12 of Annex II to Regulation (EC) No 1907/2006 (Requirements for the Compilation of Safety Data Sheets).

Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as *in vitro* methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI to Regulation (EC) No 1907/2006. The sharing of relevant data is strongly encouraged.

The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.

For substances listed in Annexes IV and V to REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.

(c) Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in mixtures in concentrations > 0,010 %.

Assessment and verification: the list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.

(d) Specified limited ingoing substances — Biocides

- (i) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any biocides added, together with information on their exact concentration in the product. The manufacturer or supplier of the biocides shall provide information on the dosage necessary to preserve the product.

- (ii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

Assessment and verification: the applicant shall provide the texts and layouts used on each type of packaging and/or an example of each different type of packaging to the competent body.

- (iii) The product may contain biocides provided that they are not bioaccumulating. A biocide is not considered bioaccumulating if BCF < 100 or logKow < 3,0. If both BCF and logKow values are available, the highest measured BCF value shall be used.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any biocide added, together with information on their BCF and/or logKow values.

(e) Colouring agents

Colouring agents allowed in the product must not be bioaccumulating. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential. A colouring agent is considered not bioaccumulating if $BCF < 100$ or $\log K_{ow} < 3,0$. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any colouring agents added, or documentation to ensure that the colouring agent is approved for use in foodstuff.

(f) Enzymes

Enzymes must be in liquid form or dust-free granulate. Enzymes must be free from micro-organism remnants from manufacture.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any enzyme added, together with documentation to ensure that the enzyme is free from micro-organism remnants.

(g) Phosphorous

The total quantity of phosphates and other phosphorous compounds must not exceed the limit values specified in table, calculated in grams of phosphorous per litre water.

The highest recommended dosage shall be used for the phosphorous calculations.

Product type Phosphorous (g P/l water)	Soft	Medium	Hard
	0-6 °dH	7-13 °dH	> 14 °dH
Pre-soaks	0,08	0,08	0,08
Detergents	0,15	0,30	0,50
Rinse aids	0,02	0,02	0,02
Multi-component systems	0,17	0,32	0,52

Assessment and verification: the applicant shall provide documentation to ensure that the limit in the above table is fulfilled.

Criterion 4 — Packaging requirements

(a) Weight/utility ratio (WUR)

The weight/utility ratio (WUR) of the product shall not exceed the following values:

Product type	WUR		
	0-6 °dH	7-13 °dH	> 14 °dH
Powders [g/l washing solution]	0,8	1,4	2,0
Liquids [g/l washing solution]	1,0	1,8	2,5

WUR shall be calculated only for primary packaging (including caps, stoppers and hand pumps/spraying devices) using the formula below:

$$WUR = \sum [(W_i + U_i) / (D_i * r_i)]$$

Where:

W_i = the weight (g) of the packaging component (i) including the label if applicable.

U_i = the weight (g) of non-recycled (virgin) material in the packaging component (i). If the proportion of recycled material in the packaging component is 0 % then $U_i = W_i$.

D_i = the number of functional units contained in the packaging component (i). The functional unit = dosage in g/l washing solution.

r_i = recycling figure, i.e. the number of times the packaging component (i) is used for the same purpose through a return or refill system. $r = 1$, if the packaging is not reused for the same purpose. If the packaging is reused r is set to 1 unless the applicant can document a higher number.

Exceptions

Plastic/paper/cardboard packaging containing more than 80 % recycled material or more than 80 % plastic from renewable origin is exempted from this requirement.

Packaging is regarded as recycled if the raw material used to make the packaging has been collected from packaging manufacturers at the distribution stage or at the consumer stage. Where the raw material is industrial waste from the material manufacturer's own production process, then the material will not be regarded as recycled.

Assessment and verification: the applicant shall provide the calculation of the WUR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. The applicant shall provide a completed and signed declaration for the content of recycled or material from renewable origin in the packaging. For approval of refill packaging, the applicant and/or retailer shall document that the refills will be/are available for purchase on the market.

(b) Plastic packaging

Only phthalates that at the time of application have been risk assessed and have not been classified according to criterion 3(b) (and combinations hereof) may be used in the plastic packaging.

In order to allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent. Caps and pumps are exempted from this requirement.

Assessment and verification: the applicant shall provide completed and signed declaration of compliance.

Criterion 5 — Washing performance (fitness for use)

The performance and efficiency of the product must be satisfactory. The product must satisfy the requirements for the user test or internal testing in accordance with Appendix II.

Assessment and verification: the applicant shall submit a detailed test report to the Competent Body, including information/documentation. See Appendix II.

Criterion 6 — Automatic dosing systems

Multi-component systems shall be offered together with an automatic and controlled dosing system.

In order to ensure correct dosage in the automatic dosing systems, customer visits must be incorporated as a normal routine for manufacturers/suppliers. These customer visits are performed at all premises at least once a year during the license period; they must include calibration of the dosage equipment. Also, a third party can perform customer visits.

In exceptional cases, customer visits may be dispensed with if the distance and method of delivery makes the visit impracticable.

Assessment and verification: the applicant shall provide a written description of responsibility for, frequency and content of customer visits.

Criterion 7 — User information — Information appearing on the EU Ecolabel

(a) Information on the packaging/product information sheet

The following recommendations must appear on the packaging, and/or on product information sheet or equivalent:

— Dose according to the degree of soil, and the water hardness. Follow the dosing instructions.

— Using this EU Ecolabelled product according to the dosage instructions will contribute to the reduction of water pollution and waste production.

(b) Information appearing on the EU Ecolabel

The logo should be visible and legible. The use of the EU Ecolabel logo is protected in primary EU law. The EU Ecolabel registration/licence number must appear on the product, it must be legible and clearly visible.

The optional label with text box shall contain the following text:

- reduced impact on aquatic ecosystems,
- limited hazardous substances,
- performance tested.

The guidelines for the use of the optional label with text box can be found in the 'Guidelines for use of the Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification (a-b): the applicant shall provide a sample of the product label and/or product sheet, together with a declaration of compliance with this criterion. Product claims shall be documented through appropriate test reports.

Appendix I

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information of the aquatic toxicity and biodegradability of ingoing substances typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabelled products. The DID list (Parts A and B) can be found on the EU Ecolabel website.

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst-case approach shall be applied, using the parameters below:

Worst-case approach:

	Acute toxicity			Chronic toxicity			Degradation		
Ingoing substance	LC50/EC50	SF _(acute)	TF _(acute)	NOEC (*)	SF _(chronic) (*)	TF _(chronic)	DF	Aerobic	Anaerobic
'Name'	1 mg/l	10 000	0,0001			0,0001	1	P	N

(*) If no acceptable chronic toxicity data are found, these columns are empty. In that case TF_(chronic) is defined as equal to TF_(acute).

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

- (1) Until 1 December 2010 and during transition period from 1 December 2010 to 1 December 2015:

The test methods for ready biodegradability provided for in Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10-days window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

- (2) After 1 December 2015 and during transition period from 1 December 2010 to 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008.

Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate degradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

- (1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)).

- (2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.
 - (3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by ^{14}C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.
-

*Appendix II***Washing performance (fitness for use)****(a) Internal testing**

The manufacturer's test laboratory can be approved to conduct testing to document effectiveness if the following additional requirements are met:

- it must be possible for ecolabelling organisations to monitor the performance of testing,
- the ecolabelling organisation must have access to all data on the product,
- performance of the effectiveness test must be described in the quality control system.

The applicant must submit documentation proving that the product has been tested under realistic conditions:

(a) Dishes soiled with spots that are representative for the kind of soiled expected in the areas where the products will be marketed.

(b) Recommended dosage and at the corresponding water hardness at the lowest recommended wash temperature

The applicant must submit documentation proving:

- the product's ability to remove soiling from the dishes,
- the product's ability to dry the dishes.

The test product must be tested against a reference product. The reference product may be a well-established product on the market and the tested product must be at least as effective as the reference.

(b) User test

1. Responses must be obtained from at least five test centres representing a random selection of customers.
 2. The procedure and dosage must conform to the manufacturer's recommendations.
 3. The test period must continue for at least four weeks with at least 400 test cycles.
 4. Every test centre must assess the effectiveness of the product or multi-component system by answering questions relating to the following aspects (or similar formulations):
 - the product's ability to remove soiling from the dishes,
 - the product's ability to dry the dishes,
 - the respondent's satisfaction with the agreement on customer visits.
 5. The response must be rated on a scale comprising at least three levels, for example, 'insufficiently effective', 'sufficiently effective' or 'very effective'. With regard to how satisfied the test centre is with visit reporting arrangements, the categories must be 'not satisfied', 'satisfied' and 'very satisfied'.
 6. At least 80 % must rate the product as sufficiently effective or very effective on all points (see point 4) and be satisfied or very satisfied with customer visiting arrangements.
 7. All raw data from the test must be specified.
 8. The test procedure must be described in detail.
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COMMISSION DECISION**of 14 November 2012****establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Laundry Detergents***(notified under document C(2012) 8055)***(Text with EEA relevance)***(2012/721/EU)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the European Union Eco-labelling Board,

Whereas:

- (1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.
- (2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.
- (3) The criteria, as well as the related assessment and verification requirements, should be valid for four years from the date of adoption of this Decision.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Article 1

The product group 'Industrial and Institutional Laundry Detergents' shall comprise: laundry detergent products performed by professional users in the industrial and institutional sector.

Included in the product group are multi-component-systems constituting of more than one component used to build up a complete detergent or a laundering program for automatic dosing system.

This product group shall not comprise products for obtaining textile attributes such as water-repellent, waterproof or fire-proof, etc. Furthermore, the product group shall not comprise

products that are dosed by carriers such as sheets, cloths or other materials, as well as washing auxiliaries used without subsequent washing, such as stain removers for carpets and furniture upholstery.

Consumer laundry detergents are excluded from the scope of this product group.

Article 2

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, an item of laundry detergent shall fall within the product group 'Industrial and Institutional Laundry Detergents' as defined in Article 1 of this Decision and shall comply with the criteria as well as the related assessment and verification requirements set out in the Annex to this Decision.

Article 3

The criteria for the product group 'Industrial and Institutional Laundry Detergents', as well as the related assessment and verification requirements, shall be valid for four years from the date of adoption of this Decision.

Article 4

For administrative purposes the code number assigned to the product group 'Industrial and Institutional Laundry Detergents' shall be '039'.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 14 November 2012.

For the Commission

Janez POTOČNIK

Member of the Commission

⁽¹⁾ OJ L 27, 30.1.2010, p. 1.

ANNEX

FRAMEWORK

The aims of the criteria

The criteria aim, in particular, at promoting products that have a reduced impact on aquatic ecosystems, contain a limited amount of hazardous substances and whose performance has been tested. The criteria furthermore aim at reducing the energy consumption from laundering by promoting products that are efficient at lower temperatures.

CRITERIA

Criteria are set for each of the following aspects:

1. Product and dosage information
2. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
3. Biodegradability
4. Excluded or limited substances and mixtures
5. Packaging requirements
6. Washing performance (fitness for use)
7. Automatic dosing systems
8. User information — Information appearing on the EU Ecolabel

(1) Assessment and verification**(a) Requirements**

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses test reports, or other evidence to show compliance with the criteria, it is understood that these may originate from the applicant and/or his supplier(s) and/or their supplier(s), et cetera, as appropriate.

Where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Appendix I makes reference to the detergent ingredient database (DID list) which contains the most widely used ingoing substances used in detergent formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) and for the assessment of the biodegradability of the ingoing substances. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website or via the websites of the individual competent bodies.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

(b) Measurement thresholds

Compliance with the ecological criteria is required for substances intentionally added, as well as for by-products and impurities from raw materials, the concentration of which equals or exceeds 0,010 % by weight of final formulation.

For biocides, colouring agents and fragrance compliance with the criteria is required regardless of their concentration.

Substances meeting the threshold limit as listed above are hereby referred to as 'Ingoing substances'.

For all products: it is the highest total dosage recommended for the individual degree of soiling which must comply with the ecological criteria. If the dosage is stated in intervals the worst case dosage must be used when the criterions are assessed.

(2) Functional unit

The functional unit for this product group shall be expressed in g/kg laundry (grams per kilo laundry).

Requirements relating to assessment and verification of the functional unit:

The full formulation indicating trade name, chemical name, CAS No, DID No (*), the ingoing quantity including and excluding water, the function and the form of all the ingoing substances (regardless of concentration) in the product shall be submitted to the competent body. A sample of the artwork including dosage recommendations must be submitted to the competent body.

Safety data sheets for each ingoing substance shall be submitted to the competent body in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽¹⁾.

Part A and Part B of the DID list can be found on the EU Ecolabel website:

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

EU ECOLABEL CRITERIA**Criterion 1 — Product and dosage information**

The recommended total dosage for 1 kg of laundry according to the degree of soiling and water hardness shall be given in g/kg laundry or ml/kg laundry. All products in a multi-component system have to be included with the worst case dosage when assessments of the criteria are made.

Examples of degree of soiling:

Light	Medium	Heavy
Hotel: bed-linen, bedclothes and towels, etc. (towels may be considered heavily soiled)	Work clothes: institutions/retail/service, etc.	Work clothes: industry/kitchen/butchering, etc.
Cloth hand towel rolls	Restaurants: table-cloths, napkins, etc.	Kitchen textiles: clothes, dish towels, etc.
	Mops and mats	Institutions as hospitals: bed-linen, bedclothes, contour sheets, patient clothing, doctor's coat or coatdress, etc.

The product name, or in case of a multi-component system, a list of all products part of that system, together with the recommended water hardness (soft, medium or hard) and the intended degree of soiling shall be provided.

The applicant must document compliance with criteria 2, 3 and 6 for all product names.

Assessment and verification: the applicant shall provide the product name, or in case of a multi-component system, a list of all products part of that system, together with exact formulation of the product(s) and the label or artwork including dosage instructions according to the three degrees of soiling and water hardness. The density (g/ml) shall be stated for all products (either on the packaging or in a Safety Data Sheet).

Criterion 2 — Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

The Critical Dilution Volume (CDV_{chronic}) of the product shall not exceed the following limits:

Soft water (0-6 °dH)	CDV _{chronic} (L/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	30 000	40 000	50 000

(*) DID No is the number of the ingoing substance on the DID list ('Detergent Ingredient Database' list), and is used in determining compliance with criteria 2 and 3. See Appendix I.

(1) OJ L 396, 30.12.2006, p. 1.

Soft water (0-6 °dH)	CDV _{chronic} (L/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Liquid	50 000	60 000	70 000
Multi-component-system	50 000	70 000	90 000
Medium water (7-13 °dH)	CDV _{chronic} (L/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	40 000	60 000	80 000
Liquid	60 000	75 000	90 000
Multi-component-system	60 000	80 000	100 000
Hard water (> 14 °dH)	CDV _{chronic} (L/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	50 000	75 000	90 000
Liquid	75 000	90 000	120 000
Multi-component-system	75 000	100 000	120 000

The Critical Dilution Volume (CDV_{chronic}) is calculated for all ingoing substances (i) in the product using the following equation:

$$CDV_{chronic} = \sum CDV_{(i)} = \sum \frac{weight_{(i)} \times DF_{(i)}}{TF_{chronic(i)}} \times 1\,000$$

Where:

weight = the weight of the ingoing substance per recommended dose

DF = the degradation factor

TF = the chronic toxicity factor of the substance as stated in the DID list.

Biocides, colouring agents and fragrances present in the product must also be included in the CDV calculation even if the concentration is lower than 0,010 % (100 ppm).

Because of the degradation of the substances in the wash process, separate rules apply to the following substances:

— Hydrogen Peroxide (H₂O₂) — not to be included in calculation of CDV

— Peracetic acid — to be included in the calculation as acetic acid.

Assessment and verification: the applicant shall provide calculation of the CDV_{chronic} of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website.

The values of the DF and TF parameters shall be as given in the Detergent Ingredient Database list (DID list). If the substance is not found on the DID list, the parameters shall be calculated using the guidelines in part B of the DID list and attaching the associated documentation.

Criterion 3 — Biodegradability

(a) Biodegradability of surfactants

All surfactants must be biodegradable under aerobic conditions.

All non-ionic and cationic surfactants must also be biodegradable under anaerobic conditions.

(b) Biodegradability of organic substances

The content of all organic substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the following limits:

aNBO

Soft water (0-6 °dH)	aNBO (g/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	0,70	1,10	1,40
Liquid	0,50	0,60	0,70
Multi-component-system	1,25	1,75	2,50

Medium water (7-13 °dH)	aNBO (g/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	1,10	1,40	1,75
Liquid	0,60	0,70	0,90
Multi-component-system	1,75	2,50	3,75

Hard water (> 14 °dH)	aNBO (g/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	1,40	1,75	2,20
Liquid	0,70	0,90	1,20
Multi-component-system	2,50	3,75	4,80

anNBO

Soft water (0-6 °dH)	anNBO (g/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	0,70	1,10	1,40
Liquid	0,50	0,60	0,70
Multi-component-system	1,25	1,75	2,50

Medium water (7-13 °dH)	anNBO (g/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	1,10	1,40	1,75
Liquid	0,60	0,70	0,90
Multi-component-system	1,75	2,50	3,75

Hard water (> 14 °dH)	anNBO (g/kg laundry)		
Product type/Degree of soiling	Light	Medium	Heavy
Powder	1,40	1,75	2,20
Liquid	0,70	0,90	1,20
Multi-component-system	2,50	3,75	4,80

Assessment and verification: the applicant shall provide documentation for the degradability of surfactants as well as the calculation of aNBO and anNBO for the product. A spreadsheet for use in calculating aNBO and anNBO values is available on the EU Ecolabel website.

For both surfactants and aNBO and anNBO values reference should be done to the DID List. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided as described in Appendix I.

Note that TAED should be considered as anaerobically biodegradable.

In the absence of documentation in accordance with the above requirements, a substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:

1. Readily degradable and has low adsorption ($A < 25\%$) or
2. Readily degradable and has high desorption ($D > 75\%$) or
3. Readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106.

Criterion 4 — Excluded or limited substances and mixtures

(a) Specified excluded substances

The following substances shall not be included in the product, either as part of the formulation nor as part of any mixture included in the formulation:

- Phosphates (phosphonates are not excluded but limited by criterion 3)
- APEO (Alkyl phenol ethoxylates) and ADP (Alkylphenols and derivatives thereof)
- EDTA (ethylene-diamine-tetra-acetic-acid) and its salts

Assessment and verification: the applicant shall provide a declaration supported by declarations from manufacturers of substances, as appropriate, confirming that the listed substances have not been included in the product.

(b) Hazardous substances and mixtures

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any component of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁽¹⁾ or Council Directive 67/548/EEC⁽²⁾ nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ OJ 196, 16.8.1967, p. 1.

List of hazard statements:

Hazard statement ⁽¹⁾	Risk phrase ⁽²⁾
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53

Hazard statement ⁽¹⁾	Risk phrase ⁽²⁾
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

⁽¹⁾ Regulation (EC) No 1272/2008.

⁽²⁾ Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended.

Note that this criterion also applies to known degradation products such as formaldehyde from formaldehyde releasers.

Substances or mixtures which change their properties upon processing (e.g. become no longer bioavailable, undergo chemical modification) so that the identified hazard no longer applies are exempted from the above requirement.

The final product must not be labelled according to the hazard statements above.

Derogations

The following substances are specifically exempted from this requirement:

Surfactants < 20 % in the final product	H400 Very toxic to aquatic life	R50
Biocides for preservations purposes (*) (only for liquids with pH between 2 and 12 and maximum 0,10 % w/w of active material)	H331: Toxic if inhaled	R23
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
	H400: Very toxic to aquatic life	R50
Enzymes (**)	H400: Very toxic to aquatic life	R50
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
Bleach catalysts (**)	H400: Very toxic to aquatic life	R50
NTA as an impurity in MGDA and GLDA (***)	H351: Suspected of causing cancer	R40

(*) Derogation is only for criterion 4(b). Biocides shall comply with criterion 4(e).

(**) Including stabilisers and other auxiliary substances in the preparations.

(***) In concentrations lower than 1,0 % in the raw material as long as the total concentration in the final product is lower than 0,10 %.

Assessment and verification: the applicant shall demonstrate compliance with this criterion by providing a declaration on the non-classification of each ingoing substance into any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) No 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII to Regulation (EC) No 1907/2006. This declaration shall be supported by summarised information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in sections 10, 11 and 12 of Annex II to Regulation (EC) No 1907/2006 (Requirements for the Compilation of Safety Data Sheets).

Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as *in vitro* methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI to Regulation (EC) No 1907/2006. The sharing of relevant data is strongly encouraged.

The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.

For substances listed in Annexes IV and V to REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.

(c) Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in mixtures in concentrations > 0,010 %.

Assessment and verification: the list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found at: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.

(d) Specified limited ingoing substances — fragrances

The product shall not contain perfumes containing nitro-musk or polycyclic musk

Any ingoing substance added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: <http://www.ifraorg.org>. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

Fragrance substances subject to the declaration requirement provided for in Regulation (EC) No 648/2004 of the European Parliament and of the Council ⁽¹⁾ on detergents (Annex VII) and which are not already excluded by criterion 4(b) shall not be present in quantities $\geq 0,010$ % (≥ 100 ppm) per substance in the final product.

Assessment and verification: the applicant shall provide a signed declaration of compliance indicating the amount of fragrances in the product. The applicant shall also provide a declaration from the fragrance manufacturer specifying the content of each of the substances in the fragrances which are listed in Annex III, Part I to Council Directive 76/768/EEC ⁽²⁾.

(e) Biocides

- (i) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any biocides added, together with information on their exact concentration in the product. The manufacturer or supplier of the biocides shall provide information on the dosage necessary to preserve the product.

- (ii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

⁽¹⁾ OJ L 104, 8.4.2004, p. 1.

⁽²⁾ OJ L 262, 27.9.1976, p. 169.

Assessment and verification: the applicant shall provide the texts and layouts used on each type of packaging and/or an example of each different type of packaging to the competent body.

- (iii) The product may contain biocides provided that they are not bioaccumulating. A biocide is not considered bioaccumulating if $BCF < 100$ or $\log K_{ow} < 3,0$. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any biocide added, together with information on their BCF and/or $\log K_{ow}$ values.

(f) Enzymes

Enzymes must be in liquid form or dust-free granulate. Enzymes must be free from micro-organism remnants from manufacture.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any enzyme added, together with documentation to ensure that the enzyme is free from micro-organism remnants.

Criterion 5 — Packaging requirements

(a) Weight/utility ratio (WUR)

The weight/utility ratio (WUR) of the product shall not exceed the following values:

Product type/water hardness	WUR (g/kg laundry)		
	Soft water	Medium water	Hard water
Powders	1,5	2,0	2,5
Liquids	2,0	2,5	3,0

WUR shall be calculated only for primary packaging and a calculation shall be made for every product within a multi-component system (including caps, stoppers and hand pumps/spraying devices) using the formula below:

$$WUR = \sum [(W_i + U_i) / (D_i * r_i)]$$

Where:

W_i = the weight (g) of the packaging component (i) including the label if applicable.

U_i = the weight (g) of non-recycled (virgin) material in the packaging component (i). If the proportion of recycled material in the packaging component is 0 % then $U_i = W_i$.

D_i = the number of functional units contained in the packaging component (i). The functional unit = dosage in g/kg laundry. Note that the highest recommended dosage for each water hardness must be used in the WUR calculation.

r_i = recycling figure, i.e. the number of times the packaging component (i) is used for the same purpose through a return or refill system. $r = 1$ if the packaging is not re-used for the same purpose. If the packaging is reused r is set to 1 unless the applicant can document a higher number.

Exceptions

Plastic/paper/cardboard packaging containing more than 80 % recycled material or more than 80 % plastic from renewable origin is exempted from this requirement.

Packaging is regarded as recycled if the raw material used to make the packaging has been collected from packaging manufacturers at the distribution stage or at the consumer stage. Where the raw material is industrial waste from the material manufacturer's own production process, then the material will not be regarded as recycled.

Assessment and verification: the applicant shall provide the calculation of the WUR for every product. A spreadsheet for this calculation is available on the EU Ecolabel website. The applicant shall provide a completed and signed declaration for the content of recycled or material from renewable origin in the packaging. For approval of refill packaging, the applicant and/or retailer shall document that the refills will be/are available for purchase on the market.

(b) Plastic packaging

Only phthalates that at the time of application have been risk assessed and have not been classified according to criterion 4(b) (and combinations hereof) may be used in the plastic packaging.

In order to allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent. Caps and pumps are exempted from this requirement.

Assessment and verification: the applicant shall provide completed and signed declaration of compliance.

Criterion 6 — Washing performance (fitness for use)

The primary laundering effects of the detergent such as dirt removal and stain removal capacity must be documented by the producer/applicant with the aid of artificially soiled test clothes which are washed in the process.

The test may be conducted by an external or internal laboratory fulfilling the requirements in Appendix II(a). The test must be conducted with the recommended dosage and at the corresponding water hardness and the degree of soiling at the lowest recommended wash temperature. The measurements must be performed on unlaundered and laundered test clothes. Evaluation of the test results shall be made by the laboratory and it shall be clearly stated in the report.

The measurements of secondary effects such as bleaching effect, bleaching/damage factor, ash content, greying and fluidity increase can for instance be made with multi wash test clothes and analysed according to standard ISO 4312.

Examples of what may be used as wash test clothes included the following:

- WFK-PCMS-55 for industrial laundering processes, consisting of 13 different small dirt patches (WFK-Cleaning Technology Research Institute, Germany)
- EMPA 102, consisting of 15 different fresh spots (Swiss EMPA-Testmaterials)
- wash clothes of DTI (Danish Technology Institute) for industrial washing processes or equivalent

As an alternative to the above mentioned laboratory test, a user test may be used to document efficiency. The user test should then meet the requirements stated in Appendix II(b).

For both laboratory test and user test the following apply:

The test product must be tested against a reference product. The reference product may be a well-established product on the market or — in the case of a user test — the product normally used by the user. The test product must show efficiency equal to or better than the reference product.

Assessment and verification: the applicant shall provide a test report stating that the product fulfils the minimum requirements defined in the chosen test; also see Appendix II(a) and II(b) respectively.

Criterion 7 — Automatic dosing systems

Multi-component systems shall be offered to the customer together with an automatic and controlled dosing system.

In order to ensure correct dosage in the automatic dosing systems, customer visits must be incorporated as a normal routine for manufacturers/suppliers. These customer visits are performed at all premises at least once a year during the license period; as a minimum they must include calibration of the dosage equipment. A third party can perform customer visits as well.

Assessment and verification: the applicant shall provide a written description of responsibility for, frequency and content of customer visits.

Criterion 8 — User information — Information appearing on the EU Ecolabel

(a) Information on the packaging/product information sheet

The following washing recommendations (or equivalent) must appear on the packaging, and/or on a product information sheet. The washing recommendations must include examples of the classification of the textiles soiling degree and shall include the following text:

- Wash at the lowest recommended temperature
- Always wash with the highest possible load, the textiles allow
- Dose according to the dosing instructions and use the dosage according to water hardness and degree of soiling
- Using this EU Ecolabelled product according to the dosage instructions will contribute to the reduction of water pollution, waste production and energy consumption.

(b) Claims on the packaging

In general, claims on the packaging shall be documented through performance testing (e.g. claims of efficiency at low temperatures, claims of removal of certain stain types, claims of benefits for certain types or colours of textile or other claims of specific properties/benefits of the product).

- E.g. if a product claims efficiency at 20 °C, the performance test must be performed at ≤ 20 °C (and correspondingly for other temperature claims below 40 °C).
- E.g. if a product claims to be efficient on certain stain types, this must be documented with performance test.

(c) Information appearing on the EU Ecolabel

The logo should be visible and legible. The use of the EU Ecolabel logo is protected in primary EU law. The EU Ecolabel registration/license number must appear on the product, it must be legible and clearly visible.

The optional label with text box shall contain the following text:

- Reduced impact on aquatic ecosystems
- Limited hazardous substances
- Performance tested.

The guidelines for the use of the optional label with text box can be found in the 'Guidelines for use of the Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification (a-c): the applicant shall provide a sample of the product label and/or product sheet, together with a declaration of compliance with this criterion. Product claims shall be documented through appropriate test reports.

Appendix I

Detergents Ingredients Database (DID) list

The DID list (part A) is a list containing information of the aquatic toxicity and biodegradability of ingoing substances typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabelled products. The DID list (part A and B) can be found on the EU Ecolabel website.

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

Ingoing substance	Acute toxicity			Chronic toxicity			Degradation		
	LC50/EC50	SF _(acute)	TF _(acute)	NOEC (*)	SF _(chronic) (*)	TF _(chronic)	DF	Aerobic	Anaerobic
'Name'	1 mg/l	10 000	0,0001			0,0001	1	P	N

(*) If no acceptable chronic toxicity data are found, these columns are empty. In that case TF(chronic) is defined as equal to TF(acute).

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

- (1) Until 1 December 2010 and during transition period from 1 December 2010 to 1 December 2015:

The test methods for ready biodegradability provided for in Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10 days window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

- (2) After 1 December 2015 and during transition period from 1 December 2010 to 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008.

Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate degradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

- (1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)).

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- (2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.
 - (3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by ^{14}C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.
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Appendix II

(a) Laboratory test

The analysis laboratory must meet the general requirements pursuant to standard EN ISO 17025 or be an officially GLP-approved analysis laboratory.

The applicant's analysis laboratory/measurement may be approved to conduct analyses and measurements if:

- the authorities monitor the sampling and analysis process, or
- the manufacturer has a quality system incorporating testing and analyses and which is certified in accordance with ISO 9001, or
- the manufacturer can show that there is conformity between a first-time test conducted as a parallel test between an impartial test institution and the manufacturer's own laboratory and that the manufacturer takes samples in accordance with a prescribed sampling plan.

The manufacturer's test laboratory can be approved to conduct testing to document effectiveness if the following additional requirements are met.

- It must be possible for ecolabelling organisations to monitor the performance of testing
- The ecolabelling organisation must have access to all data on the product
- The samples must be made anonymous for the test laboratory
- Performance of the effectiveness test must be described in the quality control system.

(b) User test

1. Responses must be obtained from at least five test centres representing a selection of customers.
 2. The procedure and dosage must conform to the manufacturer's recommendations.
 3. The test period must continue for at least four weeks.
 4. Every test centre must assess the serviceability of the product or multi-component system, dosability, compressibility, rinsing and solubility.
 5. Every test centre must assess the effectiveness of the product or multi-component system by answering questions relating to the following aspects (or similar formulations):
 - (a) ability to launder lightly, moderately or heavily soiled articles to be washed;
 - (b) an assessment of primary laundering effects such as dirt removal, stain removal capacity and bleaching effect must be rated;
 - (c) assessment of secondary laundering effects such as greying of white washing and colour-fastness and staining of coloured washing;
 - (d) assessment of the effect of the rinsing agent on drying, ironing or mangling of the articles to be washed;
 - (e) how satisfied the test subject is with customer visiting arrangements.
 6. The response must be rated on a scale comprising at least three levels, for example, 'insufficiently effective', 'sufficiently effective' or 'very effective'. With regard to how satisfied the test centre is with visit reporting arrangements, the categories must be 'not satisfied', 'satisfied' and 'very satisfied'.
 7. At least five test centres must submit responses. At least 80 % must rate the product as sufficiently effective or very effective on all points (see point 4 and be satisfied or very satisfied with customer visiting arrangements).
 8. All raw data from the test must be specified.
 9. The test procedure must be described in detail.
-

COMMISSION IMPLEMENTING DECISION

of 23 November 2012

on recognition of the ‘Roundtable on Sustainable Palm Oil RED’ scheme for demonstrating compliance with the sustainability criteria under Directives 98/70/EC and 2009/28/EC of the European Parliament and of the Council

(2012/722/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ⁽¹⁾, and in particular Article 18(6) thereof,

Having regard to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels ⁽²⁾ as amended by the Directive 2009/30/EC ⁽³⁾, and in particular Article 7c(6) thereof,

After consulting the Advisory Committee established by Article 25, paragraph 2 of Directive 2009/28/EC,

Whereas:

- (1) Directives 98/70/EC and 2009/28/EC both lay down sustainability criteria for biofuels. Provisions of Articles 7b, 7c of and Annex IV to Directive 98/70/EC are similar to provisions of Articles 17, 18 of and Annex V to Directive 2009/28/EC.
- (2) Where biofuels and bioliquids are to be taken into account for the purposes referred to in Article 17(1)(a), (b) and (c) of Directive 2009/28/EC Member States should require economic operators to show the compliance of biofuels and bioliquids with the sustainability criteria set out in Article 17(2) to (5) of Directive 2009/28/EC.
- (3) Recital 76 of Directive 2009/28/EC states that the imposition of an unreasonable burden on industry should be avoided and voluntary schemes can help create efficient solutions for proving compliance with these sustainability criteria.
- (4) The Commission may decide that a voluntary national or international scheme demonstrates that consignments of biofuel comply with the sustainability criteria set out in Article 17(3) to (5) of Directive 2009/28/EC or that a voluntary national or international scheme to measure greenhouse gas emission savings contains accurate data for the purposes of Article 17(2) of this Directive.

- (5) The Commission may recognise such a voluntary scheme for a period of five years.
- (6) When an economic operator provides proof or data obtained in accordance with a voluntary scheme that has been recognised by the Commission, to the extent covered by the recognition decision, a Member State should not require the supplier to provide further evidence of compliance with the sustainability criteria.
- (7) The ‘Roundtable on Sustainable Palm Oil RED’ scheme was submitted on 10 February 2012 to the Commission with the request for recognition. The scheme covers palm oil based products. The recognised scheme should be made available at the transparency platform established under Directive 2009/28/EC. The Commission should take into account considerations of commercial sensitivity and may decide to only partially publish the scheme.
- (8) Assessment of the ‘Roundtable on Sustainable Palm Oil RED’ scheme found it to adequately cover the sustainability criteria in Article 7b(3), (4) and (5) of Directive 98/70/EC and Article 17(3), (4) and (5) of Directive 2009/28/EC, as well as applying a chain of custody methodology in line with the requirements of Article 7c(1) of Directive 98/70/EC and Article 18(1) of Directive 2009/28/EC.
- (9) The evaluation of the ‘Roundtable on Sustainable Palm Oil RED’ scheme found that it meets adequate standards of reliability, transparency and independent auditing and also complies with the methodological requirements in Annex IV of Directive 98/70/EC and Annex V of Directive 2009/28/EC.
- (10) Any additional sustainability elements covered by the ‘Roundtable on Sustainable Palm Oil RED’ scheme are not part of the consideration of this Decision. These additional sustainability elements are not mandatory to show compliance with sustainability requirements provided for by Directives 98/70/EC and 2009/28/EC.
- (11) The ‘Roundtable on Sustainable Palm Oil RED’ scheme was assessed against legislation in force at the time of the adoption of this Commission Implementing Decision. In the case of relevant changes in the legal basis the Commission will assess the scheme with a view to establish whether the scheme is still adequately covering the sustainability criteria for which it is recognised.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Committee on the Sustainability of Biofuels and Bioliquids,

⁽¹⁾ OJ L 140, 5.6.2009, p. 16.

⁽²⁾ OJ L 350, 28.12.1998, p. 58.

⁽³⁾ OJ L 140, 5.6.2009, p. 88.

HAS ADOPTED THIS DECISION:

Article 1

The voluntary scheme 'Roundtable on Sustainable Palm Oil RED' for which the request for recognition was submitted to the Commission on 10 February 2012 demonstrates that consignments of biofuels comply with the sustainability criteria as laid down in Articles 17(3), 17(4) and 17(5) of Directive 2009/28/EC and Articles 7b(3), 7b(4) and 7b(5) of Directive 98/70/EC. The scheme also contains accurate data for purposes of Article 17(2) of Directive 2009/28/EC and Article 7b(2) of Directive 98/70/EC.

The voluntary scheme 'Roundtable on Sustainable Palm Oil RED' may be used for demonstrating compliance with Article 7c(1) of Directive 98/70/EC and Article 18(1) of Directive 2009/28/EC.

Article 2

The Decision is valid for a period of five years after it enters into force. If the scheme, after adoption of this Decision, undergoes changes to its contents in a way that might affect the basis of this Decision, such changes shall be notified to the

Commission without delay. The Commission shall assess the notified changes with a view to establish whether the scheme is still adequately covering the sustainability criteria for which it is recognised.

If it has been clearly demonstrated that the scheme has not implemented elements considered to be decisive for this Decision and if severe and structural breach of those elements has taken place, the Commission may repeal this Decision.

Article 3

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

Done at Brussels, 23 November 2012.

For the Commission

The President

José Manuel BARROSO

CORRIGENDA**Corrigendum to Council Decision 2009/1017/EU of 22 December 2009 on the granting of State aid by the authorities of the Republic of Hungary for the purchase of agricultural land between 1 January 2010 and 31 December 2013**

(Official Journal of the European Union L 348 of 29 December 2009)

On Page 55, recital 6, second indent, second phrase:

for: 'The grant may be allocated to a private person who, on the date of purchase, was involved in an agricultural activity as the owner of at least 5 hectares of plantations or 1 hectare of other agricultural land...'

read: 'The grant may be allocated to a private person who, on the date of purchase, was involved in an agricultural activity as the owner of at least 0,5 hectares of plantations or 1 hectare of other agricultural land...'.

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