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[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance

I

(Legislative acts)

DIRECTIVES

DIRECTIVE2014/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 May 2014

amending Council Directive 2001/110/EC relating to honey

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Council Directive 2001/110/EC ([3]) defines honey as the natural sweet substance produced by *Apis mellifera* bees ('bees'). Honey consists essentially of different sugars, predominantly fructose and glucose, as well as other substances such as organic acids, enzymes and solid particles derived from honey collection. Directive 2001/110/EC limits human intervention that could alter the composition of honey and thereby allows for the preservation of the natural character of honey. In particular, Directive 2001/110/EC prohibits the addition of any food ingredient to honey, including food additives, and any other addition other than honey. Similarly, that Directive prohibits the removal of any constituent particular to honey, including pollen, unless such removal is unavoidable in the removal of foreign matter. Those requirements are in line with the Codex Alimentarius standard for honey (Codex Stan 12-1981).

(2) Pollen is part of the composition criteria for honey set out in Directive 2001/110/EC. Available evidence, including empiric and scientific data, confirms that bees are the origin of the presence of pollen in honey. Pollen grains fall into nectar which is collected by bees. In the hive, collected nectar containing pollen grains is transformed into honey by bees. According to the available data, additional pollen in honey can come from pollen on bees' hair, from pollen in the air inside the hive and from pollen that was packed in cells by bees and released as a result of the accidental opening of those cells during the extraction of honey by food business operators. Pollen can therefore be said to enter the hive as a result of the activity of bees and is naturally present in honey regardless of whether or not food business operators extract that honey. Furthermore, the deliberate addition of pollen to honey by food business operators is prohibited under Directive 2001/110/EC.

([1]) OJ C 11, 15.1.2013, p. 88.
([2]) Position of the European Parliament of 16 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.
([3]) Council Directive 2001/110/EC of 20 December 2001 relating to honey (OJ L 10, 12.1.2002, p. 47).

(3) Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([1]), defines 'ingredient' as any substance used in the manufacture or preparation of a food and still present in the finished product, even in altered form. That definition implies a deliberate use of a substance in the manufacture or preparation of food. Taking into account the natural character of honey, and in particular the natural origin of the presence of constituents particular to honey, pollen, being a natural constituent particular to honey, should not be considered to be an 'ingredient' of honey within the meaning of Regulation (EU) No 1169/2011.

(4) This Directive is without prejudice to the application of Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([2]) to honey containing genetically modified pollen, since such honey constitutes food produced from genetically modified organisms within the meaning of that Regulation. In Case C-442/09 ([3]), Karl Heinz Bablok and Others v Freistaat Bayern, the Court of Justice of the European Union ruled that the determining criterion for the application of Regulation (EC) No 1829/2003, as set out in recital 16 of that Regulation, is whether material derived from the genetically modified source material is present in food. Honey containing genetically modified pollen should therefore be regarded as being 'food (partially) produced from a GMO' within the meaning of point (c) of Article 3(1) of Regulation (EC) No 1829/2003. Laying down a provision to the effect that pollen is not an ingredient of honey does not therefore affect the Court's conclusion in Case C-442/09 that honey containing genetically modified pollen is subject to Regulation (EC) No 1829/2003, in particular to the requirements thereof concerning authorisation prior to placing on the market, supervision and, where applicable, labelling.

(5) Under the labelling requirements of Regulation (EC) No 1829/2003, there is no obligation to indicate the presence of genetically modified pollen in honey on labels for honey if the following conditions are met: such pollen does not exceed 0,9 % of the honey, and its presence in the honey is adventitious or technically unavoidable. It should be recalled that Directive 2001/18/EC of the European Parliament and of the Council ([4]) provides that Member States may take appropriate measures to avoid the unintended presence of genetically modified organisms in honey.

(6) Under Directive 2001/110/EC, if honey originates in more than one Member State or third country, the mandatory indication of the countries of origin may be replaced by one of the following, as appropriate: 'blend of EC honeys', 'blend of non-EC honeys', 'blend of EC and non-EC honeys'. Following the entry into force of the Treaty of Lisbon, the European Union replaced and succeeded the European Community. It is therefore appropriate to clarify the relevant labelling requirements by replacing the reference to 'EC' by a reference to 'EU'.

(7) Directive 2001/110/EC confers power on the Commission to implement some of its provisions, in particular power to adopt measures necessary for implementation of provisions relating to adaptation to technical progress and for bringing that Directive into line with general Union legislation on foodstuffs. Furthermore, Directive 2001/110/EC confers power on the Commission to adopt methods to permit the verification of the compliance of honey with that Directive. It is necessary to review the scope of that power.

(8) In order to ensure fair commercial practices, to protect consumer interests and to enable the setting out of relevant methods of analysis, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to lay down quantitative parameters for the criterion of 'mainly' as regards the floral or vegetable origin of honey and the minimal content of pollen in filtered honey following removal of foreign inorganic or organic matter. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

([1]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

([2]) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

([3]) 2011 ECR I-07419.

([4]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(9) Following the adoption of Regulation (EC) No 178/2002 of the European Parliament and of the Council [1], which applies to all stages of production, processing and distribution of food and feed at Union and national level, general Union provisions on foodstuffs apply directly to the products covered by Directive 2001/110/EC. It is therefore no longer necessary for the Commission to have power to align the provisions of that Directive to the general Union legislation on foodstuffs. The provisions conferring such power should therefore be deleted.

(10) Following the adoption of Regulation (EU) No 182/2011 of the European Parliament and of the Council [2], it is appropriate to adapt the relevant provisions of Directive 2001/110/EC to that Regulation.

(11) In order to allow Member States to adopt the national laws, regulations and administrative provisions necessary to comply with Directive 2001/110/EC, as amended by this Directive, a transposition period of 12 months should be established. During that period, the requirements of Directive 2001/110/EC, without the amendments introduced by this Directive, remain applicable.

(12) In order to take into account the interests of food business operators who place on the market or label their products in accordance with the requirements applicable before the application of the national provisions transposing Directive 2001/110/EC, as amended by this Directive, it is necessary to establish appropriate transitional measures. Therefore, it should be possible for products placed on the market or labelled before the application of those provisions to continue to be marketed until the exhaustion of stocks.

(13) Directive 2001/110/EC should therefore be amended accordingly.

(14) Since the amendments relating to conferral of power on the Commission concern only the Commission power, they do not need to be transposed by the Member States.

(15) Since the objectives of this Directive, namely to provide that pollen, being a natural constituent particular to honey, should not be considered to be an ingredient of honey, to clarify the labelling requirements for the cases where honey originates in more than one Member State or third country, and to review the scope of the existent power conferred on the Commission, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments

Directive 2001/110/EC is amended as follows:

(1) In Article 2(4), point (a) is replaced by the following:

'(a) the country or countries of origin where the honey has been harvested shall be indicated on the label.

Notwithstanding the first subparagraph, if the honey originates in more than one Member State or third country, the indication of the countries of origin may be replaced with one of the following, as appropriate:

— "blend of EU honeys",

— "blend of non-EU honeys",

— "blend of EU and non-EU honeys".'.

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[2] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 l aying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(2) In Article 2, the following point is added:

'5. Pollen, being a natural constituent particular to honey, shall not be considered to be an ingredient, within the meaning of point (f) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council (*), of the products defined in Annex I to this Directive.

(*) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).'.

(3) Article 4 is replaced by the following:

'Article 4

1. For the purposes of the second paragraph of Article 9 of this Directive, the Commission may, taking into account international standards and technical progress, by means of implementing acts that are in accordance with Regulation (EC) No 882/2004 of the European Parliament and of the Council (*), set out methods of analysis to verify whether honey is compliant with the provisions of this Directive. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 7(2) of this Directive. Until the adoption of such methods, Member States shall, whenever possible, use internationally recognised validated methods of analysis such as those approved by the Codex Alimentarius to verify compliance with the provisions of this Directive.

2. For the purpose of ensuring fair commercial practices and protecting consumer interests and enabling the setting out of relevant methods of analysis, the Commission shall be empowered to adopt delegated acts in accordance with Article 6 to supplement this Directive by laying down the quantitative parameters relating to the following:

(a) the criterion of "mainly" as regards the floral or vegetable origin of honey as referred to in the first indent of Article 2(2)(b); and,

(b) the minimal content of pollen in filtered honey following removal of foreign inorganic or organic matter referred to in point 2(b)(viii) of Annex I.

The Commission shall provide, in those delegated acts, for appropriate transitional arrangements for products placed on the market before the date of application of those delegated acts.

(*) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).'.

(4) Article 6 is replaced by the following:

'Article 6

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 4(2) shall be conferred on the Commission for a period of five years from 23 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 4(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of the delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 4(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months from the date of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'.

(5) Article 7 is replaced by the following:

'*Article 7*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health (the "Committee") established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*). The Committee is a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (**).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).'.

(6) In Annex II, the third paragraph is replaced by the following:

'Without prejudice to point 2(b)(viii) of Annex I, neither pollen nor any other constituent particular to honey, may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter.'.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with points (1), (2) and (6) of Article 1 and Article 3. They shall forthwith communicate to the Commission the text of those measures.

When Member States adopt those measures, 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 apply the measures referred to in paragraph 1 from 24 June 2015.

Article 3

Transitional measures

Products which are placed on the market or labelled before 24 June 2015, in accordance with Directive 2001/110/EC, may continue to be marketed until the exhaustion of stocks.

Article 4

Entry into force

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

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 15 May 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

DECISIONS

DECISION No 585/2014/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 May 2014

on the deployment of the interoperable EU-wide eCall service

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Under Article 3(d) of Directive 2010/40/EU of the European Parliament and of the Council ([3]), the harmonised provision for an interoperable EU-wide eCall service constitutes a priority action (the 'eCall priority action') for the development and use of specifications and standards.

(2) Pursuant to Articles 6 and 7 of Directive 2010/40/EU, the Commission is to adopt delegated acts as regards the specifications necessary to ensure the compatibility, interoperability and continuity for the deployment and operational use of intelligent transport systems ('ITS') for the priority actions.

(3) Commission Delegated Regulation (EU) No 305/2013 ([4]) establishes the specifications for the upgrading of the Public Safety Answering Point (PSAP) infrastructure required for the proper receipt and handling of eCalls using the 112 number, in order to ensure the compatibility, interoperability and continuity of the harmonised EU-wide eCall service.

(4) Pursuant to Directive 2010/40/EU, the Commission is to present at the latest 12 months after the adoption of Delegated Regulation (EU) No 305/2013, where appropriate and after conducting an impact assessment including a cost-benefit analysis, a proposal to the European Parliament and the Council, in accordance with Article 294 of the Treaty on the Functioning of the European Union, on the deployment of the eCall priority action in accordance with the specifications laid down in Delegated Regulation (EU) No 305/2013.

([1]) OJ C 341, 21.11.2013, p. 47.
([2]) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.
([3]) Directive 2010/40/EU of the European Parliament and of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport (OJ L 207, 6.8.2010, p. 1).
([4]) Commission Delegated Regulation (EU) No 305/2013 of 26 November 2012 supplementing Directive 2010/40/EU of the European Parliament and of the Council with regard to the harmonised provision for an interoperable EU-wide eCall (OJ L 91, 3.4.2013, p. 1).

(5) It is expected that, by reducing the response time of the emergency services, the interoperable EU-wide eCall service will reduce the number of fatalities in the Union as well as the severity of injuries caused by road accidents. The interoperable EU-wide eCall service is also expected to bring savings to society by improving incident management and by reducing road congestion and secondary accidents.

(6) In order to ensure the full functionality, compatibility, interoperability, continuity and conformity of the service throughout the Union, and to reduce the costs of implementation for the Union as a whole, all Member States should deploy the eCall priority action in accordance with the common specifications established in Delegated Regulation (EU) No 305/2013. That should be without prejudice to the right of each Member State to deploy additional technical means to handle other emergency calls.

(7) Member States should ensure that data transmitted via the EU-wide eCall service are used exclusively to attain the objectives of this Decision.

(8) As experience with other emergency calls systems has demonstrated, manually triggered eCalls may include a share of assistance calls. If necessary, Member States should be able to implement all appropriate technical and organisational means in order to filter those assistance calls so as to ensure that only real emergency calls are handled by eCall PSAPs.

(9) Since not all Union citizens are familiar with the use of the EU-wide eCall service, its deployment should be preceded by an awareness-raising campaign supported by the Commission, explaining to citizens the benefits, functionalities and data protection safeguards of the new system. The campaign should take place in Member States and should aim at informing users on how to use the system properly and how to avoid false alarms.

(10) In line with the recommendations made by the Working Party on the Protection of Individuals with regard to the Processing of Personal Data (the 'Article 29 Data Protection Working Party') in its Working document on data protection and privacy implications in eCall initiative, adopted on 26 September 2006, when deploying the eCall PSAP infrastructure, Member States are to ensure that the processing of personal data in the context of handling eCalls fully complies with the personal data protection rules provided for in Directive 95/46/EC of the European Parliament and of the Council [1] and in Directive 2002/58/EC of the European Parliament and of the Council [2].

(11) Since eCalls are emergency calls, as defined in Delegated Regulation (EU) No 305/2013, the handling of those calls should be provided free of charge to users of the EU-wide eCall service.

(12) Depending on the organisation of the handling of emergency calls in each Member State, such calls can be first received under the responsibility of a public authority or a private organisation recognised by the Member State concerned. In particular, eCalls can be dealt with in a different way depending on the type of eCall activation (manual or automatic).

(13) In accordance with national procedures determined by the national authority concerned, data can be transferred to service partners, defined as public or private organisations recognised by national authorities that play a role in the handling of incidents related to eCalls (including road operators and assistance services), which should be subject to the same privacy and data protection rules as are applicable to the eCall PSAPs.

(14) Since the objectives of this Decision, namely to ensure the coordinated and coherent deployment of the interoperable EU-wide eCall service and to guarantee the full functionality, compatibility, interoperability, continuity and conformity of the service throughout Europe, cannot be sufficiently achieved by the Member States and/or the private sector but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives,

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[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[2] Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

HAVE ADOPTED THIS DECISION:

Article 1

1. Member States shall deploy on their territory, at least six months before the date of application of the Regulation of the European Parliament and of the Council concerning the type-approval requirements for the deployment of the eCall in-vehicle system and amending Directive 2007/46/EC and in any case no later than 1 October 2017, the eCall PSAP infrastructure required for the proper receipt and handling of all eCalls, if necessary purged of non-emergency calls, in accordance with the specifications laid down in Delegated Regulation (EU) No 305/2013, in order to ensure the full functionality, compatibility, interoperability, continuity and conformity of the interoperable EU-wide eCall service.

2. Paragraph 1 is without prejudice to the right of each Member State to organise its emergency services in a way which is most cost-effective and most appropriate to its needs, including the ability to reject calls that are not emergency calls and might not be handled by eCall PSAPs, in particular in the case of manually triggered eCalls.

This paragraph and paragraph 1 are without prejudice to the right of each Member State to allow private organisations recognised by it to deal with the receipt and handling of some or all eCalls, in accordance with the specifications laid down in Delegated Regulation (EU) No 305/2013.

3. Member States shall ensure that data transmitted via the eCall service are used exclusively for the attainment of the objectives of this Decision.

Article 2

Member States shall ensure that the handling of eCalls is provided free of charge to users of the EU-wide eCall service.

Article 3

By 24 December 2015, Member States shall report to the Commission on the state of implementation of this Decision. In their reports, they shall include at least the list of competent authorities entrusted with the assessment of the conformity of operations of the eCall PSAPs with the requirements listed in Article 3 of Delegated Regulation (EU) No 305/2013, the list and geographical coverage of the eCall PSAPs, the description of the conformance tests and the description of the privacy and data protection protocols.

Article 4

Member States shall ensure that eCalls can originate from anywhere in their territory, provided there is at least one public mobile wireless communications network available.

Article 5

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

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 15 May 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 586/2014

of 2 June 2014

derogating from Council Regulation (EC) No 1967/2006 as regards the prohibition to fish above protected habitats and the minimum distance from the coast and depth for the 'gangui' trawlers fishing in certain territorial waters of France (Provence-Alpes-Côte d'Azur)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1967/2006 of 21 December 2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea ([1]), and in particular Articles 4(5) and 13(5) and (10) thereof,

Whereas:

(1) Article 4(1) of Regulation (EC) No 1967/2006 prohibits fishing with trawl nets, dredges, purse seines, boat seines, shore seines or similar nets above seagrass beds of, in particular, *Posidonia oceanica* or other marine phanerogams.

(2) The Commission may allow a derogation from Article 4(1) of Regulation (EC) No 1967/2006, provided that the conditions set out in Article 4(5) are fulfilled.

(3) Article 13(1) of Regulation (EC) No 1967/2006 prohibits the use of towed gears within 3 nautical miles of the coast or within the 50 m isobath where that depth is reached at a shorter distance from the coast.

(4) At the request of a Member State, the Commission may allow a derogation from Article 13(1) of Regulation (EC) No 1967/2006, provided that the conditions set out in Article 13(5) and(9) are fulfilled.

(5) On 18 May 2011 the Commission received a request from France for a derogation from the first subparagraph of Article 4(1), from the first subparagraph of Article 13(1) and from Article 13(2) of that Regulation, for the use of 'gangui' trawlers in certain sea areas situated within the territorial waters of France, above seagrass beds of *Posidonia oceanica* and within 3 nautical miles from the coast, irrespective of the depth.

(6) France provided up-to-date scientific and technical justifications for the derogations.

(7) The Scientific, Technical and Economic Committee for Fisheries (STECF) assessed the derogation requested by France and the related draft management plan at its plenary session held from 11 to 15 July 2011.

(8) The derogations requested by France comply with the conditions laid down in Article 4(5) and in Article 13(5) and (9) of Regulation (EC) No 1967/2006.

([1]) OJ L 36, 8.2.2007, p. 6.

(9) The request concerns fishing activities by vessels of less than or equal to 12 meters overall length and engine power of less than or equal to 85 kW with bottom towed nets traditionally undertaken on Posidonia beds, in accordance with the first subparagraph of Article 4(5) of Regulation (EC) No 1967/2006.

(10) The fishing activities concerned affect approximately 27,5 % of the area covered by seagrass beds of *Posidonia oceanica* within the area covered by the management plan and 9 % of seagrass beds in the territorial waters of France, in line with the requirements of points (ii) and (iii) of the first subparagraph of Article 4(5) of Regulation (EC) No 1967/2006.

(11) There are specific geographical constraints given the limited size of the continental shelf.

(12) The fishery has no significant impact on marine environment.

(13) The derogation requested by France affects a limited number of only 36 vessels.

(14) The fishery conducted with 'gangui' trawlers target a wide variety of species which correspond to an ecological niche; the catch composition of this fishery, in particular as regards the number of species caught, is not reflected in any other fishing gear. Therefore, the fishery cannot be undertaken with other gears.

(15) The management plan guarantees no future increase in the fishing effort, as fishing authorisations will be issued only to specified 36 vessels involving a total effort of 1 745 kW that are already authorised to fish by France.

(16) The request covers vessels with a track record in the fishery of more than five years and which operate under a management plan adopted by France on 15 April 2014 ([1]) in accordance with Article 19(2) of Regulation (EC) No 1967/2006.

(17) Those vessels are included on a list communicated to the Commission in line with the requirements of Article 13(9) of Regulation (EC) No 1967/2006.

(18) The fishing activities concerned fulfil the requirements of Article 4, Article 8(1)(h) and Article 9(3) of Regulation (EC) No 1967/2006.

(19) The fishing activities concerned fulfil the recording requirements set out in Article 14 of Council Regulation (EC) No 1224/2009 ([2]).

(20) The fishing activities concerned do not interfere with the activities of vessels using gears other than trawls, seines or similar towed nets.

(21) The activity of 'gangui' trawlers is regulated in the French management plan to ensure that catches of species mentioned in Annex III to Regulation (EC) No 1967/2006 are minimal.

(22) 'Gangui' trawlers do not target cephalopods.

(23) The French management plan includes measures for the monitoring of fishing activities, as provided for in the fifth subparagraph of Article 4(5) and in the third subparagraph of Article 13(9) of Regulation (EC) No 1967/2006.

(24) The requested derogations should therefore be granted.

(25) France should report to the Commission in due time and in accordance with the monitoring plan provided for in the French management plan.

([1]) Reference JORF No 0101, 30.4.2014, p. 7452.

([2]) Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

(26) A limitation in duration of the derogation should be established in order to allow prompt corrective management measures in case the report to the Commission shows a poor conservation status of the exploited stock while providing scope to improve the scientific basis for an improved management plan.

(27) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Derogations

Articles 4(1) and 13(1) and (2) of Regulation (EC) No 1967/2006 shall not apply in territorial waters of France adjacent to the coast of the Provence-Alpes- Côte d'Azur region to 'gangui' trawlers:

(a) bearing the registration number mentioned in the French management plan;

(b) having a track record in the fishery of more than five years and not involving any future increase in the fishing effort deployed; and

(c) holding a fishing authorisation and operating under the management plan adopted by France in accordance with Article 19(2) of Regulation (EC) No 1967/2006.

Article 2

Monitoring plan and reporting

France shall communicate to the Commission, within three years following the entry into force of this Regulation, a report drawn up in accordance with the monitoring plan established in the management plan referred to in Article 1(c).

Article 3

Entry into force and period of application

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

It shall apply until 6 June 2017.

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

Done at Brussels, 2 June 2014.

For the Commission
The President
José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 587/2014

of 2 June 2014

derogating from Council Regulation (EC) No 1967/2006 as regards the minimum distance from the coast and depth for shore seines fishing in certain territorial waters of France (Languedoc-Roussillon and Provence-Alpes-Côte d'Azur)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1967/2006 of 21 December 2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea [1], and in particular Article 13(5) thereof,

Whereas:

(1) Article 13(1) of Regulation (EC) No 1967/2006 prohibits the use of towed gears within 3 nautical miles of the coast or within the 50 m isobath where that depth is reached at a shorter distance from the coast.

(2) At the request of a Member State, the Commission may allow a derogation from Article 13(1) of Regulation (EC) No 1967/2006, provided that a number of conditions set out in Article 13(5) and (9) are fulfilled.

(3) On 1 October 2013 the Commission received a request from France for a derogation from the first subparagraph of Article 13(1) of that Regulation, for the use of shore seines in certain sea areas situated within the territorial waters of France, irrespective of the depth.

(4) France provided up-to-date scientific and technical justifications for the derogation.

(5) The Scientific, Technical and Economic Committee for Fisheries (STECF) assessed the derogation requested by France and the related draft management plan at its plenary session held from 4 to 8 November 2013.

(6) The derogation requested by France complies with the conditions laid down in Article 13(5) and (9) of Regulation (EC) No 1967/2006.

(7) There are specific geographical constraints given the limited size of the continental shelf.

(8) The shore seines fishery has no significant impact on marine environment.

(9) The derogation requested by France affects a limited number of only 23 vessels.

(10) Shore seine fishing is carried out from the shore in shallow depths and targets a variety of species. The nature of this type of fishery is such that it cannot be undertaken with any other gear.

(11) The management plan guarantees no future increase in the fishing effort, as fishing authorisations will be issued to specified 23 vessels involving a total effort of 1 225 Kw that are already authorised to fish by France.

(12) The request covers vessels with a track record in the fishery of more than five years and which operate under a management plan adopted by France on 15 April 2014 [2] in accordance with Article 19(2) of Regulation (EC) No 1967/2006.

(13) Those vessels are included on a list communicated to the Commission in line with the requirements of Article 13(9) of Regulation (EC) No 1967/2006.

(14) The fishing activities concerned fulfil the requirements of Article 4 of Regulation (EC) No 1967/2006 since the French management plan explicitly prohibits to fish above protected habitats.

(15) The requirement of Article 8(1)(h) of Regulation (EC) No 1967/2006 are not applicable since they relate to trawlers.

[1] OJ L 36, 8.2.2007, p. 6.
[2] Reference JORF No 0101, 30.4.2014, p. 7452.

(16) As regards the requirement to comply with Article 9(3) establishing the minimum mesh size, the Commission notes that given the fishing activities concerned are highly selective, have a negligible effect on the marine environment and are not carried out above protected habitats, in line with Article 9(7) of Regulation (EC) No 1967/2006 France authorised a derogation from these provisions in its management plan.

(17) The fishing activities concerned fulfil the recording requirements set out in Article 14 of Council Regulation (EC) No 1224/2009 ([1]).

(18) The fishing activities concerned do not interfere with the activities of vessels using gears other than trawls, seines or similar towed nets.

(19) The activity of shore seines is regulated in the French management plan to ensure that catches of species mentioned in Annex III to Regulation (EC) No 1967/2006 are minimal.

(20) Shore seines do not target cephalopods.

(21) The French management plan includes measures for the monitoring of fishing activities, as provided for in the third subparagraph of Article 13(9) of Regulation (EC) No 1967/2006.

(22) The requested derogation should therefore be granted.

(23) France should report to the Commission in due time and in accordance with the monitoring plan provided for in the French management plan.

(24) Article 15(11) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council ([2]) requires that for the species subject to the landing obligation as specified in Article 15(1) of the same Regulation, the use of catches of species below the minimum conservation reference size shall be restricted to purposes other than direct human consumption.

(25) The French management plan includes a derogation to the minimum size of marine organisms for fries of sardine landed for human consumption and targeted by the fishing activities regulated therein, in accordance with Article 15(3) of Regulation (EC) No 1967/2006.

(26) A limitation in duration of the derogation should be introduced, to reflect the calendar of the entry into force of the landing obligation as defined in Article 15(1) of Regulation (EU) No 1380/2013.

(27) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

Derogation

Article 13(1) of Regulation (EC) No 1967/2006 shall not apply in territorial waters of France adjacent to the coast of Languedoc-Roussillon and Provence-Alpes-Côte d'Azur to shore seines used by vessels:

(a) bearing the registration number mentioned in the French management plan;

(b) having a track record in the fishery of more than five years and not involving any future increase in the fishing effort deployed; and

(c) holding a fishing authorisation and operating under the management plan adopted by France in accordance with Article 19(2) of Regulation (EC) No 1967/2006.

([1]) Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

([2]) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

Article 2

Monitoring plan and reporting

France shall communicate to the Commission, within one year following the entry into force of this Regulation, a report drawn up in accordance with the monitoring plan established in the management plan referred to in Article 1(c).

Article 3

Entry into force and period of application

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

It shall apply until 31 December 2014.

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

Done at Brussels, 2 June 2014.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 588/2014

of 2 June 2014

amending Annexes III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for orange oil, *Phlebiopsis gigantea*, gibberellic acid, *Paecilomyces fumosoroseus* strain FE 9901, *Spodoptera littoralis* nucleopolyhedrovirus, *Spodoptera exigua* nuclear polyhedrosis virus, *Bacillus firmus* I-1582, s-abscisic acid, L-ascorbic acid and *Helicoverpa armigera* nucleopolyhedrovirus in or on certain products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 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 ([1]), and in particular Article 5(1) thereof,

Whereas:

(1) For gibberellic acid maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For *Phlebiopsis gigantea*, *Paecilomyces fumosoroseus* strain FE 9901, *Spodoptera littoralis* nucleopolyhedrovirus, *Spodoptera exigua* nuclear polyhedrosis virus, *Bacillus firmus* I-1582, orange oil, s-abscisic acid, L-ascorbic acid and *Helicoverpa armigera* nucleopolyhedrovirus, no specific MRLs were set nor were the substances included in Annex IV to Regulation (EC) No 396/2005, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) of that Regulation applies'.

(2) As regards *Phlebiopsis gigantea* ([2]), *Paecilomyces fumosoroseus* strain FE 9901 ([3]), *Spodoptera littoralis* nucleopolyhedrovirus ([4]), *Spodoptera exigua* nuclear polyhedrosis virus ([5]), *Bacillus firmus* I-1582 ([6]) and *Helicoverpa armigera* nucleopolyhedrovirus ([7]) the European Food Safety Authority, (the Authority) concluded that these substances are not pathogenic to humans and do not require a quantitative consumer risk assessment. In view of that conclusion, the Commission considers that the inclusion of such substances in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(3) For orange oil ([8]), the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Orange oil is naturally occurring in plants and is used as a flavouring agent for medicine and food. In view of this it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of EFSA's reasoned opinion in accordance with Article 12(1).

([1]) OJ L 70, 16.3.2005, p. 1.
([2]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Phlebiopsis gigantea*. *EFSA Journal* 2013;11(1):3033. [31 pp.] doi:10.2903/j.efsa.2013.3033.
([3]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Paecilomyces fumosoroseus* strain FE 9901. *EFSA Journal* 2012;10(9):2869. [26 pp.] doi:10.2903/j.efsa.2012.2869.
([4]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Spodoptera littoralis* nucleopolyhedrovirus. *EFSA Journal* 2012;10(9):2864. [33 pp.] doi:10.2903/j.efsa.2012.2864.
([5]) EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). *EFSA Journal* 2013;11(11):3449, 108 pp. doi:10.2903/j.efsa.2013.3449.
([6]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus firmus* I-1582. *EFSA Journal* 2012;10(10):2868. [33 pp.] doi:10.2903/j.efsa.2012.2868.
([7]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Helicoverpa armigera* nucleopolyhedrovirus. *EFSA Journal* 2012;10(9):2865. [31 pp.] doi:10.2903/j.efsa.2012.2865.
([8]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance orange oil. *EFSA Journal* 2013;11(2):3090. [55 pp.] doi:10.2903/j.efsa.2013.3090.

(4) For gibberellic acid ([1]), the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Gibberellic acid is naturally occurring in a wide range of plants. The Authority did not propose MRLs for grapes as residues were shown to be below the LOQ in treated and control samples and since it would not be possible to distinguish between exogenous and natural occurring gibberellins. In view of these reasons it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of EFSA's reasoned opinion in accordance with Article 12(1).

(5) For s-abscisic acid ([2]), the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. S-abscisic acid is naturally occurring in plants. In view of this it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of EFSA's reasoned opinion in accordance with Article 12(1).

(6) As regards L-ascorbic acid, the Authority concluded ([3]) that its inclusion in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(7) Based on the scientific opinion and conclusions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the relevant requirements of Article 5(1) and Article 14(2) of Regulation (EC) No 396/2005.

(8) Regulation (EC) No 396/2005 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

1. In Annex III to Regulation (EC) No 396/2005 the column for gibberellic acid is deleted.

2. In Annex IV, the entries: 'orange oil (*)', '*Phlebiopsis gigantea*', 'gibberellic acid (*)', '*Paecilomyces fumosoroseus* strain FE 9901', '*Spodoptera littoralis* nucleopolyhedrovirus', '*Spodoptera exigua* nuclear polyhedrosis virus', '*Bacillus firmus* I-1582', 's-abscisic acid (*)', 'L-ascorbic acid', and '*Helicoverpa armigera* nucleopolyhedrovirus' are added, in alphabetical order.

(*) Substances temporarily included in Annex IV, pending finalisation of their evaluation under Directive. 91/414/EEC and pending submission of EFSA's reasoned opinion in accordance with Article 12(1).

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, 2 June 2014.

For the Commission
The President
José Manuel BARROSO

([1]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance gibberellic acid. *EFSA Journal* 2012;10(1):2507. [45 pp.] doi:10.2903/j.efsa.2012.2507.
([2]) European Food Safety Authority, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance S-abscisic acid. *EFSA Journal* 2013;11(8):3341, 78 pp. doi:10.2903/j.efsa.2013.3341.
([3]) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance L-ascorbic acid. *EFSA Journal* 2013;11(4):3197. [54 pp.] doi:10.2903/j.efsa.2013.3197.

COMMISSION REGULATION (EU) No 589/2014

of 2 June 2014

laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([1]), and in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 ([2]) provides for maximum levels for non-dioxin-like PCBs, dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs in certain foodstuffs.

(2) Commission Recommendation 2013/711/EU ([3]) sets out action levels in order to stimulate a pro-active approach to reduce the presence of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like PCBs in food. Those action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination.

(3) Commission Regulation (EU) No 252/2012 of 21 March 2012 ([4]) establishes specific provisions concerning the sampling procedure and the methods of analysis to be applied for the official control.

(4) The provisions laid down in this Regulation relate only to the sampling and analysis of dioxins, dioxin-like PCBs and non-dioxin-like PCBs for the implementation of Regulation (EC) 1881/2006 and Recommendation 2013/711/EU. They do not affect the sampling strategy, sampling levels and frequency as specified in Annexes III and IV to Council Directive 96/23/EC ([5]). They do not affect the targeting criteria for sampling as laid down in Commission Decision 98/179/EC ([6]).

(5) A screening method of analysis with widely acceptable validation and high throughput can be used to identify the samples with significant levels of PCDD/Fs and dioxin-like PCBs (preferably selecting samples exceeding action levels and ensuring the selection of samples exceeding maximum levels). The levels of PCDD/Fs and dioxin-like PCBs in these samples need to be determined by a confirmatory method of analysis. It is therefore appropriate to establish appropriate requirements for the screening method making sure that the false-compliant rate with respect to maximum levels is below 5 % and strict requirements for the confirmatory methods of analysis. Furthermore, confirmatory methods with sufficient sensitivity allow the determination of levels also in the low background range. That is important for to follow time trends, exposure assessment and for the re-evaluation of maximum and action levels.

(6) For the sampling of very large fish, it is necessary that the sampling is specified in order to ensure a harmonised approach throughout the Union.

([1]) OJ L 165, 30.4.2004, p. 1.

([2]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([3]) Commission Recommendation 2013/711/EU of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food (OJ L 323, 4.12.2013, p. 37).

([4]) Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006 (OJ L 84, 23.3.2012, p. 1).

([5]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

([6]) Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products (OJ L 65, 5.3.1998, p. 31).

(7) In fish of the same species originating from the same region, the level of dioxins, dioxin-like PCBs and non-dioxin-like PCBs can be different depending on the size and/or the age of the fish. Moreover, the level of dioxins, dioxin-like PCBs and non-dioxin-like PCBs is not necessarily the same in all parts of the fish. Therefore, it is necessary that the sampling and sample preparation is specified in order to ensure a harmonised approach throughout the Union.

(8) It is important that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach throughout the Union.

(9) In addition to the gas chromatography/high resolution mass spectrometry (GC-HRMS), technical progress and developments have shown that also gas chromatography/tandem mass spectrometry (GC-MS/MS) can be used as a confirmatory method for checking compliance with the maximum level (ML). Regulation (EU) No 252/2012 should therefore be replaced by a new Regulation providing for the use of gas chromatography/tandem mass spectrometry (GC-MS/MS) as an appropriate confirmatory method for checking compliance with the maximum level.

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

HAS ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the definitions and abbreviations set out in Annex I shall apply.

Article 2

Sampling for the official control of the levels of dioxins, furans, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the methods set out in Annex II to this Regulation.

Article 3

Sample preparation and analyses for the control of the levels of dioxins, furans and dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the methods set out in Annex III to this Regulation.

Article 4

Analyses for the control of the levels of non-dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the requirements for methods of analysis set out in Annex IV to this Regulation.

Article 5

Regulation (EU) No 252/2012 is hereby repealed.

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

Article 6

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

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

Done at Brussels, 2 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

DEFINITIONS AND ABBREVIATIONS

I. DEFINITIONS

For the purposes of this Regulation the definitions laid down in Annex I to Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results ([1]) shall apply.

Further to these definitions, the following definitions shall apply for the purposes of this Regulation:

1.1. 'Action level' means the level of a given substance, as laid down in Annex to Recommendation 2013/711/EU, which triggers investigations to identify the source of that substance in cases where increased levels of the substance are detected.

1.2. 'Screening methods' means methods used for selection of those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels or the action levels. They shall allow a cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks to consumers. Screening methods shall be based on bioanalytical or GC-MS methods. Results from samples exceeding the cut-off value to check compliance with the maximum level shall be verified by a full re-analysis from the original sample by a confirmatory method.

1.3. 'Confirmatory methods' means methods that provide full or complementary information enabling the PCDD/Fs and dioxin-like PCBs to be identified and quantified unequivocally at the maximum or in case of need at the action level. Such methods utilise gas chromatography/high resolution mass spectrometry (GC-HRMS) or gas chromatography/tandem mass spectrometry (GC-MS/MS).

1.4. 'Bioanalytical methods' means methods based on the use of biological principles like cell-based assays, receptor-assays or immunoassays. They do not give results at the congener level but merely an indication ([2]) of the TEQ level, expressed in Bioanalytical Equivalents (BEQ) to acknowledge the fact that not all compounds present in a sample extract that produce a response in the test may obey all requirements of the TEQ-principle.

1.5. 'Bioassay apparent recovery' means the BEQ level calculated from the TCDD or PCB 126 calibration curve corrected for the blank and then divided by the TEQ level determined by the confirmatory method. It attempts to correct factors like the loss of PCDD/PCDFs and dioxin-like compounds during the extraction and clean-up steps, co-extracted compounds increasing or decreasing the response (agonistic and antagonistic effects), the quality of the curve fit, or differences between the TEF and the REP values. The bioassay apparent recovery is calculated from suitable reference samples with representative congener patterns around the maximum or action level.

1.6. 'Semi-quantitative methods' means methods which give an approximate indication of the concentration of the putative analyte, while the numerical result does not meet the requirements for quantitative methods.

1.7. 'Accepted specific limit of quantification of an individual congener in a sample' means the lowest content of the analyte that can be measured with reasonable statistical certainty, fulfilling the identification criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC/HRMS and of indicator PCBs by GC/HRMS) and/or in EPA methods 1613 and 1668 as revised.

The limit of quantification of an individual congener may be identified as

(a) the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with a S/N (signal/noise) ratio of 3:1 for the less intensive raw data signal;

or, if for technical reasons the signal-to-noise calculation does not provide reliable results,

(b) The lowest concentration point on a calibration curve that gives an acceptable (≤ 30 %) and consistent (measured at least at the start and at the end of an analytical series of samples) deviation to the average relative response factor calculated for all points on the calibration curve in each series of samples ([3]).

([1]) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8).

([2]) Bioanalytical methods are not specific to those congeners included in the TEF-scheme. Other structurally related AhR-active compounds may be present in the sample extract which contribute to the overall response. Therefore, bioanalytical results cannot be an estimate but rather an indication of the TEQ level in the sample.

([3]) The LOQ is calculated from the lowest concentration point taking into account the recovery of internal standards and sample intake.

1.8. 'Upper-bound' means the concept which requires using the limit of quantification for the contribution of each non-quantified congener.

1.9. 'Lower-bound' means the concept which requires using zero for the contribution of each non-quantified congener.

1.10. 'Medium-bound' means the concept which requires using half of the limit of quantification calculating the contribution of each non-quantified congener.

1.11. 'Lot' means an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish and fishery products, also the size of fish shall be comparable. In case the size and/or weight of the fish is not comparable within a consignment, the consignment may still be considered as a lot but a specific sampling procedure has to be applied.

1.12. 'Sublot' means designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.

1.13. 'Incremental sample' means a quantity of material taken from a single place in the lot or sublot.

1.14. 'Aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot.

1.15. 'Laboratory sample': a representative part/quantity of the aggregate sample intended for the laboratory.

II. ABBREVIATIONS USED

BEQ	Bioanalytical Equivalents
GC	Gas chromatography
HRMS	High resolution mass spectrometry
LRMS	Low resolution mass spectrometry
MS/MS	Tandem mass spectrometry
PCB	Polychlorinated biphenyls
PCDD	Polychlorinated dibenzo-p-dioxins
PCDF	Polychlorinated dibenzofurans
QC	Quality control
REP	Relative potency
TEF	Toxic Equivalency Factor
TEQ	Toxic Equivalents
TCDD	Tetrachlorodibenzodioxin
U	Expanded measurement uncertainty

ANNEX II

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF LEVELS OF DIOXINS (PCDD/PCDF), DIOXIN-LIKE PCBs AND NON-DIOXIN-LIKE PCBs IN CERTAIN FOODSTUFFS

I. SCOPE

Samples intended for the official control of the levels of dioxins (PCDD/PCDF), dioxin-like PCBs and non-dioxin-like PCBs, hereafter referred to as dioxins and PCBs, in foodstuffs shall be taken according to the methods described in this Annex. Aggregate samples thus obtained shall be considered as representative of the lots or sublots from which they are taken. Compliance with maximum levels laid down in Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs shall be established on the basis of the levels determined in the laboratory samples.

II. GENERAL PROVISIONS

1. **Personnel**

Sampling shall be performed by an authorised person as designated by the Member State.

2. **Material to be sampled**

Each lot or sublot, which is to be examined, shall be sampled separately.

3. **Precautions to be taken**

In the course of sampling and preparation of the samples, precautions shall be taken to avoid any changes, which would affect the content of dioxins and PCBs, adversely affect the analytical determination or make the aggregate samples unrepresentative.

4. **Incremental samples**

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from such procedure shall be recorded in the record provided for under point II.8 of this Annex.

5. **Preparation of the aggregate sample**

The aggregate sample shall be made up by combining the incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled or when the product has a very high commercial value.

6. **Replicate samples**

The replicate samples for enforcement, defence and reference purposes shall be taken from the homogenised aggregate sample, unless such procedure conflicts with Member States' rules as regard the rights of the food business operator. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

7. **Packaging and transmission of samples**

Each sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample, which might arise during transportation or storage.

8. **Sealing and labelling of samples**

Each sample taken for official use shall be sealed at the place of sampling and identified following the rules of the Member States.

A record shall be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

III. SAMPLING PLAN

The sampling method applied shall ensure that the aggregate sample is representative for the (sub)lot that is to be controlled.

1. **Division of lots into sublots**

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

Table 1

Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 50 and ≤ 300	100 tonnes
< 50	—

Table 2

Subdivision of lots into sublots for other products

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

2. **Number of incremental samples**

The aggregate sample uniting all incremental samples shall be at least 1 kg (see point II.5 of this Annex).

The minimum number of incremental samples to be taken from the lot or sublot shall be as given in Tables 3 and 4.

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

The incremental samples shall be of similar weight. The weight of an incremental sample shall be at least 100 grams.

Departure from this procedure must be recorded in the record provided for under point II.8 of this Annex. In accordance with the provisions of Decision 97/747/EC fixing the levels and frequencies of sampling provided for by Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products, the aggregate sample size for hen eggs is at least 12 eggs (for bulk lots as well for lots consisting of individual packages, tables 3 and 4 shall apply).

Table 3

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

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

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

Table 4

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

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

3. **Specific provisions for the sampling of lots containing whole fishes of comparable size and weight**

Fishes are considered as being of comparable size and weight in case the difference in size and weight does not exceed about 50 %.

The number of incremental samples to be taken from the lot are defined in Table 3. The aggregate sample uniting all incremental samples shall be at least 1 kg (see point II.5).

— In case the lot to be sampled contains small fishes (individual fishes weighing < about 1 kg), the whole fish is taken as incremental sample to form the aggregate sample. In case the resulting aggregate sample weighs more than 3 kg, the incremental samples may consist of the middle part, weighing each at least 100 grams, of the fishes forming the aggregate sample. The whole part to which the maximum level is applicable is used for homogenisation of the sample.

  The middle part of the fish is where the centre of gravity is. This is located in most cases at the dorsal fin (in case the fish has a dorsal fin) or halfway between the gill opening and the anus.

— In case the lot to be sampled contains larger fishes (individual fishes weighing more than about 1 kg), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams.

  For fishes of intermediate size (about 1-6 kg) the incremental sample is taken as a slice of the fish from backbone to belly in the middle part of the fish.

  For very large fishes (e.g. > about 6 kg), the incremental part is taken from the right side (frontal view) dorsolateral muscle meat in the middle part of the fish In case the taking of such a piece of the middle part of the fish would result in a significant economic damage, taking of three incremental samples of at least 350 grams each may be considered as being sufficient, independently of the size of the lot or alternatively an equal part of the muscled meat close to the tail part and the muscle meat close to the head part of one fish may be taken to form the incremental sample being representative for the level of dioxins in the whole fish.

4. **Sampling of lots of fish containing whole fishes of different size and/or weight**

— The provisions of point III.3 as regards sample constitution shall apply.

— In case a size or weight class/category is predominant (about 80 % or more of the lot), the sample is taken from fishes with the predominant size or weight. This sample is to be considered as being representative for the whole lot.

— In case no particular size or weight class/category predominates, then it must be ensured that the fishes selected for the sample are representative for the lot. Specific guidance for such cases is provided in 'Guidance on sampling of whole fishes of different size and/or weight' ([1]).

5. **Sampling at retail stage**

Sampling of foodstuffs at retail stage shall be done where possible in accordance with the sampling provisions set out in point III.2 of this Annex.

([1]) http://ec.europa.eu/food/food/chemicalsafety/contaminants/dioxins_en.htm

Where this is not possible, an alternative method of sampling at retail stage may be used provided that it ensures sufficient representativeness for the sampled lot or sublot.

IV. COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

1. **As regards non-dioxin-like PCBs**

The lot is accepted, if the analytical result does not exceed the maximum level of non-dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty.

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound analytical result confirmed by duplicate analysis (*), exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty. The mean of the two determinations, taking into account the measurement uncertainty is used for verification of compliance.

The measurement uncertainty may be taken into account according to one of the following approaches:

— by calculating the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the measured value minus U is above the established permitted level,

— by establishing the decision limit (CCα) according to the provisions of Commission Decision 2002/657/EC (point 3.1.2.5 of the Annex I to that Decision — the case of substances with an established permitted level). A lot or sublot is non-compliant if the measured value is equal to or above the CCα.

The abovementioned rules shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

2. **As regards dioxins (PCDD/PCDF) and dioxin-like PCBs**

The lot is accepted, if the result of a single analysis

— performed by a screening method with a false-compliant rate below 5 % indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006,

— performed by a confirmatory method does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty.

For screening assays a cut-off value shall be established for the decision on the compliance with the respective maximum levels set for either PCDD/Fs, or for the sum of PCDD/Fs and dioxin-like PCBs.

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound analytical result obtained with a confirmatory method and confirmed by duplicate analysis (**), exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty. The mean of the two determinations, taking into account the measurement uncertainty is used for verification of compliance.

The measurement uncertainty may be taken into account according to one of the following approaches:

— by calculating the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the measured value minus U is above the established permitted level. In case of a separate determination of PCDD/Fs and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/Fs and dioxin-like PCBs has to be used for the estimated expanded uncertainty of the sum of PCDD/Fs and dioxin-like PCBs,

— by establishing the decision limit (CCα) according to the provisions of Decision 2002/657/EC (point 3.1.2.5 of the Annex I to that Decision — the case of substances with established permitted level) a lot or sublot is non-compliant if the measured value is equal to or above the CCα.

The abovementioned rules shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

(*) The duplicate analysis is necessary if the result of the first determination applying confirmatory methods with the use of ^{13}C-labelled internal standard for the relevant analytes is not compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the frame of a contamination incident, confirmation by duplicate analysis might be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

(**) Identical explanation and requirements for duplicate analysis for control of action levels as in footnote (*) for maximum levels.

V. EXCEEDANCE OF ACTION LEVELS

Action levels serve as tool for selection of samples in those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. Screening methods shall establish appropriate cut-off values for selection of these samples. In case significant efforts are necessary to identify a source and to reduce or eliminate the contamination, it might be appropriate to confirm exceedance of the action level by duplicate sample analysis using a confirmatory method and taking into account the measurement uncertainty (**).

ANNEX III

SAMPLE PREPARATION AND REQUIREMENTS FOR METHODS OF ANALYSIS USED IN CONTROL OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND DIOXIN-LIKE PCBS IN CERTAIN FOODSTUFFS

1. FIELD OF APPLICATION

The requirements set out in this Annex shall be applied where foodstuffs are analysed for the official control of the levels of 2,3,7,8-substituted polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like polychlorinated biphenyls (dioxin-like PCBs) and for other regulatory purposes.

Monitoring for the presence of PCDD/Fs and dioxin-like PCBs in foodstuffs may be performed with two different types of analytical methods:

(a) **Screening methods**

The goal of screening methods is to select those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels or the action levels. Screening methods should allow cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks of consumers. Their application should aim at avoiding false-compliant results. They may comprise bioanalytical and GC/MS methods.

Screening methods compare the analytical result with a cut-off value, providing a yes/no-decision over possible exceedance of the maximum or action level. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in samples suspected to be non-compliant with the maximum level must be determined/confirmed by a confirmatory method.

In addition, screening methods may give an indication of the levels of PCDD/Fs and dioxin-like PCBs present in the sample. In case of application of bioanalytical screening methods the result is expressed as Bioanalytical Equivalents (BEQ), whereas in case of application of physico-chemical GC-MS methods it is expressed as Toxic Equivalents (TEQ). The numerically indicated results of screening methods are suitable for demonstrating compliance or suspected non-compliance or exceedance of action levels and give an indication of the range of levels in case of follow-up by confirmatory methods. They are not suitable for purposes such as evaluation of background levels, estimation of intake, following of time trends in levels or re-evaluation of action and maximum levels.

(b) **Confirmatory methods**

Confirmatory methods allow the unequivocal identification and quantification of PCDD/Fs and dioxin-like PCBs present in a sample and provide full information on congener basis. Therefore, these methods allow the control of maximum and action levels, including the confirmation of results obtained by screening methods. Furthermore, results may be used for other purposes such as determination of low background levels in food monitoring, following of time trends, exposure assessment of the population and building of database for possible re-evaluation of action and maximum levels. They are also important for establishing congener patterns in order to identify the source of a possible contamination. Such methods utilise GC-HRMS. For confirming compliance or non-compliance with the maximum level, also GC-MS/MS can be used.

2. BACKGROUND

For calculation of Toxic Equivalents (TEQ) concentrations, the concentrations of the individual substances in a given sample shall be multiplied by their respective Toxic Equivalency Factor (TEF), as established by the World Health Organization and listed in the Appendix to this Annex, and subsequently summed to give the total concentration of dioxin-like compounds expressed as TEQs.

Screening and confirmatory methods may only be applied for control of a certain matrix if the methods are sensitive enough to detect levels reliably at the maximum or action level.

3. QUALITY ASSURANCE REQUIREMENTS

— Measures must be taken to avoid cross-contamination at each stage of the sampling and analysis procedure.

— The samples must be stored and transported in glass, aluminium, polypropylene or polyethylene containers suitable for storage without any influence on the levels of PCDD/Fs and dioxin-like PCBs in the samples. Traces of paper dust must be removed from the sample container.

— The sample storage and transportation has to be performed in a way that maintains the integrity of the foodstuff sample.

— Insofar as relevant, finely grind and mix thoroughly each laboratory sample using a process that has been demonstrated to achieve complete homogenisation (e.g. ground to pass a 1 mm sieve); samples have to be dried before grinding if moisture content is too high.

— Control of reagents, glassware and equipment for possible influence of TEQ- or BEQ-based results is of general importance.

— A blank analysis shall be performed by carrying out the entire analytical procedure omitting only the sample.

— For bioanalytical methods, it is of great importance that all glassware and solvents used in analysis shall be tested to be free of compounds that interfere with the detection of target compounds in the working range. Glassware shall be rinsed with solvents or/and heated at temperatures suitable to remove traces of PCDD/Fs, dioxin-like compounds and interfering compounds from its surface.

— Sample quantity used for the extraction must be sufficient to fulfil the requirements with respect to a sufficiently low working range including the concentrations of maximum or action levels.

— The specific sample preparation procedures used for the products under consideration shall follow internationally accepted guidelines.

— In the case of fish, the skin has to be removed as the maximum level applies to muscle meat without skin. However it is necessary that all remaining muscle meat and fat tissue on the inner side of the skin are carefully and completely scraped off from the skin and added to the sample to be analysed.

4. REQUIREMENTS FOR LABORATORIES

— In accordance with the provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council ([1]), laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

— Laboratory proficiency shall be proven by the continuous successful participation in interlaboratory studies for the determination of PCDD/Fs and dioxin-like PCBs in relevant food matrices and concentration ranges.

— Laboratories applying screening methods for routine control of samples shall establish a close cooperation with laboratories applying the confirmatory method, both for quality control and confirmation of the analytical result of suspected samples.

5. BASIC REQUIREMENTS TO BE MET BY ANALYTICAL PROCEDURE FOR DIOXINS (PCDD/FS) AND DIOXIN-LIKE PCBS

5.1. **Low working range and limits of quantification**

— For PCDD/Fs, detectable quantities have to be in the upper femtogram (10^{-15} g) range because of extreme toxicity of some of these compounds. For most PCB congeners limit of quantification in the nanogram (10^{-9} g) range is already sufficient. However, for the measurement of the more toxic dioxin-like PCB congeners (in particular non-ortho substituted congeners) the lower end of the working range must reach the low picogram (10^{-12} g) levels.

5.2. **High selectivity (specificity)**

— A distinction is required between PCDD/Fs and dioxin-like PCBs and a multitude of other, coextracted and possibly interfering compounds present at concentrations up to several orders of magnitude higher than those of the analytes of interest. For gas chromatography/mass spectrometry (GC-MS) methods, a differentiation among various congeners is necessary, such as between toxic (e.g. the seventeen 2,3,7,8-substituted PCDD/Fs, and twelve dioxin-like PCBs) and other congeners.

— Bioanalytical methods shall be able to detect the target compounds as the sum of PCDD/Fs, and/or dioxin-like PCBs. Sample clean-up shall aim at removing compounds causing false-non-compliant results or compounds that may decrease the response, causing false-compliant results.

([1]) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

5.3. **High accuracy (trueness and precision, bioassay apparent recovery)**

— For GC-MS methods, the determination shall provide a valid estimate of the true concentration in a sample. High accuracy (accuracy of the measurement: the closeness of the agreement between the result of a measurement with the true or assigned value of the measurand) is necessary to avoid the rejection of a sample analysis result on the basis of poor reliability of the determined TEQ level. Accuracy is expressed as *trueness* (difference between the mean value measured for an analyte in a certified material and its certified value, expressed as percentage of this value) and *precision* (RSD_R relative standard deviation calculated from results generated under reproducibility conditions).

— For bioanalytical methods, the bioassay apparent recovery shall be determined.

5.4. **Validation in the range of maximum level and general quality control measures**

— Laboratories shall demonstrate the performance of a method in the range of the maximum level, e.g. 0,5 ×, 1 × and 2 × the maximum level with an acceptable coefficient of variation for repeated analysis, during the validation procedure and/or during routine analysis.

— Regular blank controls and spiking experiments or analysis of control samples (preferably, if available, certified reference material) shall be performed as internal quality control measures. Quality control (QC) charts for blank controls, spiking experiments or analysis of control samples shall be recorded and checked to make sure the analytical performance is in accordance with the requirements.

5.5. **Limit of quantification**

— For a bioanalytical screening method, establishment of the LOQ is not an indispensable requirement but the method shall prove that it can differentiate between the blank and the cut-off value. When providing a BEQ-level, a reporting level shall be established to deal with samples showing a response below this level. The reporting level shall be demonstrated to be different from procedure blank samples at least by a factor of three, with a response below the working range. It shall therefore be calculated from samples containing the target compounds around the required minimum level, and not from a S/N ratio or an assay blank.

— Limit of quantification (LOQ) for a confirmatory method shall be about one fifth of the maximum level.

5.6. **Analytical criteria**

— For reliable results from confirmatory or screening methods, the following criteria must be met in the range of the maximum level or action level for the TEQ value respectively the BEQ value, whether determined as total TEQ (as sum of PCDD/F and dioxin-like PCBs) or separately for PCDD/F and dioxin-like PCBs.

	Screening with bioanalytical or physico-chemical methods	Confirmatory methods
False-compliant rate (*)	< 5 %	
Trueness		− 20 % to + 20 %
Repeatability (RSD_r)	< 20 %	
Within-laboratory reproducibility (RSD_R)	< 25 %	< 15 %

(*) With respect to the maximum levels.

5.7. **Specific requirements for screening methods**

— Both GC-MS and bioanalytical methods may be used for screening. For GC-MS methods the requirements as laid down in point 6 of this Annex are to be used. For cell based bioanalytical methods specific requirements are laid down in point 7 of this Annex.

— Laboratories applying screening methods for routine control of samples shall establish a close cooperation with laboratories applying the confirmatory method.

— Performance verification of the screening method is required during routine analysis, by analytical quality control and on-going method validation. There must be a continuous programme for control of compliant results.

— Check on possible suppression of the cell response and cytotoxicity

20 % of the sample extracts shall be measured in routine screening without and with 2,3,7,8-TCDD added corresponding to the maximum or action level, to check if the response is possibly suppressed by interfering substances present in the sample extract. The measured concentration of the spiked sample is compared to the sum of the concentration of the unspiked extract plus the spiking concentration. If this measured concentration is more than 25 % lower than the calculated (sum) concentration, this is an indication of a potential signal suppression and the respective sample must be submitted to confirmatory analysis. Results shall be monitored in quality control charts.

— Quality control on compliant samples

Approximately 2 to 10 % of the compliant samples, depending on sample matrix and laboratory experience, shall be confirmed.

— Determination of false-compliant rates from QC data

The rate of false-compliant results from screening of samples below and above the maximum level or the action level shall be determined. Actual false-compliant rates shall be below 5 %.

After a minimum of 20 confirmed results per matrix/matrix group is available from the quality control of compliant samples, conclusions on the false-compliant rate shall be drawn from this database. The results from samples analysed in ring trials or during contamination incidents, covering a concentration range up to e.g. 2 × the maximum level (ML), may also be included in the minimum of 20 results for evaluation of the false-compliant rate. The samples shall cover most frequent congener patterns, representing various sources.

Although screening assays shall preferentially aim at detecting samples exceeding the action level, the criterion for determining false-compliant rates is the maximum level, taking into account the measurement uncertainty of the confirmatory method.

— Potential non-compliant results from screening shall always be verified by a full re-analysis of the original sample by a confirmatory method. These samples may also be used to evaluate the rate of false-non-compliant results. For screening methods, the rate of 'false-non-compliant results' is the fraction of results confirmed to be compliant from confirmatory analysis, while in previous screening the sample had been declared to be suspected to be non-compliant. However, evaluation of the advantageousness of the screening method shall be based on comparison of false-non-compliant samples with the total number of samples checked. This rate shall be low enough to make the use of a screening tool advantageous.

— At least under validation conditions, bioanalytical methods shall provide a valid indication of the TEQ level, calculated and expressed as BEQ.

— Also for bioanalytical methods carried out under repeatability conditions, the intra-laboratory RSD_r would typically be smaller than the reproducibility RSD_R.

6. SPECIFIC REQUIREMENTS FOR GC-MS METHODS TO BE COMPLIED WITH FOR SCREENING OR CONFIRMATORY PURPOSES

6.1. **Acceptable differences between upperbound and lowerbound WHO-TEQ levels**

— The difference between upperbound level and lowerbound level shall not exceed 20 % for confirmation of the exceedance of maximum or in case of need of action levels.

6.2. **Control of recoveries**

— Addition of ^{13}C-labelled 2,3,7,8-chlorine substituted internal PCDD/F standards and of ^{13}C-labelled internal dioxin-like PCB standards must be carried out at the very beginning of the analytical method e.g. prior to extraction in order to validate the analytical procedure. At least one congener for each of the tetra- to octa-chlorinated homologous groups for PCDD/Fs and at least one congener for each of the homologous groups for dioxin-like PCBs must be added (alternatively, at least one congener for each mass spectrometric selected ion recording function used for monitoring PCDD/Fs and dioxin-like PCBs). In case of confirmatory methods, all 17 ^{13}C-labelled 2,3,7,8-substituted internal PCDD/F standards and all 12 ^{13}C-labelled internal dioxin-like PCB standards shall be used.

— Relative response factors shall also be determined for those congeners for which no ^{13}C-labelled analogue is added by using appropriate calibration solutions.

— For foodstuffs of plant origin and foodstuffs of animal origin containing less than 10 % fat, the addition of the internal standards is mandatory prior to extraction. For foodstuffs of animal origin containing more than 10 % fat, the internal standards may be added either before or after fat extraction. An appropriate validation of the extraction efficiency shall be carried out, depending on the stage at which internal standards are introduced and on whether results are reported on product or fat basis.

— Prior to GC-MS analysis, 1 or 2 recovery (surrogate) standard(s) must be added.

— Control of recovery is necessary. For confirmatory methods, the recoveries of the individual internal standards shall be in the range of 60 to 120 %. Lower or higher recoveries for individual congeners, in particular for some hepta- and octa- chlorinated dibenzo-p-dioxins and dibenzofurans, are acceptable on the condition that their contribution to the TEQ value does not exceed 10 % of the total TEQ value (based on sum of PCDD/F and dioxin-like PCBs). For GC-MS screening methods, the recoveries shall be in the range of 30 to 140 %.

6.3. **Removal of interfering substances**

— Separation of PCDD/Fs from interfering chlorinated compounds such as non-dioxin-like PCBs and chlorinated diphenyl ethers shall be carried out by suitable chromatographic techniques (preferably with a florisil, alumina and/or carbon column).

— Gas-chromatographic separation of isomers shall be sufficient (< 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF).

6.4. **Calibration with standard curve**

— The range of the calibration curve shall cover the relevant range of maximum or action levels.

6.5. **Specific criteria for confirmatory methods**

— For GC-HRMS:

In HRMS, the resolution shall typically be greater than or equal to 10 000 for the entire mass range at 10 % valley.

Fulfilment of further identification and confirmation criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC/HRMS and of indicator PCBs by GC/HRMS) and/or in EPA methods 1613 and 1668 as revised.

— For GC-MS/MS:

Monitoring of at least 2 specific precursor ions, each with one specific corresponding transition product ion, for all labelled and unlabelled analytes in the scope of analysis.

Maximum permitted tolerance of relative ion intensities of ± 15 % for selected transition product ions in comparison to calculated or measured values (average from calibration standards), applying identical MS/MS conditions, in particular collision energy and collision gas pressure, for each transition of an analyte.

Resolution for each quadrupole to be set equal to or better than unit mass resolution (unit mass resolution: sufficient resolution to separate two peaks one mass unit apart) in order to minimise possible interferences on the analytes of interest.

Fulfilment of the further criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC/HRMS and of indicator PCBs by GC/HRMS) and/or in EPA methods 1613 and 1668 as revised, except the obligation to use GC-HRMS.

7. SPECIFIC REQUIREMENTS FOR BIOANALYTICAL METHODS

Bioanalytical methods are methods based on the use of biological principles like cell-based assays, receptor-assays or immunoassays. This point 7 establishes requirements for bioanalytical methods in general.

A screening method in principle classifies a sample as compliant or suspected to be non-compliant. For this, the calculated BEQ level is compared to the cut-off value (see 7.3). Samples below the cut-off value are declared compliant, samples equal or above the cut-off value as suspected to be non-compliant, requiring analysis by a confirmatory method. In practice, a BEQ level corresponding to 2/3 of the maximum level may serve as cut-off value provided that a false-compliant rate below 5 % and an acceptable rate for false-non-compliant results are ensured. With separate maximum levels for PCDD/Fs and for the sum of PCDD/Fs and dioxin-like PCBs, checking compliance of samples without fractionation requires appropriate bioassay cut-off values for PCDD/Fs. For checking of samples exceeding the action levels, an appropriate percentage of the respective action level would suit as cut-off value.

Furthermore, in the case of certain bioanalytical methods, an indicative level expressed in BEQs may be given for samples in the working range and exceeding the reporting limit (see 7.1.1 and 7.1.6).

7.1. **Evaluation of the test response**

7.1.1. *General requirements*

— When calculating the concentrations from a TCDD calibration curve, values at the lower and higher end of the curve will show a high variation (high coefficient of variation (CV)). The working range is the area where this CV is smaller than 15 %. The lower end of the working range (reporting limit) must further be set significantly (at least by a factor of three) above the procedure blanks. The upper end of theworking range is usually represented by the EC_{70} value (70 % of maximal effective concentration), but lower if the CV is higher than 15 % in this range. The working range shall be established during validation. Cut-off values (7.3) must be well within the working range.

— Standard solutions and sample extracts shall be tested at least in duplicate. When using duplicates, a standard solution or a control extract tested in 4 to 6 wells divided over the plate shall produce a response or concentration (only possible in the working range) based on a CV < 15 %.

7.1.2. *Calibration*

7.1.2.1. Calibration with standard curve

— Levels in samples may be estimated by comparison of the test response with a calibration curve of TCDD (or PCB 126 or a PCDD/F/dioxin-like PCB standard mixture) to calculate the BEQ level in the extract and subsequently in the sample.

— Calibration curves shall contain 8 to 12 concentrations (at least in duplicates), with enough concentrations in the lower part of the curve (working range). Special attention shall be paid to the quality of the curve-fit in the working range. As such, the R^2 value is of little or no value in estimating the goodness of fit in non-linear regression. A better fit will be achieved by minimising the difference between calculated and observed levels in the working range of the curve (e.g. by minimising the sum of squared residuals).

— The estimated level in the sample extract is subsequently corrected for the BEQ level calculated for a matrix/solvent blank sample (to account for impurities from solvents and chemicals used), and the apparent recovery (calculated from the BEQ level of suitable reference samples with representative congener patterns around the maximum or action level). For performing a recovery correction, the apparent recovery must always be within the required range (see point 7.1.4). Reference samples used for recovery correction must comply with requirements as given in point 7.2.

7.1.2.2. Calibration with reference samples

Alternatively, a calibration curve prepared from at least 4 reference samples (see point 7.2): one matrix blank, plus three reference samples at 0,5 ×, 1,0 × and 2,0 × the maximum or action level may be used, eliminating the need to correct for blank and recovery. In this case, the test response corresponding to 2/3 of the maximum level (see 7.3) may be calculated directly from these samples and used as cut-off value. For checking of samples exceeding the action levels, an appropriate percentage of these action levels would suit as cut-off value.

7.1.3. *Separate determination of PCDD/Fs and dioxin-like PCBs*

Extracts may be split into fractions containing PCDD/Fs and dioxin-like PCBs, allowing a separate indication of PCDD/Fs and dioxin-like PCB TEQ levels (in BEQs). A PCB 126 standard calibration curve shall preferentially be used to evaluate results for the fraction containing dioxin-like PCBs.

7.1.4. *Bioassay apparent recoveries*

The 'bioassay apparent recovery' shall be calculated from suitable reference samples with representative congener patterns around the maximum or action level and expressed as percentage of the BEQ level in comparison to the TEQ level. Depending on the type of assay and TEFs ([1]) used, the differences between TEF and REP factors for dioxin-like PCBs may cause low apparent recoveries for dioxin-like PCBs in comparison to PCDD/Fs. Therefore, if a separate determination of PCDD/Fs and dioxin-like PCBs is performed, bioassay apparent recoveries shall be: for dioxin-like PCBs 20 % to 60 %, for PCDD/Fs 50 % to 130 % (ranges apply for TCDD calibration curve). As the contribution of dioxin-like PCBs to the sum of PCDD/Fs and dioxin-like PCBs may vary between different matrices and samples, bioassay apparent recoveries for the sum parameter reflect these ranges and shall be between 30 % to 130 %.

7.1.5. *Control of recoveries for clean-up*

The loss of compounds during the clean-up shall be checked during validation. A blank sample spiked with a mixture of the different congeners shall be submitted to clean-up (at least n=3) and the recovery and variability checked by a confirmatory method. The recovery shall be within 60 to 120 % especially for congeners contributing more than 10 % to the TEQ-level in various mixtures.

7.1.6. *Reporting Limit*

When reporting BEQ levels, a reporting limit shall be determined from relevant matrix samples involving typical congener patterns, but not from the calibration curve of the standards due to low precision in the lower range of the curve. Effects from extraction and clean-up must be taken into account. The reporting limit must be set significantly (at least by a factor of three) above the procedure blanks.

7.2. **Use of reference samples**

— Reference samples shall represent sample matrix, congener patterns and concentration ranges for PCDD/Fs and dioxin-like PCBs around the maximum or action level.

— A procedure blank, or preferably a matrix blank, and a reference sample at the maximum or action level have to be included in each test series. These samples must be extracted and tested at the same time under identical conditions. The reference sample must show a clearly elevated response in comparison to the blank sample, thus ensuring the suitability of the test. These samples may be used for blank and recovery corrections.

— Reference samples chosen for performing a recovery correction shall be representative for the test samples, meaning that congener patterns shall not lead to an underestimation of levels.

— Extra reference samples at e.g. 0,5 × and 2 × the maximum or action level may be included to demonstrate the proper performance of the test in the range of interest for the control of the maximum or action level. Combined, these samples may be used for calculating the BEQ-levels in test samples (7.1.2.2).

7.3. **Determination of cut-off values**

The relationship between bioanalytical results in BEQ and results from confirmatory methods in TEQ shall be established (e.g. by matrix-matched calibration experiments, involving reference samples spiked at 0, 0,5 ×, 1 × and 2 × the maximum level (ML), with 6 repetitions on each level (n=24)). Correction factors (blank and recovery) may be estimated from this relationship but shall be checked in each test series by including procedure/matrix blanks and recovery samples (7.2).

Cut-off values shall be established for decision over sample compliance with maximum levels or for control of action levels, if of interest, with the respective maximum or action levels set for either PCDD/Fs and dioxin-like PCBs alone, or for the sum of PCDD/Fs and dioxin-like PCBs. They are represented by the *lower* endpoint of the distribution of bioanalytical results (corrected for blank and recovery) corresponding to the decision limit of the confirmatory method based on a 95 % level of confidence, implying a false-compliant rate < 5 %, and on a RSD_R < 25 %. The decision limit of the confirmatory method is the maximum level, taking into account the measurement uncertainty.

([1]) Current requirements are based on the TEFs published in: M. Van den Berg et al, Toxicol Sci 93 (2), 223–241 (2006).

In practice, the cut-off value (in BEQ) may be calculated from the following approaches (see Figure 1):

7.3.1. Use of the *lower* band of the 95 % prediction interval at the decision limit of the confirmatory method

$$\text{Cut-off value} = BEQ_{DL} - s_{y,x} * t_{\alpha,f=m-2}\sqrt{1/n + 1/m + (x_i - \overline{x})^2/Q_{xx}}$$

with:

BEQ_{DL} BEQ corresponding to the decision limit of the confirmatory method, being the ML including measurement uncertainty

$s_{y,x}$ residual standard deviation

$t_{\alpha,f=m-2}$ Student factor (α = 5 %, f = degrees of freedom, single-sided)

m total number of calibration points (index j)

n number of repetitions on each level

x_i Sample concentration (in TEQ) of calibration point i determined by a confirmatory method

$\overline{x}$ mean of the concentrations (in TEQ) of all calibration samples

$Q_{xx} = \sum_{j=1}^{m}(x_i - \overline{x})^2$ square sum parameter

i = index for calibration point i

7.3.2. Calculation from bioanalytical results (corrected for blank and recovery) of multiple analyses of samples (n ≥ 6) contaminated at the decision limit of the confirmatory method, as the *lower* endpoint of the data distribution at the corresponding mean BEQ value:

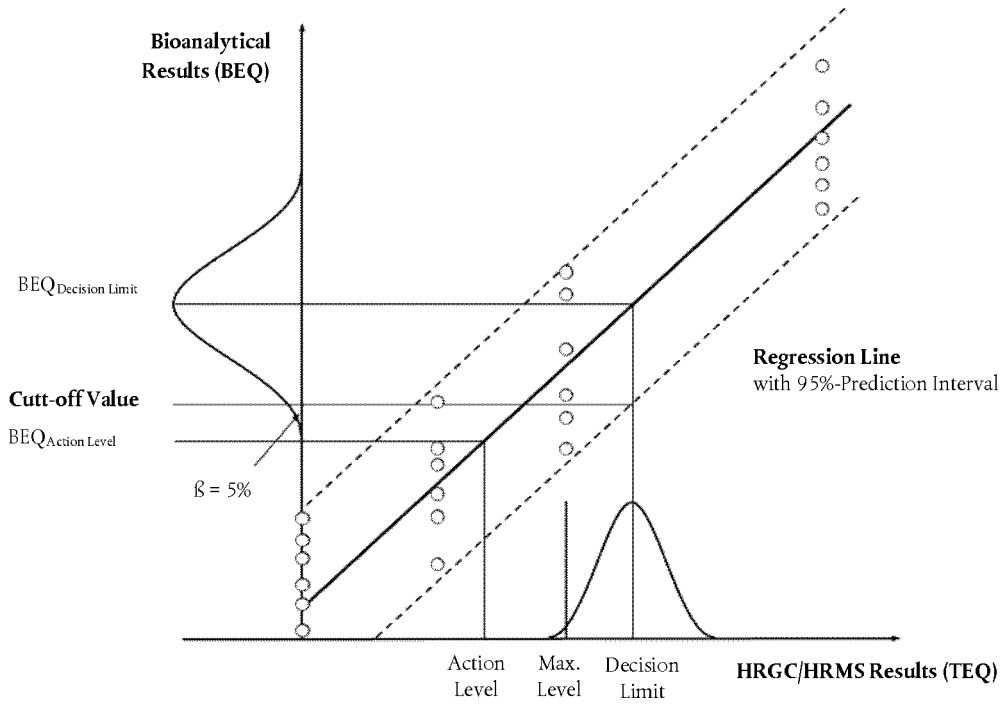
$$\text{Cut-off value} = BEQ_{DL} - 1{,}64 \times SD_R$$

with

SD_R standard deviation of bioassay results at BEQ_{DL}, measured under within-laboratory reproducibility conditions

7.3.3. Calculation as mean value of bioanalytical results (in BEQ, corrected for blank and recovery) from multiple analysis of samples (n > 6) contaminated at 2/3 of the maximum or action level. This is based on the observation that this level will be around the cut-off determined under 7.3.1 or 7.3.2.

Figure 1



Calculation of cut-off values based on a 95 % level of confidence implying a false-compliant rate < 5 %, and a RSD_R < 25 %:

1. from the *lower* band of the 95 % prediction interval at the decision limit of the confirmatory method,

2. from multiple analysis of samples (n ≥ 6) contaminated at the decision limit of the confirmatory method as the *lower* endpoint of the data distribution (represented in the figure by a bell-shaped curve) at the corresponding mean BEQ value.

7.3.4. Restrictions to cut-off values:

BEQ-based cut-off values calculated from the RSD_R achieved during validation using a limited number of samples with different matrix/congener patterns may be higher than the TEQ-based maximum or action levels due to a better precision than attainable in routine when an unknown spectrum of possible congener patterns has to be controlled. In such cases, cut-off values shall be calculated from an RSD_R = 25 %, or two-thirds of the maximum or action level shall be preferred.

7.4. **Performance characteristics**

— Since no internal standards can be used in bioanalytical methods, tests on repeatability shall be carried out to obtain information on the standard deviation within and between test series. Repeatability shall be below 20 %, intra-laboratory reproducibility below 25 %. This shall be based on the calculated levels in BEQs after blank and recovery correction.

— As part of the validation process, the test must be shown to discriminate between a blank sample and a level at the cut-off value, allowing the identification of samples above the corresponding cut-off value (see 7.1.2).

— Target compounds, possible interferences and maximum tolerable blank levels shall be defined.

— The percent standard deviation in the response or concentration calculated from the response (only possible in working range) of a triplicate determination of a sample extract shall not be above 15 %.

— The uncorrected results of the reference sample(s) expressed in BEQs (blank and at the maximum or action level) shall be used for evaluation of the performance of the bioanalytical method over a constant time period.

— Quality control (QC) charts for procedure blanks and each type of reference sample shall be recorded and checked to make sure the analytical performance is in accordance with the requirements, in particular for the procedure blanks with regard to the requested minimum difference to the lower end of the working range and for the reference samples with regard to within-laboratory reproducibility. Procedure blanks must be well controlled in order to avoid false-compliant results when subtracted.

— The results from the confirmatory methods of suspected samples and 2 to 10 % of the compliant samples (minimum of 20 samples per matrix) shall be collected and used to evaluate the performance of the screening method and the relationship between BEQs and TEQs. This database might be used for re-evaluation of cut-off values applicable to routine samples for the validated matrices.

— Successful method performance may also be demonstrated by participation in ring trials. The results from samples analysed in ring trials, covering a concentration range up to e.g. 2 × ML, may also be included in the evaluation of the false-compliant rate, if a laboratory is able to demonstrate its successful performance. The samples shall cover most frequent congener patterns, representing various sources.

— During incidents, the cut-off values may be re-evaluated, reflecting the specific matrix and congener patterns of this single incident.

8. REPORTING OF THE RESULT

Confirmatory methods

— Insofar as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCDD/F and dioxin-like PCB congeners and be reported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

— The report shall also include the method used for extraction of PCDD/Fs, dioxin-like PCBs and lipids. The lipid content of the sample shall be determined and reported for food samples with maximum levels expressed on fat basis and an expected fat concentration in the range of 0 — 2 % (in correspondence to existing legislation), for other samples is the determination of the lipid content optional.

— The recoveries of the individual internal standards must be made available in case the recoveries are outside the range mentioned in point 6.2, in case the maximum level is exceeded (in this case, the recoveries for one of the two duplicate analysis) and in other cases upon request.

— As the uncertainty of measurement is to be taken into account when deciding about the compliance of a sample, this parameter shall also be made available. Thus, analytical results shall be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approximately 95 %. In case of a separate determination of PCDD/Fs and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/Fs and dioxin-like PCBs has to be used for the sum of PCDD/Fs and dioxin-like PCBs.

— If the uncertainty of measurement is taken into account by applying CCα (as described in Annex II, point IV.-2), this parameter shall be reported.

— The results shall be expressed in the same units and with (at least) the same number of significant figures as the maximum levels laid down in Regulation (EC) No 1881/2006.

Bioanalytical screening methods

— The result of the screening shall be expressed as compliant or suspected to be non-compliant (suspected).

— In addition, a result for PCDD/F and/or dioxin-like PCBs expressed in Bioanalytical Equivalents (BEQ) (not TEQ) may be given (see Annex III, point 1). Samples with a response below the reporting limit shall be expressed as lower than the reporting limit.

— For each type of sample matrix, the report shall mention the maximum or action level on which the evaluation is based.

— The report shall mention the type of test applied, the basic test principle and kind of calibration.

— The report shall also include the method used for extraction of PCDD/Fs, dioxin-like PCBs and lipids. The lipid content of the sample shall be determined and reported for food samples with maximum or action levels expressed on fat basis and an expected fat concentration in the range of 0 — 2 % (in correspondence to existing legislation), for other samples is the determination of the lipid content optional.

— In case of samples suspected to be non-compliant, the report needs to include a note on the action to be taken. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in those samples with elevated levels has to be determined/confirmed by a confirmatory method.

Appendix to ANNEX III

WHO-TEFs for human risk assessment based on the conclusions of the World Health Organization (WHO) — International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006))

Congener	TEF value	Congener	TEF value
Dibenzo-p-dioxins (PCDDs)		'Dioxin-like' PCBs **Non-ortho PCBs + Mono-ortho PCBs**	
2,3,7,8-TCDD	1	**Non-ortho PCBs**	
1,2,3,7,8-PeCDD	1		
1,2,3,4,7,8-HxCDD	0,1	PCB 77	0,0001
1,2,3,6,7,8-HxCDD	0,1	PCB 81	0,0003
1,2,3,7,8,9-HxCDD	0,1	PCB 126	0,1
1,2,3,4,6,7,8-HpCDD	0,01	PCB 169	0,03
OCDD	0,0003		
Dibenzofurans (PCDFs)		**Mono-ortho PCBs**	
2,3,7,8-TCDF	0,1	PCB 105	0,00003
1,2,3,7,8-PeCDF	0,03	PCB 114	0,00003
2,3,4,7,8-PeCDF	0,3	PCB 118	0,00003
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,00003
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,00003
1,2,3,7,8,9-HxCDF	0,1	PCB 157	0,00003
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00003
1,2,3,4,6,7,8-HpCDF	0,01	PCB 189	0,00003
1,2,3,4,7,8,9-HpCDF	0,01		
OCDF	0,0003		

Abbreviations used: 'T' = tetra; 'Pe' = penta; 'Hx' = hexa; 'Hp' = hepta; 'O' = octa; 'CDD' = chlorodibenzodioxin; 'CDF' = chlorodibenzofuran; 'CB' = chlorobiphenyl.

ANNEX IV

SAMPLE PREPARATION AND REQUIREMENTS FOR METHODS OF ANALYSIS USED IN CONTROL OF THE LEVELS OF NON-DIOXIN-LIKE PCBS (PCB # 28, 52, 101, 138, 153, 180) IN CERTAIN FOODSTUFFS

The requirements set out in this Annex shall be applied where foodstuffs are analysed for the official control of the levels of non-dioxin-like polychlorinated biphenyls (non-dioxin-like PCBs) and for other regulatory purposes.

1. **Applicable detection methods:**

Gas Chromatography/Electron Capture Detection (GC-ECD), GC-LRMS, GC-MS/MS, GC-HRMS or equivalent methods.

2. **Identification and confirmation of analytes of interest:**

— Relative retention time in relation to internal standards or reference standards (acceptable deviation of +/– 0,25 %).

— Gas chromatographic separation of all six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) from interfering substances, especially co-eluting PCBs, in particular if levels of samples are in the range of legal limits and non-compliance is to be confirmed.

(Congeners often found to co-elute are e.g. PCB 28/31, PCB 52/69 and PCB 138/163/164. For GC-MS also possible interferences from fragments of higher chlorinated congeners have to be considered.)

— For GC-MS techniques:

— Monitoring of at least:

— two specific ions for HRMS,

— two specific ions of m/z > 200 or three specific ions of m/z >100 for LRMS,

— 1 precursor and 2 product ions for MS-MS.

— Maximum permitted tolerances for abundance ratios for selected mass fragments:

Relative deviation of abundance ratio of selected mass fragments from theoretical abundance or calibration standard for target ion (most abundant ion monitored) and qualifier ion(s):

Relative intensity of qualifier ion(s) compared to target ion	GC-EI-MS (relative deviation)	GC-CI-MS, GC-MS^n (relative deviation)
> 50 %	± 10 %	± 20 %
> 20 % to 50 %	± 15 %	± 25 %
> 10 % to 20 %	± 20 %	± 30 %
≤ 10 %	± 50 % (*)	± 50 % (*)

(*) Sufficient number of mass fragments with relative intensity > 10 % available, therefore not recommendable to use qualifier ion(s) with a relative intensity of less than 10 % compared to the target ion.

— For GC-ECD:

Confirmation of results exceeding the tolerance with two GC columns with stationary phases of different polarity.

3. **Demonstration of performance of method:**

Validation in the range of the maximum level (0,5 to 2 times the maximum level) with an acceptable coefficient of variation for repeated analysis (see requirements for intermediate precision in point 8).

4. **Limit of quantification:**

The blank values shall not be higher than 30 % of the level of contamination corresponding to the maximum level ([1]).

5. **Quality control:**

Regular blank controls, analysis of spiked samples, quality control samples, participation in interlaboratory studies on relevant matrices.

6. **Control of recoveries:**

— Use of suitable internal standards with physico-chemical properties comparable to analytes of interest.

— Addition of internal standards:

  — Addition to products (before extraction and clean-up process);

  — Addition also possible to extracted fat (before clean-up process), if maximum level is expressed on fat basis.

— Requirements for methods using all six isotope-labelled indicator PCB congeners:

  — Correction of results for recoveries of internal standards;

  — Generally acceptable recoveries of isotope-labelled internal standards are between 50 and 120 %;

  — Lower or higher recoveries for individual congeners with a contribution to the sum of the six indicator PCBs below 10 % are acceptable.

— Requirements for methods using not all six isotope-labelled internal standards or other internal standards:

  — Control of recovery of internal standard(s) for every sample;

  — Acceptable recoveries of internal standard(s) between 60 and 120 %;

  — Correction of results for recoveries of internal standards.

— The recoveries of unlabelled congeners shall be checked by spiked samples or quality control samples with concentrations in the range of the maximum level. Acceptable recoveries for these congeners are between 70 and 120 %.

7. **Requirements for laboratories:**

In accordance with the provisions of Regulation (EC) No 882/2004, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

8. **Performance characteristics: Criteria for the sum of the six indicator PCBs at the maximum level:**

Trueness	− 30 to + 30 %
Intermediate precision (RSD%)	≤ 20 %
Difference between upper and lower bound calculation	≤ 20 %

9. **Reporting of results**

— Insofar as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCB congeners and be reported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

— The report shall also include the method used for extraction of PCBs and lipids. The lipid content of the sample shall be determined and reported for food samples with maximum levels expressed on fat basis and an expected fat concentration in the range of 0 — 2 % (in correspondence to existing legislation), for other samples is the determination of the lipid content optional.

([1]) It is highly recommendable to have a lower contribution of the reagent blank level to the level of a contaminant in a sample. It is in the responsibility of the laboratory to control the variation of blank levels, in particular, if the blank levels are subtracted.

— The recoveries of the individual internal standards must be made available in case the recoveries are outside the range mentioned in point 6, in case the maximum level is exceeded and in other cases upon request.

— As the uncertainty of measurement is to be taken into account when deciding about the compliance of a sample, this parameter shall also be made available. Thus, analytical results shall be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

— If the uncertainty of measurement is taken into account by applying CCα (as described in Annex II, point IV.1), this parameter shall be reported.

— The results shall be expressed in the same units and with (at least) the same number of significant figures as the maximum levels laid down in Regulation (EC) No 1881/2006.

COMMISSION IMPLEMENTING REGULATION (EU) No 590/2014

of 2 June 2014

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

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 2 June 2014.

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

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MK	64,8
	TR	64,5
	ZZ	64,7
0707 00 05	AL	25,2
	MK	40,7
	TR	121,6
	ZZ	62,5
0709 93 10	TR	114,5
	ZZ	114,5
0805 50 10	TR	121,8
	ZA	129,3
	ZZ	125,6
0808 10 80	AR	104,3
	BR	77,8
	CL	99,5
	CN	127,0
	NZ	137,5
	US	161,6
	UY	70,3
	ZA	120,5
	ZZ	112,3
0809 29 00	TR	444,9
	ZZ	444,9

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

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION EUCAP SAHEL MALI/1/2014

of 26 May 2014

on the appointment of the Head of Mission of the European Union CSDP mission in Mali (EUCAP Sahel Mali)

(2014/310/CFSP)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to Council Decision 2014/219/CFSP of 15 April 2014 on the European Union CSDP mission in Mali (EUCAP Sahel Mali) ([1]), and in particular Article 7(1) thereof,

Whereas:

(1) Pursuant to Decision 2014/219/CFSP, the Political and Security Committee is authorised, in accordance with Article 38 of the Treaty, to take the relevant decisions for the purpose of political control and strategic direction of the EUCAP Sahel Mali mission, including the decision to appoint a Head of Mission.

(2) The High Representative of the Union for Foreign Affairs and Security Policy has proposed the appointment of Mr Albrecht CONZE as Head of Mission of EUCAP Sahel Mali from 26 May 2014 to 14 January 2015,

HAS ADOPTED THIS DECISION:

Article 1

Mr Albrecht CONZE is hereby appointed Head of the European Union CSDP mission in Mali (EUCAP Sahel Mali) from 26 May 2014 to 14 January 2015.

Article 2

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

Done at Brussels, 26 May 2014.

For the Political and Security Committee

The Chairperson

W. STEVENS

([1]) OJ L 113, 16.4.2014, p. 21.

COUNCIL DECISION

of 26 May 2014

appointing two Belgian members and a Belgian alternate member of the Committee of the Regions

(2014/311/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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 Belgian 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. On 26 November 2012, by Council Decision 2012/736/EU [3], Mr Alain HUTCHINSON was appointed as member until 25 January 2015 following the end of the term of office of Mr Charles PICQUÉ and Mr Charles PICQUÉ was appointed as alternate member. On 28 January 2013, by Council Decision 2013/68/EU [4], Mr Jean-Luc VANRAES was appointed member until 25 January 2015 following the end of the term of office of Mr Jos CHABERT.

(2) Two members' seats on the Committee of the Regions are vacant following the end of the electoral mandates on the basis of which Mr Jean-Luc VANRAES and Mr Alain HUTCHINSON were appointed. An alternate member's seat is vacant following the end of the electoral mandate on the basis of which Mr Charles PICQUÉ was appointed,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions with effect from 26 May 2014 for the remainder of the current term of office, which runs until 25 January 2015:

a) as members:

— Mr Jean-Luc VANRAES, *Gemeenteraadslid in Ukkel*

— Mr Alain HUTCHINSON, *Conseiller communal à Saint-Gilles*

and

b) as alternate member:

— Mr Charles PICQUÉ, *Bourgmestre de la commune de Saint-Gilles*.

Article 2

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

Done at Brussels, 26 May 2014.

For the Council
The President
Ch. VASILAKOS

[1] OJ L 348, 29.12.2009, p. 22.
[2] OJ L 12, 19.1.2010, p. 11.
[3] OJ L 329, 29.11.2012, p. 18.
[4] OJ L 32, 1.2.2013, p. 16.

COMMISSION DECISION

of 28 May 2014

establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes

(notified under document C(2014) 3429)

(Text with EEA relevance)

(2014/312/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 products which have 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) In order to better reflect the state of the art of the market for this product group and take into account the innovation of the last years, it is considered appropriate to modify the scope of the product group and establish a revised set of ecological criteria.

(4) Commission Decision 2009/543/EC ([2]) and Commission Decision 2009/544/EC ([3]) addressed separately indoor and outdoor paints. These have been amalgamated into one criteria document in order to reduce the administrative burden for competent bodies and applicants. Moreover, the revised criteria reflect new requirements on hazardous substances that were introduced subsequent to the previous decisions by Regulation (EC) No 66/2010.

(5) The criteria aim, in particular, at promoting products that have a lower environmental impact along their life cycle, are of high quality, have good performance and long durability, products which contain a limited amount of hazardous substances ([4]) and a limited amount of volatile organic compounds. Products with improved performance in relation to these aspects should be promoted via the Ecolabel. It is therefore appropriate to establish EU Ecolabel criteria for the product group 'paints and varnishes'.

(6) The revised criteria, as well as the related assessment and verification requirements should be valid for four years from the date of adoption of this Decision, taking into account the innovation cycle for this product group.

(7) Decisions 2009/543/EC and 2009/544/EC should therefore be replaced by this Decision.

([1]) OJ L 27, 30.1.2010, p. 1.

([2]) Commission Decision 2009/543/EC of 13 August 2008 establishing the ecological criteria for the award of the Community eco-label to outdoor paints and varnishes (OJ L 181, 14.7.2009, p. 27).

([3]) Commission Decision 2009/544/EC of 13 August 2008 establishing the ecological criteria for the award of the Community eco-label to indoor paints and varnishes (OJ L 181, 14.7.2009, p. 39).

([4]) Substances with hazard classifications established under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (the CLP Regulation) (OJ L 353, 31.12.2008, p. 1).

(8) A transitional period should be allowed for producers whose products have been awarded the EU Ecolabel for indoor and outdoor paints and varnishes on the basis of the criteria set out in Decisions 2009/543/EC and 2009/544/EC, so that they have sufficient time to adapt their products to comply with the revised criteria and requirements.

(9) 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

1. The product group of 'indoor and outdoor paints and varnishes' shall comprise indoor and outdoor decorative paints and varnishes, woodstains and related products intended for use by consumers and professional users falling under the scope of Directive 2004/42/CE of the European Parliament and of the Council ([1]).

2. The product group of 'indoor and outdoor paints and varnishes' shall comprise: floor coatings and floor paints; paint products which are tinted by distributors at the request of consumer (non-professional) or professional decorators, tinting systems, decorative paints in liquid or paste formulas which may have been pre-conditioned, tinted or prepared by the manufacturer to meet consumer's needs, including wood paints, wood and decking stains, masonry coatings and metal finishes primers and undercoats of such product systems as defined in Annex I to Directive 2004/42/CE.

3. The product group shall not comprise the following products:

(a) anti-fouling coatings;

(b) preservation products for wood impregnation;

(c) coatings for particular industrial and professional uses, including heavy-duty coatings;

(d) powder coatings;

(e) UV curable paint systems;

(f) paints primarily intended for vehicles;

(g) product which primary function is not to form a film over the substrate, e.g. oils and waxes;

(h) fillers as defined by EN ISO 4618;

(i) road-marking paints.

Article 2

For the purpose of this Decision, the following definitions shall apply:

(1) 'Paint' means a pigmented coating material, supplied in a liquid paste or powder form, which, when applied to a substrate, forms an opaque film having protective, decorative or specific technical properties and after application dries to a solid, adherent and protective coating;

(2) 'Varnish' means a clear coating material which, when applied to a substrate forms a solid transparent film having protective, decorative or specific technical properties and after application dries to a solid, adherent and protective coating;

(3) 'Decorative paints and varnishes' means paints and varnishes that are applied in-situ to buildings, their trim and fittings, for decorative and protective purposes;

(4) 'Lasure' means coatings producing a transparent or semi-transparent film for decoration and protection of wood against weathering, which enables maintenance to be carried out easily;

([1]) Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (OJ L 143, 30.4.2004, p. 87).

(5) 'Tinting system' means a method for preparing coloured paints by mixing a 'base' with coloured tints;

(6) 'Masonry coating' means a coating that produce a decorative and protective film for use on concrete, paintable brickwork, blockwork, rendering, calcium silicate board or fibre-reinforced cement;

(7) 'Binding primers' means coatings designed to stabilise loose substrate particles or impact hydrophobic properties;

(8) 'UV curable paint system' means the hardening of coating materials by exposure to artificial ultra-violet radiation;

(9) 'Powder coating' means protective or decorative coating formed by the application of a coating powder to a substrate and fusion to give a continuous film;

(10) 'In-can preservatives' are products used for the preservation of manufactured products during storage by the control of microbial deterioration to ensure their shelf life;

(11) 'Dry-film preservatives' are products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects;

(12) 'Anti-skinning substances' are additives that are added to the coating materials to prevent skinning during production or storage of the coating material;

(13) 'Volatile organic compounds' (VOC) means any organic compounds having an initial boiling point less than or equal to 250 °C measured at a standard pressure of 101,3 kPa as defined in Directive 2004/42/EC and which, in a capillary column, are eluting up to and including Tetradecane ($C_{14}H_{30}$) for non-polar systems or Diethyl adipate ($C_{10}H_{18}O_4$) for polar systems;

(14) 'Semi volatile organic compounds' (SVOCs) means any organic compound having a boiling point of greater than 250 °C and which, in a capillary column ([1]) are eluting with a retention range between n-Tetradecane ($C_{14}H_{30}$) and n-Docosane ($C_{22}H_{46}$) for non-polar systems and diethyl adipate ($C_{10}H_{18}O_4$) and methyl palmitate ($C_{17}H_{34}O_2$) for polar systems;

(15) 'White and light coloured' paints are those with a tri-stimulus (Y-value) > 70 %;

(16) 'Gloss paints' are those which at an angle of incidence of 60° show a reflectance of ≥ 60;

(17) 'Mid sheen paints' (also referred to as semi-gloss, satin, semi matt) are those which at an angle of incidence of 60° or at 85° show a reflectance of < 60 and ≥ 10;

(18) 'Matt paints' are those which at an angle of incidence of 85° show a reflectance of < 10;

(19) 'Dead matt paints' are those which at an angle of incidence of 85° show a reflectance of < 5;

(20) 'Transparent' and 'semi-transparent' means a film with a contrast ratio of < 98 % at 120µ wet film thickness;

(21) 'Opaque' means a film with a contrast ratio of > 98 % at 120µ wet film thickness.

Article 3

The criteria for awarding the EU Ecolabel under Regulation (EC) No 66/2010, for a product falling within the product group 'paints and varnishes' defined in Article 1 of this Decision as well as the related assessment and verification requirements are set out in the Annex.

Article 4

The criteria and the related assessment requirements set out in the Annex, shall be valid for four years from the date of adoption of this Decision.

Article 5

For administrative purposes, the code number assigned to the product group 'indoor and outdoor paints and varnishes' shall be '044'.

([1]) As specified in 8.2.2 of FprCEN/TS 16516.

Article 6

Decisions 2009/543/EC and 2009/544/EC are repealed.

Article 7

1. Applications for the EU Ecolabel for products falling within the product group 'paints and varnishes' submitted within two months from the date of adoption of this Decision may be based either on the criteria set out in Decision 2009/543/EC or 2009/544/EC, or on the criteria set out in this Decision. Applications shall be evaluated in accordance with the criteria on which they are based.

2. EU Ecolabel licences awarded in accordance with the criteria set out in Decision 2009/543/EC or 2009/544/EC may be used for 12 months from the date of adoption of this Decision.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 28 May 2014.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX

EU ECOLABEL CRITERIA AND ASSESSMENT AND VERIFICATION REQUIREMENTS

Criteria for awarding the EU Ecolabel to paints and varnishes:

1. White pigment and wet scrub resistance
2. Titanium dioxide
3. Efficiency in use
   (a) Spreading rate
   (b) Resistance to water
   (c) Adhesion
   (d) Abrasion
   (e) Weathering
   (f) Water vapour permeability
   (g) Liquid water permeability
   (h) Fungal resistance
   (i) Crack bridging
   (j) Alkali resistance
   (k) Corrosion resistance
4. Volatile and Semi-volatile Organic Compounds (VOCs, SVOCs)
5. Restriction of hazardous substances and mixtures
   (a) Overall restrictions that apply to hazard classifications and risk phrases
   (b) Restrictions that apply to Substances of Very High Concern
   (c) Restrictions that apply to specific hazardous substances
6. Consumer information
7. Information appearing on the EU Ecolabel

The Ecolabel criteria reflect the best environmental performing products on the market of paints and varnishes. High quality and performance standards of the paint are required to ensure the longevity of the product and contribute that way to the significant reduction of the paints' overall life cycle impacts. Moreover, the criteria aim at minimizing the use of volatile and semi-volatile organic substances in the paint formulation.

Whilst the use of chemical products and release of pollutants is part of the production process, a product that bears the EU Ecolabel guarantees the consumer that the use of such substances has been limited to the extent technically possible without prejudice to its fitness for use. Moreover, the final paint or varnish product may not be classified as being an acute toxin or hazardous to the environment under European legislation on the labelling of products.

The criteria exclude whenever possible or restrict to a minimum the concentration (required for providing specific functions and properties) of a number of substances identified as hazardous to human health and the environment that may be used in the formulation of paints and varnishes. Only where a substance is required to meet consumer performance expectations or mandated requirements for the product (for instance paint preservation), and where there are no applied and tested available alternatives, derogation for such a substance to be used in the Ecolabel is granted.

Derogations are evaluated on the basis of the precautionary principle and scientific and technical evidence, especially if safer products are available on the market.

Testing of the final product for the presence of restricted hazardous substances may be requested in order to provide a high level of assurance to consumers.

Where appropriate, strict conditions are also imposed on the handling of substances in manufacturing processes for paints and varnishes to avoid workforce exposure. The verification of compliance with the criteria is formulated in a way that provides a high level of assurance to consumers, reflects the practical potential for applicants to obtain information from the supply chain and excludes the potential for 'free riding' by applicants.

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, these may originate from the applicant and/or his supplier(s) and/or their supplier(s), as appropriate.

In the case of changes such as in supplier, the paint formulation or an extension of a product range that results in a change in how the paint or varnish complies with one or more criteria (as relevant) then the licenseholder shall, in advance of any change, submit information to the relevant Competent Body demonstrating the products ongoing compliance as specified in the relevant criteria.

Where appropriate, test methods other than those indicated for each criterion may be used if these are described in the user manual of the Ecolabel criteria application and the competent body assessing the application accepts their equivalence.

Competent bodies shall preferentially recognise tests which are accredited according to ISO 17025 and verifications performed by bodies which are accredited under the EN 45011 standard or an equivalent international standard.

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

(b) Measurement thresholds

Unless otherwise indicated compliance with the Ecolabel criteria is required for intentionally added substances and mixtures, 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.

(c) The exact formulation of the product, including the function and the physical form of all ingredients identified within the criteria, as well as any additional functional ingredients, and their ingoing concentration shall be provided to the competent body. The chemical name, CAS number and CLP classification according to Regulation (EC) No 1272/2008 shall be provided for each ingredient. All ingredients identified within the criteria, as well as any additional functional ingredients and known impurities, that are present at concentrations in the product of greater than 0,010 % shall be reported unless a lower concentration is required in order to comply with a derogation requirement.

Where ingredients are referred to in the criteria, this includes substances and preparations or mixtures. The definitions of 'substances' and 'mixtures' are given in Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council [1] ('the REACH Regulation'.

Safety data sheets and/or CAS numbers and CLP classifications for each ingredient shall be submitted to the competent body in accordance with the REACH Regulation.

(d) For all criteria, apart from Criterion 4 Volatile and Semi-volatile Organic Compounds (VOCs, SVOCs), the limits shall apply to the paint or varnish in its packaging. In line with Directive 2004/42/EC the VOC limits relate to the ready to use product and so the maximum VOC content shall be measured or calculated including any recommended additions such as colorants and/or thinners. For this calculation or measurement, data supplied by the raw material suppliers regarding solids content, VOC content and product density will be required. The above is also applicable in the measurement or calculation of SVOCs. Competent bodies may request testing for SVOC's in order to validate calculations.

Criterion 1. White pigment and Wet Scrub Resistance

1(a) *Minimum requirement for white pigment content*

Indoor wall and ceiling paints for which Class 1 and 2 wet scrub resistance claims are made shall have a white pigment content (white inorganic pigments with a refractive index higher than 1,8) per m^2 of dry film equal to or lower than that described in Table 1, with 98 % opacity. For tinting systems this requirement only applies to the base paint.

Table 1

Relationship between wet scrub resistance and TiO_2 content for indoor paints

Wet scrub resistance	Indoor limit (g/m^2)
Class 1	40
Class 2	36

For all other paints, including limed paints, silicate paints, primers, anti-rust paints and facade paints, the white pigment content (white inorganic pigments with a refractive index higher than 1,8) shall not exceed 36 g/m^2 for indoor products and 38 g/m^2 for outdoor products. In the case of paints for both indoor and outdoor use the more stringent limit shall apply.

In case the above mentioned products fall under the exemption indicated in part (b) then the white pigment content (white inorganic pigments with a refractive index higher than 1,8) shall not exceed 25 g/m^2 of dry film, with 98 % opacity.

1(b) *Minimum requirement for Wet Scrub Resistance (for indoor paints only)*

All indoor wall and ceiling paints (finishes) shall achieve class 1 or class 2 in wet scrub resistance (WSR) according to EN 13300 and EN ISO 11998. This requirement only applies to tinting bases (base paints).

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

Exempted from this requirement are indoor wall and ceiling paints with a white pigment content (white inorganic pigments with a refractive index higher than 1,8) that is equal or lower to 25 g/m^{2}of dry film, with 98 % opacity.

Only WSR class 1 and 2 ecolabelled paints may claim wet scrub resistance on the label or other marketing documentation.

Assessment and verification: the requirements of both 1(a) and 1(b) shall be fulfilled. the applicant shall provide documentation showing that the content of white pigments is compliant with this criterion.

The applicant shall provide a test report according to EN 13300 using the method EN ISO 11998 (Test for cleanability and scrub resistance). For ceiling paints and indoor wall paints the labelling for the packaging, including the accompanying text, shall be provided as evidence regarding claims of wet scrub resistance.

Criterion 2. Titanium Dioxide pigment

If the product contains more than 3,0 % w/w of titanium dioxide, the emissions and discharges of wastes from the production of any titanium dioxide pigment used shall not exceed the following ([1]):

For the sulphate process:

— SOx calculated as SO_2 : 7,0 kg/tonne TiO_2 pigment

— Sulphate waste: 500 kg/tonne TiO_2 pigment

For the chloride process:

— If natural rutile ore is used, 103 kg chloride waste/tonne TiO_2 pigment

— If synthetic rutile ore is used: 179 kg chloride waste/tonne TiO_2 pigment

— If slag ore is used: 329 kg chloride waste/tonne TiO_2 pigment

If more than one type of ore is used, the values will apply in proportion to the quantity of the individual ore types used.

Note:

SOx emissions only apply to the sulphate process.

The Waste Framework Directive 2008/98/EC of the European Parliament and of the Council ([2]), Article 3 shall be used for the definition of waste. If the TiO_2 producer can satisfy Article 5 (by-product production) of the Waste Framework Directive for its solid wastes then, the wastes shall be exempted.

Assessment and verification: the applicant shall submit supporting documentation showing compliance by the titanium dioxide producer manufacturing the raw material for the paint product either in the form of a declaration of non-use or a declaration supported by data indicating that the respective levels of process emissions and waste discharges of wastes are met.

Criterion 3. Efficiency in use

In order to demonstrate the efficiency in use of paints and varnishes the following tests per type of paint and/or varnish, as indicated in Table 2, shall be undertaken:

([1]) As derived from the Reference Document on Best Available Technology for the Manufacture of Large Volume Inorganic Chemicals (BREF), August 2007.

([2]) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

Table 2

Performance requirements for different kind of paints and varnishes

Criteria	Paints and Varnishes (with their subcategories identified according to the Directive 2004/42/EC)							
	Indoor paint (a, b)	Outdoor paint (c)	Trim and cladding (d)	Thick decorative coating indoor and outdoor (l)	Varnish and woodstain (e, f)	One pack performance and floor covering paint (i)	Primer (g)	Undercoat and primer (h)
3(a) Spreading rate (only for white and light coloured paints, including the white base paints used in tinting systems)) — ISO 6504/1	8 m^2/L	4 m^2/L (elastomeric paint) 6 m^2/L (masonry paint)	Outdoor products 6 m^2/L Indoor products 8 m^2/L	1 m^2/L	—	Outdoor products 6 m^2/L Indoor products 8 m^2/L	6 m^2/L (without opacity) 8 m^2/L (with opacity)	6 m^2/L (without opacity) 8 m^2/L (with opacity)
3(b) Resistance to water — ISO 2812-3	—	—	—	—	Resistant to water	Resistant to water	—	—
3(c) Adhesion — EN 24624		—	—	—	—	Score 2	1,5 MPa (masonry paint)	1,5 MPa (masonry paint)
3(d) Abrasion — EN ISO 7784-2	—	—	—	—	—	70 mg weight loss	—	—
3(e) Weathering — EN 11507/EN 927-6	—	1 000 h	1 000 h (outdoor)	1 000 h (outdoor)	1 000 h (outdoor)	1 000 h (outdoor)	—	—
3(f) Water vapour permeability [1] — EN ISO 7783	—	Class II or better	—	Class II or better (outdoor)	—	—	—	—
3(g) Liquid water permeability [1] — EN 1062-3	—	Where claims are made Class III All other products Class II or better	—	Class II or better (outdoor)	—	—	—	—

Criteria	Paints and Varnishes (with their subcategories identified according to the Directive 2004/42/EC)							
	Indoor paint (a, b)	Outdoor paint (c)	Trim and cladding (d)	Thick decorative coating indoor and outdoor (l)	Varnish and woodstain (e, f)	One pack performance and floor covering paint (i)	Primer (g)	Undercoat and primer (h)
3(h) Fungal resistance ([1]) — EN 15457	—	Class 1 or lower (masonry or wood paints)	Class 0 (outdoor wood products)	Class 1 or lower (outdoor)	—	—	—	—
3(h) Algal resistance — EN 15458 ([1])	—	Class 1 or lower (masonry or wood paints)	Class 0 (outdoor wood products)	Class 1 or lower (outdoor)	—	—	—	—
3(i) Crack bridging ([1]) — EN 1062-7	—	A1 (elastomeric paint only)	—	—	—	—	—	—
3(j) Alkali resistance — ISO 2812-4	—	Masonry paint	—	—	—	—	Outdoor for masonry	Outdoor for masonry
3(k) Corrosion resistance ([1]) EN ISO 12944-2 and 12944-6, ISO 9227, ISO 4628-2 and 4628-3	—	Anti-rust paint Blistering: ≥ size 3/density 3 Rusting: ≥ Ri2	Anti-rust paint Blistering: ≥ size 3/density 3 Rusting: ≥ Ri2	—	—	Anti-rust paint Blistering: ≥ size 3/density 3 Rusting: ≥ Ri2	Anti-rust paint Blistering: ≥ size 3/density 3 Rusting: ≥ Ri2	Anti-rust paint Blistering: ≥ size 3/density 3 Rusting: ≥ Ri2

([1]) Only required where marketing claims are made about the paints

3(a) *Spreading rate*

Spreading rate requirement shall apply to white and light coloured paint products. For paints that are available in more colours the spreading rate shall apply to the lightest colour.

White paints and light-coloured paints (including finishes and intermediates) shall have a spreading rate (at a hiding power of 98 %) of at least 8 m^2 per litre of product for indoor paints and 6 m^2 for outdoor paints. Products marketed for both — indoor and outdoor shall have a spreading rate (at a hiding power of 98 %) of at least 8 m^2 per litre.

For tinting systems, this criterion applies only to the white base (the base containing the most TiO_2). In cases where the white base is unable to achieve this requirement, the criterion shall be met after tinting the white base to produce the standard colour RAL 9010.

For paints that are a part of a tinting system, the applicant must advise the end-user on the product packaging and POS which shade or primer/undercoat (if possible bearing the Community Eco-label) should be used as a basecoat before applying the darker shade.

Transparent and semi-transparent primers and undercoats shall have a spreading rate of at least 6 m^2 and those with opacity at least 8 m^2. Opaque primers with specific blocking/sealing, penetrating/binding properties and primers with special adhesion properties shall have a spreading rate of at least 6 m^2 per litre of product.

Thick decorative coatings (paints that are specially designed to give a three-dimensional decorative effect and are therefore characterised by a very thick coat) shall alternatively have a spreading rate of 1 m^2 per kg of product.

Opaque elastomeric paints shall have a spreading rate of at least 4 m^2 per litre of product.

This requirement does not apply to varnishes, lasures, transparent adhesion primers or any other transparent coatings.

Assessment and verification: the applicant shall provide a test report using the method ISO 6504/1 (Paints and varnishes — determination of hiding power — Part 1: Kubelka-Munk method for white and light-coloured paints) or 6504/3 (Part 3: determination of contrast ratio (opacity) of light-coloured paints at a fixed spreading rate), or for paints specially designed to give a three-dimensional decorative effect and characterised by a very thick coat the method NF T 30 073. For bases used to produce tinted products not evaluated according to the above-mentioned requirements, the applicant shall produce evidence of how the end-user will be advised to use a primer and/or grey (or other relevant shade) of undercoat before application of the product.

3(b) *Resistance to water*

All varnishes, floor coatings and floor paints shall have resistance to water, as determined by ISO 2812-3 such that after 24 hours' exposure and 16 hours' recovery no change of gloss or of colour occurs.

Assessment and verification: the applicant shall provide a test report using the method ISO 2812-3.

3(c) *Adhesion*

Pigmented masonry primers for exterior uses shall score a pass in the EN 24624 (ISO 4624) pull-off test where the cohesive strength of the substrate is less than the adhesive strength of the paint, otherwise the adhesion of the paint must be in excess of a pass value of 1,5 MPa.

Floor coatings, floor paints, floor undercoats, interior masonry primers, metal and wood undercoats shall score 2 or less in the EN 2409 test for adhesion.

Transparent primers are not included in this requirement.

The applicant shall evaluate the primer and/or finish alone or both applied together. When testing the finish alone this shall be considered the worst case scenario concerning adhesion.

Assessment and verification: the applicant shall provide a test report using the method EN ISO 2409 or EN 24624 (ISO 4624) as applicable.

3(d) *Abrasion*

Floor coatings and floor paints shall have an abrasion resistance not exceeding 70 mg weight loss after 1000 test cycles with a 1000 g load and a CS10 wheel according to EN ISO 7784-2.

Assessment and verification: the applicant shall provide a test report showing compliance with this criterion using the method EN ISO 7784-2.

3(e) *Weathering (for outdoor paints and varnishes)*

Masonry finish paints and wood and metal finishes including varnishes shall be exposed to artificial weathering in apparatus including fluorescent UV lamps and condensation or water spray according to ISO 11507. They shall be exposed to test conditions for 1000 hours. Test conditions are: UVA 4 h/60 °C + humidity 4 h/50 °C.

Alternatively, outdoor wood finishes and wood varnishes shall be exposed to weathering for 1000 hours in the QUV accelerated weathering apparatus with cyclic exposure with UV(A) radiation and spraying according to EN 927-6.

According to ISO 7724 3, the colour change of samples exposed to weathering shall not be greater than $\Delta E^* = 4$. It is not applicable to varnishes and bases.

Decrease of gloss for gloss paints and varnishes exposed to weathering shall not be greater than 30 % of its initial value and shall be measured using ISO 2813. This requirement is not applicable to mid sheen and matt-finishes ([1]) which have an initial gloss value less than 60 % at 60° angle of incidence.

Chalking shall be tested using method EN ISO 4628-6 on masonry finish coats and wood and metal finishes (where applicable) after the samples have been exposed to weathering. Coatings shall achieve a score of 1,5 or better (0,5 or 1,0) in this test. In the standard there are illustrated references.

The following parameters shall also be evaluated on masonry finish coats and wood and metal finishes after the samples have been exposed to weathering:

Flaking according to ISO 4628-5; flake density 2 or less, flake size 2 or less

Cracking according to ISO 4628-4; crack quantity 2 or less, crack size 3 or less

Blistering according to ISO 4628-2; blister density 3 or less, blister size 3 or less.

Tests should be performed on the tinting base.

Assessment and verification: the applicant shall provide test reports using either ISO 11507 according to the specified parameters or EN 927-6, or both. The applicant shall provide test reports using EN ISO 4628-2, 4, 5, 6 and a test report in conformance ISO 7724-3 where applicable.

3(f) *Water vapour permeability*

Where claims are made that exterior masonry and concrete paints are breathable the paint shall be classified according to EN1062-1 as class II (medium vapour permeability) or better according to the test method EN ISO 7783.

([1]) EN ISO 2813.

Due to the large number of potential tinting colours, this criterion will be restricted to testing of the base paint.

Assessment and verification: the applicant shall provide a test report using methodology EN ISO 7783 and classification according EN1062-1.

3(g) *Liquid water permeability*

Where claims are made that exterior masonry and concrete paints are water repellent or elastomeric, the coating shall be classified according to EN1062-1 as class III (low liquid permeability) according to method EN 1062-3.

Due to the large number of potential tinting colours, this criterion will be restricted to the testing of the base paint.

All other masonry paints shall be classified according to EN1062-1 as class II (medium liquid permeability) or better according to the test method EN 1062-3.

Assessment and verification: the applicant shall provide a test report using methodology EN 1062-3 and classification according EN1062-1.

3(h) *Fungal and algal resistance*

Where claims are made that exterior masonry finish and wood paints have anti-fungal and algal properties, and in accordance with PT7 of the Biocide Regulation (EU) No 528/2012 of the European Parliament and of the Council ([1]), the following requirements shall be determined using EN 15457 and EN 15458.

Masonry paints shall have a score of class 1 or lower (1 or 0) for fungal resistance, (i.e. less than 10 % fungal coverage) and a score of class 1 or lower for algal resistance.

Wood paints shall have a score of 0 for fungal resistance and 0 for algal resistance.

Due to the large number of possible tinting colours, this criterion will be restricted to the testing of the base paint.

Assessment and verification: the applicant shall provide a test report using the methodology in EN 15457 and EN 15458.

3(i) *Crack bridging*

Where claims are made that masonry (or concrete) paint has elastomeric properties, the paint shall be at least classified as A1 at 23 °C according to EN 1062.

Due to the large number of potential tinting colours, this criterion will be restricted to the testing of the base paint.

Assessment and verification: the applicant shall provide a test report using methodology DIN EN 1062-7.

3(j) *Alkali resistance*

Masonry paints and primers shall show no noticeable damage when the coating is spotted for 24 hours with 10 % NaOH solution according to method ISO 2812-4. The evaluation is done after 24 hours drying-recovery.

Assessment and verification: the applicant shall provide a test report using methodology ISO 2812-4.

3(k) *Corrosion resistance*

Simulated corrosion stresses shall be applied to a substrate for the purpose of rating according to the appropriate atmospheric corrosivity category or categories in EN ISO 12944-2 and the accompanying test procedures specified in EN ISO 12944-6. Anti-rust paints for steel substrates shall be tested after 240 h salt spray following ISO 9227. The results shall be rated using ISO 4628-2 for blistering and ISO 4628-3 for rusting. The paint shall achieve result not worse than size 3 and density 3 in blistering and not worse than Ri2 in rusting test.

([1]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27/06/2012, p. 1).

Assessment and verification: the applicant shall provide testing and rating reports to confirm compliance with this criterion.

Criterion 4. Content of Volatile and Semi-volatile Organic Compounds (VOCs, SVOCs)

The maximum content of Volatile Organic Compounds (VOCs) and Semi-Volatile Organic Compounds (SVOCs) shall not exceed the limits given in Table 3.

The content of VOCs and SVOCs shall be determined for the ready to use product and shall include any recommended additions prior to application such as colourants and/or thinners.

Products with a VOC content that is in accordance with the limits in Table 3 may display the text 'reduced VOC content' and the VOC content in g/l next to the Ecolabel.

Table 3

VOC and SVOC content limits

Product description (with subcategory denotation according to Directive 2004/42/EC)	VOC limits (g/l including water)	SVOC limits (g/l including water)
a. Interior matt walls and ceilings (Gloss < 25@60°)	10	30 (1)/40 (2)
b. Interior glossy walls and ceilings (Gloss > 25@60°)	40	30 (1)/40 (2)
c. Exterior walls of mineral substrate	25	40
d. Interior/Exterior trim and cladding paints for wood and metal	80	50 (1)/60 (2)
e. Interior trim varnishes and woodstains, including opaque woodstains	65	30
e. Exterior trim varnishes and woodstains, including opaque woodstains	75	60
f. Interior and Exterior minimal build woodstains	50	30 (1)/40 (2)
g. Primers	15	30 (1)/40 (2)
h. Binding primers	15	30 (1)/40 (2)
i. One-pack performance coatings	80	50 (1)/60 (2)
j. Two-pack reactive performance coatings for specific end use such as floors	80	50 (1)/60 (2)
l. Decorative effect coatings	80	50 (1)/60 (2)
Anti-rust paints	80	60

(1) Indoor white paints and varnishes
(2) Indoor tinted paints/outdoor paints and varnishes

The VOC content shall be determined either by calculation based on the ingredients and raw materials or by using the methods given in ISO 11890-2 or, alternatively for products with a VOC content of less than 1.0 g/l, the methods given in ISO 17895. The SVOC content shall be determined using the method given in ISO 11890-2. The markers given in Table 4 shall be used as the basis for delimiting the Gas Chromatography results for SVOC's. In the case of products used both indoors and outdoors the strictest SVOC limit value for indoor paints shall prevail.

Table 4

Marker compounds to be used in the determination of SVOC content

	Polar systems (water-borne coating products)	Non-polar systems (solvent-borne coating products)
SVOC	Diethyl adipate ($C_{10}H_{18}O_4$) to methylpalmitate ($C_{17}H_{34}O_2$)	n-Tetradecane ($C_{14}H_{30}$) to n-Docosan ($C_{22}H_{46}$)

Assessment and verification: the applicant shall provide for the VOC content of the ready to use product either a test report using the methods given in ISO 11890-2 or ISO 17895 that demonstrates compliance or a declaration of compliance supported by calculations based on the paint ingredients and raw materials.

The applicant shall provide for the SVOC content of the ready to use product either a test report using the method given in ISO 11890-2 or a declaration of compliance supported by calculations based on the paint ingredients and raw materials. The test should be carried out with reference to the markers specified in Table 4 and the Criteria User Manual. At the request of a Competent Body applicants may be required to validate calculations using the specified test method.

Criterion 5. Restriction of hazardous substances and mixtures

The final product shall not contain hazardous substances and mixtures in accordance with the rules set out in the following sub-criteria which apply to:

— Hazard classifications and risk phrases

— Substances of Very High Concern

— Specific other listed substances

Applicants are required to evidence that the final product formulation complies with the overall assessment and verification requirements together with any additional requirements contained within the Appendix.

5(a) *Overall restrictions to hazard classifications and risk phrases*

The final product formulation, including all intentionally added ingredients present at a concentration of greater than 0,010 %, shall not, unless expressly derogated in the Appendix, contain substances or mixtures classified as toxic, hazardous to the environment, respiratory or skin sensitisers, or carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008 or Council Directive 67/548/EC [1] and as interpreted according to the hazard statements and risk phrases listed in Table 5 of this criteria.

Table 5

Restricted hazard classifications and their categorisation

Acute toxicity	
Category 1 and 2	Category 3
H300 Fatal if swallowed (R28)	H301 Toxic if swallowed (R25)
H310 Fatal in contact with skin (R27)	H311 Toxic in contact with skin (R24)

[1] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

Acute toxicity	
Category 1 and 2	Category 3
H330 Fatal if inhaled (R23/26)	H331 Toxic if inhaled (R23)
H304 May be fatal if swallowed and enters airways (R65)	EUH070 Toxic by eye contact (R39/41)

Specific target organ toxicity	
Category 1	Category 2
H370 Causes damage to organs (R39/23, R39/24, R39/25, R39/26, R39/27, R39/28)	H371 May cause damage to organs (R68/20, R68/21, R68/22)
H372 Causes damage to organs (R48/25, R48/24, R48/23)	H373 May cause damage to organs (R48/20, R48/21, R48/22)

Respiratory and skin sensitisation	
Category 1A	Category 1B
H317: May cause allergic skin reaction (R43)	H317: May cause allergic skin reaction (R43)
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled (R42)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled (R42)

Carcinogenic, mutagenic or toxic for reproduction	
Category 1A and 1B	Category 2
H340 May cause genetic defects (R46)	H341 Suspected of causing genetic defects (R68)
H350 May cause cancer (R45)	H351 Suspected of causing cancer (R40)
H350i May cause cancer by inhalation (R49)	
H360F May damage fertility (R60)	H361f Suspected of damaging fertility (R62)
H360D May damage the unborn child (R61)	H361d Suspected of damaging the unborn child (R63)
H360FD May damage fertility. May damage the unborn child (R60, R60/61)	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child (R62/63)
H360Fd May damage fertility. Suspected of damaging the unborn child (R60/63)	H362 May cause harm to breast fed children (R64)
H360Df May damage the unborn child. Suspected of damaging fertility (R61/62)	

Acute toxicity	
Category 1 and 2	Category 3
Hazardous to the aquatic environment	
Category 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life (R50)	H412 Harmful to aquatic life with long-lasting effects (R52/53)
H410 Very toxic to aquatic life with long-lasting effects (R50/53)	H413 May cause long-lasting effects to aquatic life (R53)
H411 Toxic to aquatic life with long-lasting effects (R51/53)	

Hazardous to the ozone layer	
EUH059 Hazardous to the ozone layer (R59)	

The most recent classification rules adopted by the Union shall take precedence over the listed hazard classifications and risk phrases. In accordance with Article 15 of Regulation (EC) No 1272/2008 applicants shall therefore ensure that classifications are based on the most recent rules on the classification, labelling and packaging of substances and mixtures.

Applicants are required to calculate the hazard classification of the final paint product in order to demonstrate compliance. This shall be in accordance with the methodologies for the classification of mixtures contained in Regulation (EC) No 1272/2008 and all amending legislation. Equivalence between mixture classifications according to the Dangerous Substances Directive 67/548/EEC (referred to as DSD) and those made according to Regulation (EC) No 1272/2008 (the CLP Regulation) can be found in Table 6.

The final product shall not be classified and labelled as being acutely toxic, a specific target organ toxicant, a respiratory or skin sensitiser, or carcinogenic, mutagenic or toxic for reproduction hazardous to the environment, in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EEC.

Table 6

Final product classification: CLP versus DSD equivalence

CLP Mixture classification	DSD equivalent
Acutely toxic	T or T+
Specific target organ toxicant	T, T+ or Xn
A respiratory or skin sensitiser	—
A carcinogen, mutagen or reproductive toxicant	Carcinogen, Mutagen or Reproductive toxicant categories 1-3
Hazardous to the environment	N (excluding R53 and R52/53)

5(a)(i) *Derogations applying to substance groups*

For the purpose of this product group, derogations have been granted for defined groups of substances that may be contained within the final product. These derogations stipulate the hazard classifications that are derogated for each specific substance group and the associated derogation conditions and concentration limits that apply. The derogations are set out in the Appendix and apply to the following substance groups:

1. Preservatives added to colourants, binders and the final product
   (a) In-can preservatives
   (b) Tinting machine preservatives
   (c) Dry film preservatives
   (d) Preservative stabilisers
2. Drying and anti-skinning agents
   (a) Drying agents
   (b) Anti-skinning agents
3. Corrosion inhibitors
   (a) Corrosion inhibitors
   (b) Verdigris prevention
4. Surfactants
   (a) General purpose surfactants
   (b) Alkylphenolethoxylates (APEOs)
   (c) Perfluorinated surfactants
5. Miscellaneous functional substances with general application
   (a) Silicon resin emulsion in white paints, colourant and tinting bases
   (b) Metals and their compounds
   (c) Mineral raw materials including fillers
   (d) Neutralising agents
   (e) Optical brighteners
   (f) Pigments
6. Miscellaneous functional substances with specialist applications
   (a) UV protectors and stabilisers
   (b) Plasticisers
7. Residual substances that may be present in the final product
   (a) Formaldehyde
   (b) Solvents
   (c) Unreacted monomers
   (d) Volatile Aromatic Compounds and halogenated compounds

5(a)(ii) *Derogation conditions applying to production sites*

Additional conditions relating to production of paints and varnishes shall apply in the case of derogations for acute toxins or specific target organ toxins. In this case applicants shall submit evidence that they have met the following requirements:

— Substances to which an acute toxic or specific target organ toxins classification applies shall demonstrate compliance with relevant European indicative Occupational Exposure Limit Values (OELV's) or Member State OELV's for the substance(s), with the strictest applying;

— Where there is no reference OELV then the applicant shall demonstrate how health and safety procedures for the handling of the ingoing substance(s) at production sites for the final ecolabelled paint product minimise exposure;

— Substances to which a classification applies as an aerosol or vapour shall demonstrate that workers are not exposed in this form;

— Substances to which the classification applies to in their dry form shall demonstrate that workers cannot come into contact with the substance in this form during manufacturing.

Assessment and verification: the applicant shall demonstrate compliance with this criterion by providing a declaration of the classification and/or non-classification for:

— The final paint or varnish product based on the methodologies for the classification of mixtures contained in Regulation (EC) No 1272/2008 and all amending legislation

— Paint or varnish formula ingredients that fall within the groups of substances listed in 5(a)(i) and that are present at concentrations of more than 0,010 %

This declaration shall be based on information collected according to the requirements in the Appendix.

Active ingredients to which specific concentration limits may apply under Regulation (EC) No 1272/2008 and which may fall below the cut-off value of 0,010 % shall also be identified.

The following technical information shall be provided to support the declaration of the classification or non-classification of ingredients:

(i) For substances that have not been registered under the REACH Regulation or which do not yet have a harmonised CLP classification: Information meeting the requirements listed in Annex VII to the REACH Regulation;

(ii) For substances that have been registered under the REACH Regulation and which do not meet the requirements for CLP classification: Information based on the REACH registration dossier confirming the non-classified status of the substance;

(iii) For substances that have a harmonised classification or are self-classified: safety data sheets where available. If these are not available or the substance is self-classified then information shall be provided relevant to the substances hazard classification according to Annex II to the REACH Regulation;

(iv) In the case of mixtures: Safety data sheets where available. If these are not available then calculation of the mixture classification shall be provided according to the rules under Regulation (EC) No 1272/2008 together with information relevant to the mixtures hazard classification according to Annex II to the REACH Regulation;

Substances and mixtures shall be characterised in accordance with sections 10, 11 and 12 of Annex II to the REACH Regulation (Requirements for the Compilation of Safety Data Sheets). This shall include information on the physical form and state of the ingredients and shall include identification of manufactured nanomaterial ingredients for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm.

The applicant shall also identify substances and mixtures used in the paint formulation which fall under the specific requirements for derogation as set out in the Appendix. For each derogated substance or mixture supporting information shall be provided showing how the derogation requirements have been met.

5(b) *Restrictions that apply to Substances of Very High Concern*

In accordance with Article 6(7) of Regulation (EC) No 66/2010 the final product and any ingredients or raw materials, shall not, unless specifically derogated, contain substances that:

— Meet the criteria in Article 57 of the REACH Regulation;

— Have been identified according to the procedure described in Article 59(1) of the REACH Regulation which establishes the Candidate List for Substances of Very High Concern.

No derogation shall be given concerning substances that meet one or both of these conditions, and which are present in a paint or varnish product at concentrations higher than 0.10 % (weight by weight).

Assessment and verification: the applicant shall provide a declaration of compliance with this criterion, supported by declarations of compliance signed by their suppliers. Applicants shall demonstrate that they have carried out a screening of ingoing substances against the current Candidate List for Substances of Very High Concern and the criteria in Article 57 of the REACH Regulation.

5(c) *Restrictions that apply to specific hazardous substances*

The final product shall not contain the hazardous substances that are specifically identified in the Appendix at or above the specified concentration limits. The restrictions on substances in the Appendix apply to the following paint and varnish ingredients and residues:

(i) Dry film preservatives

(ii) Tinting machine preservatives

(iii) In-can preservatives

(iv) Preservative stabilisers

(v) Alkylphenolethoxylates (APEOs) surfactants

(vi) Perfluorinated surfactants

(vii) Metals and their compounds

(viii) Pigments

(ix) Plasticisers

(x) Free formaldehyde

Assessment and verification: verification and testing requirements are as specified in the Appendix for each substance and as relevant to specific forms of paint and varnish.

Criterion 6. Consumer information

6(a) The following texts shall appear on or be attached to the packaging:

— 'Minimise paint wastage by estimating how much paint you will need'

— 'Recover unused paint for re-use'.

— 'Reuse of paint can effectively minimise the products' life cycle environmental impact'

6(b) The following general information and advice shall be provided on or be attached to the packaging:

— How to estimate the amount of paint needed prior to purchase in order to minimise paint wastage and a recommended amount as a guideline (e.g. for 1 m^2 of wall x litres of paint is needed).

— How to deal with the 'unused paint' together with, where available, a web-link or contact details from which the consumer can find more detailed information.

6(c) The following advice and recommendations on how to handle the paint shall be provided on or be attached to the packaging:

— Safety measures for the user. This shall include basic recommendation on personal protective equipment that should be worn. It shall also include additional measures that should be taken when using spray equipment.

— The use of cleaning equipment and appropriate waste management (in order to limit water and soil pollution). For example, text advising that unused paint requires specialist handling for safe environmental disposal and therefore it should not be thrown away with household or commercial waste (e.g. 'Do not put residual paint down the kitchen sink or toilet, or into a waste bin').

— Storage of the paint in appropriate conditions (before and after opening), including, where appropriate, safety advice.

Assessment and verification: the applicant shall declare that the product complies with the requirement and provide the competent body with the artwork or samples of the user information and/or a link to a manufacturer's website containing this information as part of the application. The recommended amount of paint given as a guideline shall be provided.

Criterion 7. Information appearing on the EU Ecolabel

The optional label with text box shall contain, where relevant, the following texts:

— Minimised content of hazardous substances

— Reduced content of volatile organic compounds (VOCs): x g/l

— Good performance for indoor use *(where indoor criteria have been met)* or

— Good performance for outdoor use *(where outdoor criteria have been met)* or

— Good performance for both indoor and outdoor use *(where both indoor and outdoor criteria have been met)*

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: the applicant shall provide a sample of the product label or an artwork of the packaging where the EU Ecolabel is placed, together with a declaration of compliance with this criterion.

Appendix

HAZARDOUS SUBSTANCE RESTRICTION AND DEROGATION LIST

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification

1. **Preservatives added to colourants, binders and the final product**

(i) Rules relating to biocide authorisation status

The paint formulation shall only contain preservatives that meet the requirements of 1a, 1b and 1c (as applicable), which are authorised under Directive 98/8/EC of the European Parliament and of the Council [1] and Regulation (EU) No 528/2012 and for which a risk assessment for professional and/or consumer (non-professional) use is provided in the Assessment Report. Applicants should consult the most current authorisation list.

Preservatives for which a dossier has been submitted for evaluation pending a decision on authorisation or non-inclusion may be used in the interim period up until the adoption of the Decision.

(ii) Permitted sum totals of in-can and dry film preservatives in the ready to use product

In-can and dry film preservatives may be used in indoor and outdoor products according to the sum total concentrations detailed in the following table.

Sum total preservatives permitted in paint and varnish products

Preservation type	Indoor products	Outdoor products
In-can preservatives	0,060 %	0,060 %
Dry film preservatives	Not permitted	0,30 %
Derogated exceptions:		
(i) Paints for use in high humidity areas	0,10 %	n/a
(ii) IPBC combinations for outdoor protection	n/a	0,65 %
Sum total preservatives	0,060 %	0,360 %
With derogated exceptions (i) or (ii) for dry film preservation	0,160 %	0,710 %

(iii) Permitted sum totals of isothiazolinone substances and compounds in the ready to use product

The sum total of isothiazolinone compounds in any paint or varnish product shall not exceed 0,050 % (500 ppm) with the exception of outdoor wood paints and varnishes which shall not exceed 0,20 %. The following preservatives are derogated for use subject to specific limits on their contribution to the sum total of isothiazolinone compounds in the final ready to use product.

2-methyl-2H-isothiazol-3one: 0,0200 %

1,2-Benzisothiazol-2(2H)-one: 0,0500 %

2-Octyl-2H-Isothiazol-3-one: 0,0500 % with the exception of outdoor wood paints and varnishes in which it may be used at higher concentrations

5-chloro-2-methyl-4-isothiazolin-3-one/2- methyl-4-isothiazolin-3-one: 0,0015 %

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
(a) In-can preservatives Applicability: All products unless specified otherwise	In-can preservatives classified with the following derogated hazard classifications may be used in ecolabelled products: Derogated classifications: H331 (R23), H400 (R50), H410 (R50/53), H411 (R51/53), H412 (R52/53), H317 (R43) In-can preservatives classified with these derogated classifications must also meet the following derogation conditions: — The sum total concentration shall not exceed 0,060 % w/w — Substances classified with H400 (R50) and/or H410 (R50/53) shall be non-bioaccumulative. Non-bioaccumulative substances shall have a Log Kow ≤ 3,2 or a Bioconcentration Factor (BCF) ≤ 100. — Evidence shall be provided that Authorisation conditions under Directive 98/8/EC and Regulation (EU) No 528/2012 are respected for the product. — Where preservatives that are formaldehyde donors are used then formaldehyde content and emissions from the final product must meet the requirements in substance restriction 7(a) Specific concentration limits applies to the following preservatives: (i) Zinc pyrithione (ii) N-(3-aminopropyl)-N-dodecylpropane-1, 3-diamine	In-can preservatives Sum total in the final product: 0,060 % w/w Concentration limit 0,050 % 0,050 %	Verification: Declaration by the applicant and their binder supplier supported by CAS numbers and classifications for the active ingredients in the final product and its binder. This shall include calculation by the applicant of the concentration of the active ingredient in the final product. In line with the requirements of the Biocide Regulation (EU) No 528/2012 Article 58(3) all manufactured active ingredients for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm shall be identified.
(b) Tinting (colourant) machine preservatives	The derogated hazard classifications and the derogation conditions listed under 1(a) shall apply also to preservatives used to protect colour tints whilst stored in machines prior to mixing with base paints. Preservatives added to protect tints that will be dispensed from machines shall not exceed a sum total of 0,20 % w/w. The following preservatives are subject to specific maximum concentration limits contributing to the sum total of preservatives in the colourant: (i) 3-iodo-2-propynyl butylcarbamate (IPBC) (ii) Zinc pyrithione (iii) N-(3-aminopropyl)-N-dodecylpropane-1, 3-diamine	Sum total preservatives in the colourant: 0,20 % w/w 0,10 % 0,050 % 0,050 %	Verification: Declaration by the applicant and/or their tint supplier supported by CAS numbers and classifications for the active ingredients in the final product and its binder. This shall include calculation of the concentration of the active ingredient in the final tint product. In line with the requirements of the Biocide Regulation (EU) No 528/2012 Article 58(3) all manufactured active ingredients for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm. shall be identified.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
(c) Dry film preservatives Applicability: Outdoor paints, indoor paints for specific applications	Dry film preservatives and their stabilisers classified with the following derogated hazard classifications may be used in all outdoor products and only specific indoor products: Derogated classifications: H400 (R50), H410 (R50/53), H411 (R51/53), H412 (R52/53), H317 (R43) Dry film preservatives classified with these derogated classifications must also meet the following derogation conditions: — The sum total concentration shall not exceed 0,10 % w/w or 0,30 % w/w (as relevant) — Substances classified with H400 (R50) and/or H410 (R50/53) shall be non-bioaccumulative. Non-bioaccumulative substances shall have a Log Kow ≤ 3,2 or a Bioconcentration Factor (BCF) ≤ 100. — Evidence shall be provided that the conditions set out in the Authorisation conditions for preservatives under the Biocide Directive 98/8/EC and the Biocide Regulation (EU) No 528/2012 are being respected. A higher sum total applies to the following dry film preservatives for the specified applications only: 3-iodo-2-propynyl butylcarbamate (IPBC) combinations Outdoor paints and varnishes Specific concentration limits applies to the following preservatives: Zinc pyrithione	Dry film preservatives Sum total in the final product: Indoor paints intended for use in areas with high humidity, including kitchens and bathrooms 0,10 % w/w All outdoor paint applications 0,30 % w/w Outdoor paints sum total for IPBC combinations: 0,650 % 0,050 %	Verification: Declaration by the applicant and their binder supplier supported by CAS numbers and classifications for the active ingredients in the final product and its binder. This shall include calculation by the applicant of the concentration of the active ingredient in the final product. In line with the requirements of the Biocide Regulation (EU) No 528/2012 Article 58(3) all manufactured active ingredients for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm. shall be identified.
(d) Preservative stabiliser	Zinc oxide is derogated for use as a stabiliser for dry film preservative combinations that require zinc pyrithione or 1,2 Benzisothiazol-3(2H)-one (BIT).	0,050 %	Verification: Declaration by the applicant and their raw material suppliers.

2. **Drying and anti-skinning agents**

(a) Driers Applicability: All paints products unless specified otherwise.	Derogated classifications: H301 (R24), H317 (R43), H373 (H48/20-22), H412 (R52/53), H413 (R53) Cobalt driers in alkyd paints, which are additionally classified with H400 (R50) and H410, are derogated for white and light coloured paints only up to the following concentration limit:	Sum total drier content 0,10 % w/w Cobalt drier content limit 0,050 %	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
(b) Anti-skinning agents Applicability: All paints products	Derogated classifications: H412 (R52/53), H413 (R53), H317 (R43)	0,40 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
3. **Corrosion inhibitors**			
(a) Anti- corrosion pigments Applicability: Where required	Derogated classifications: H410 (R50/53), H411 (R51/53), H412 (R52/53), H413 (R53) Concentration limits that shall apply: (i) Paints Directive 2004/42/EC classes d, i, j (ii) All other products	8,0 % w/w 2,0 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by SDS.
(b) Verdigris prevention Applicability: Where required	Derogated classifications: H412 (R52/53), H413 (R53)	0,50 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
4. **Surfactants**			
(a) General purpose surfactants Applicability: Surfactants used in all products.	Derogated classifications: H411 (R51/53), H412 (R52/53), H413 (R53) The following sum total values apply to the ready to use final product: — White and light coloured products — All other colours The derogation applies to the surfactant formulation supplied to the paint manufacturer. Specific restrictions apply to Alkylphenolethoxylates (APEOs) and Perfluorinated surfactants.	Sum total surfactants in the ready to use product: 1,0 % w/w 3,0 % w/w	Verification: Declaration shall be provided by the applicant, raw material suppliers and/or their surfactant supplier supported by CAS No's and classifications for the surfactants used.
(b) Alkylphenolethoxylates (APEOs) Applicability: Surfactants used in all products.	Alkylphenolethoxylates (APEOs) and their derivatives shall not be used in any paint or varnish preparations or formulations.	n/a	Verification: A declaration of non-use shall be provided by the applicant and their raw material suppliers supported by CAS No's and classifications for the surfactants used.
(c) Perfluorinated surfactants Applicability: Surfactants used in specific products.	Long chain perfluorinated surfactants, as specified in the OECD definition below, shall not be used: (i) Perfluorocarboxylic acids with carbon chain lengths ≥ C8, including perfluorooctanoic acid (PFOA); (ii) Perfluoroalkyl sulfonates with carbon chain lengths ≥ C6, including perfluorohexane sulfonic acid (PFHxS) and perfluorooctane sulfonate (PFOS); and (iii) Related compounds that may degrade to the substances identified in (i) or (ii) shall not be present in the surfactant or as a residue in the paint or varnish product.	n/a	Verification: A declaration of non-use shall be provided by the applicant and their raw material suppliers supported by CAS numbers and identification of chain length for the surfactants used.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
	Perfluorinated surfactants that do not meet (i),(ii) or (iii) may only be used in paint that is required to be resistant or repellent to water (see efficiency of use criteria 3(b) and 3(g) respectively) and to have a spreading rate of greater than 8 m^2/l (see efficiency of use criteria 3(a).		

5. **Miscellaneous functional substances with general application**

(a) Silicon resin emulsion in white paints, colourant and tinting bases Applicability: All paints products	Derogated classifications: H412 (R52/53), H413 (R53)	2,0 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
(b) Metals and their compounds Applicability: All products	The following metals or their compounds shall not be present in the product or the ingredients used in the product above the specified cut-off limit: Cadmium, lead, chromium VI, mercury, arsenic, barium, selenium, antimony and cobalt. The following derogations apply: — Barium, antimony and cobalt in pigments (see restriction 5(f)) — Cobalt in driers (see restriction 2(a))	0,010 % cut-off per listed metal	Verification: Declaration by the applicant and their raw material suppliers.
(c) Mineral raw materials including fillers Applicability: All paints products	Mineral raw materials including crystalline silica and leucophyllite minerals containing crystalline silica are derogated for H373 (R48/20). Mineral raw materials containing metals referred to in restriction 5(b) may be used if laboratory testing shows that the metal is bonded within a crystal lattice and is insoluble (see test method applicable). The following fillers are derogated on this basis: Nepheline syenite, containing barium		Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications. Applicants wishing to use binders containing restricted metals shall submit test reports carried out in accordance with the listed standard. Test method: DIN 53770-1 or equivalent
(d) Neutralising agents Applicability: All paints products unless specified	Derogated classifications: H311 (R24), H331 (R23), H400 (R50), H410 (R50/53), H411 (R51/53), H412 (R52/53), H413 (R53) The following concentration limits shall apply: — Varnishes and floor paints — All other products	 1,0 % w/w 0,50 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
(e) Optical brighteners Applicability: All paints products	Derogated classifications: H413 (R53)	0,10 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
(f) Pigments Applicability: All products	Pigments containing metals shall only be used where laboratory testing of the pigment shows that the metal chromophore is bonded within a crystal lattice and is insoluble. The following metal containing pigments are derogated for use without the need for testing: — Barium sulphate — Antimony nickel within an insoluble TiO_2 lattice — Cobalt aluminate blue spinel — Cobalt chromite blue-green spinel	n/a	Verification: Test results demonstrating that the pigment chromophore is bonded within a crystal lattice and is insoluble. Test method: DIN 53770-1 or equivalent

6. **Miscellaneous functional substances with specialist applications**

(a) UV protectors and stabilising agents for outdoor paints Applicability: Outdoor paints	Derogated classifications: H317 (R43), H411 (R51/53), H412 (R52/53), H413 (R53),	0,60 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
(b) Plasticisers in paint and varnish. Applicability: Where included in the formulation	The following phthalates shall not be intentionally added as plasticisers: DEHP (Bis-(2-ethylhexyl)-phthalate) BBP (Butylbenzylphthalate) DBP (Dibutylphthalate) DMEP (Bis2-methoxyethyl) phthalate DIBP (Diisobutylphthalate) DIHP (Di-C6-8-branched alkyphthalates) DHNUP (Di-C7-11-branched alkylphthalates) DHP (Di-n-hexylphthalate)	Concentration limit for any individual phthalate: 0,010 %	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
7. **Residual substances that may be present in the final product**			
(a) Formaldehyde Applicability: All products.	Free formaldehyde shall not be intentionally added to the final product. The final product shall be tested in order to determine its free formaldehyde content. The sampling requirements for testing shall reflect the product range. The following sum total limit value shall apply:		Verification: The free formaldehyde content shall be determined for the white base or transparent tinting base predicted to contain the highest theoretical amount of formaldehyde. The content of the colour tint which is predicted to contain the highest theoretical amount of formaldehyde shall also be determined. Test method:
	The following derogations are made from this requirement: (i) Where preservatives that are formaldehyde donors are required as an in-can preservative to protect a specific type of paint or varnish and where the formaldehyde donor is used in the place of isothiazolinone preservatives.	0,0010 %	0,0010 % limit value: Determination of the in-can concentration using the Merckoquant method. If the outcome is not definitive according to this method then high-performance liquid chromatography (HPLC) shall be used to confirm the in-can concentration.
	(ii) Where polymer dispersions (binders) provide, through residual levels of formaldehyde, the function of formaldehyde donors instead of in-can preservatives. In these cases the sum total shall not exceed the following limit value:	0,010 %	0,010 % limit value: (1) All paints: Determination of the in-can formaldehyde concentration by means of analysis using VdL-RL 03 or high-performance liquid chromatography (HPLC). and (2) Indoor paints and varnishes: Determination by means of analysis according to ISO 16000-3. Emissions must not exceed 0,25 ppm upon first application and they must be less than 0,05 ppm after 24 hours from the first application.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
(b) Solvents Applicability: All products.	Derogated classifications: H304 (R65)	2,0 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
(c) Unreacted monomers Applicability: Polymer binder systems	Unreacted monomers present from binders including acrylic acid may be present in the final product up to a sum total limit.	0,050 % w/w	Verification: Declaration shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.
(d) Volatile Aromatic Hydrocarbons and halogenated solvents Applicability: All products.	Volatile Aromatic Hydrocarbons and halogenated solvents shall not be present in the final product.	residual limit value of 0,01 %	Verification: A declaration of non-use shall be provided by the applicant and their raw material suppliers supported by CAS numbers and classifications.

(1) 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 (OJ L 123, 24.4.1998, p. 1).

COMMISSION DECISION

of 28 May 2014

amending Decisions 2011/263/EU, 2011/264/EU, 2011/382/EU, 2011/383/EU, 2012/720/EU and 2012/721/EU in order to take account of developments in the classification of substances

(notified under document C(2014) 3468)

(Text with EEA relevance)

(2014/313/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) In accordance with Article 6(6) of Regulation (EC) No 66/2010 the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) or to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]). In accordance with Article 6(7) of Regulation (EC) No 66/2010, for specific categories of goods containing those substances, where it is not technically feasible to substitute those goods as such or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environmental performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from Article 6(6) of that Regulation.

(2) Commission Decisions 2011/263/EU ([4]), 2011/264/EU ([5]), 2011/382/EU ([6]), 2011/383/EU ([7]), 2012/720/EU ([8]) and 2012/721/EU ([9]) established the ecological criteria for the award of the EU Ecolabel for detergents for dishwashers, laundry detergents, hand dishwashing detergents, all-purpose cleaners and sanitary cleaners, industrial and institutional automatic dishwasher detergents and industrial and institutional laundry detergents. Subsequent to the adoption of those Decisions, Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) No 286/2011 ([10]). The amendments to Regulation (EC) No 1272/2008 became applicable in respect of substances from 1 December 2012 and will become applicable in respect of mixtures from 1 June 2015. Regulation (EU) No 286/2011 added new classification criteria for long-term aquatic hazard based on chronic aquatic

([1]) OJ L 27, 30.1.2010, p. 1.
([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).
([4]) Commission Decision 2011/263/EU of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel to detergents for dishwashers (OJ L 111, 30.4.2011, p. 22).
([5]) Commission Decision 2011/264/EU of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel for laundry detergents (OJ L 111, 30.4.2011, p. 34).
([6]) Commission Decision 2011/382/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents (OJ L 169, 29.6.2011, p. 40).
([7]) Commission Decision 2011/383/EU of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners (OJ L 169, 29.6.2011, p. 52).
([8]) Commission Decision 2012/720/EU of 14 November 2012 establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents (OJ L 326, 24.11.2012, p. 25).
([9]) Commission Decision 2012/721/EU of 14 November 2012 establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Laundry Detergents (OJ L 326, 24.11.2012, p. 38).
([10]) Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 83, 30.3.2011, p. 1).

toxicity and biodegradability data. On the basis of the new criteria, the majority of readily-degradable surfactants currently used in detergents and cleaning products has become classified as Chronic category 3 (H412) and in some cases, specifically relevant to hand dishwashing detergents, as Chronic category 2 (H411), and therefore are banned from use in products bearing the EU Ecolabel. This would make it difficult for the established ecological criteria for the award of the EU Ecolabel for detergents for dishwashers, laundry detergents, hand dishwashing detergents, all-purpose cleaners and sanitary cleaners, industrial and institutional automatic dishwasher detergents and industrial and institutional laundry detergents to correspond indicatively to the best 10-20 % of detergents and cleaning products available on the Union market in terms of environmental performance throughout their life-cycle, as there is no evidence that alternative surfactants are available. Assessment and verification text is updated, in order to provide guidance to help applicants to prove compliance with the new requirement.

(3) The consequences of introduction of new classification criteria were not known during the review of the criteria for the award of the EU Ecolabel for detergents for dishwashers, laundry detergents, hand dishwashing detergents, all-purpose cleaners and sanitary cleaners set out in Decisions 2011/263/EU, 2011/264/EU, 2011/382/EU and 2011/383/EU and during the development of criteria for the award of the EU Ecolabel for industrial and institutional automatic dishwasher detergents and industrial and institutional laundry detergents and the considerations of derogations for surfactants set out in Decisions 2012/720/EU and 2012/721/EU.

(4) This amendment is applied retroactively from 1 December 2012, in order to ensure continuity of the validity of EU Ecolabel criteria for detergents for dishwashers, laundry detergents, hand dishwashing detergents, all-purpose cleaners and sanitary cleaners, industrial and institutional automatic dishwasher detergents and industrial and institutional laundry detergents.

(5) Decisions 2011/263/EU, 2011/264/EU, 2011/382/EU, 2011/383/EU, 2012/720/EU and 2012/721/EU should therefore be amended accordingly.

(6) 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 Annex to Decision 2011/263/EU is amended as set out in Annex I to this Decision.

Article 2

The Annex to Decision 2011/264/EU is amended as set out in Annex II to this Decision.

Article 3

The Annex to Decision 2011/382/EU is amended as set out in Annex III to this Decision.

Article 4

The Annex to Decision 2011/383/EU is amended as set out in Annex IV to this Decision.

Article 5

The Annex to Decision 2012/720/EU is amended as set out in Annex V to this Decision.

Article 6

The Annex to Decision 2012/721/EU is amended as set out in Annex VI to this Decision.

Article 7

This Decision shall apply in respect of substances from 1 December 2012.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 28 May 2014.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX I

The Annex to Decision 2011/263/EU is amended as follows:

(1) in Criterion 2, point (b), fifth paragraph, the table of derogations is replaced by the following table:

'Surfactants in total concentrations < 25 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides used for preservation purposes (**)	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
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.
(**) Referred to in Criterion 2(e). This derogation is applicable provided that biocides' bioaccumulation potentials are characterised by log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100.
(***) 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 %';

(2) in Criterion 2, point (b) the following paragraph is added to the *Assessment and verification* text:

'For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.'.

ANNEX II

The Annex to Decision 2011/264/EU is amended as follows:

(1) in Criterion 4, point (b), fifth paragraph, the table of derogations is replaced by the following table:

'Surfactants in total concentrations < 25 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides used for preservation purposes (**)	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
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
Bleach catalysts (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40
Optical brighteners (only for heavy duty laundry detergent)	H413: May cause long lasting effects to aquatic life	R53

(*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.
(**) Referred to in Criterion 4(e). This derogation is applicable provided that biocides' bioaccumulation potentials are characterised by log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100.
(***) 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 %.';

(2) in Criterion 4, point (b) the following paragraph is added to the *Assessment and verification* text:

'For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.'.

ANNEX III

The Annex to Decision 2011/382/EU is amended as follows:

(1) in Criterion 3, point (c), fourth paragraph, the table of derogations is replaced by the following table:

'Surfactants in total concentrations < 25 % in the final product (*)	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (**)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Surfactants in total concentrations < 2,5 % in the final product (**)	H411: Toxic to aquatic life with long-lasting effects	R51-53
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(*) The percentage must be divided by the M-factor established in accordance with the Regulation (EC) No 1272/2008.
(**) This derogation is applicable provided that they are ready degradable and anaerobically degradable.
(***) 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 %.';

(2) in Criterion 3, point (c) the following paragraph is added to the *Assessment and verification* text:

'For derogated surfactants meeting the criteria for classification with the hazard classes H412 and/or H411, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.'.

ANNEX IV

The Annex to Decision 2011/383/EU is amended as follows:

(1) in Criterion 3, point (c), fourth paragraph, the table of derogations is replaced by the following table:

'Surfactants in total concentrations < 25 % in the final product (*)	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (**)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(*) The percentage must be divided by the M-factor established in accordance with the Regulation (EC) No 1272/2008.
(**) This derogation is applicable provided that they are ready degradable and anaerobically degradable.
(***) 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 %.';

(2) in Criterion 3, point (c) the following paragraph is added to the *Assessment and verification* text:

'For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.'.

ANNEX V

The Annex to Decision 2012/720/EU is amended as follows:

(1) in Criterion 3, point (b), sixth paragraph, the table of derogations is replaced by the following table:

'Surfactants in total concentrations < 15 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product	H412: Harmful to aquatic life with long-lasting effects	R52-53
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 an 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 %';

(2) in Criterion 3, point (b) the following paragraph is added to the Assessment and verification text:

'For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.'.

ANNEX VI

The Annex to Decision 2012/721/EU is amended as follows:

(1) in Criterion 4, point (b), sixth paragraph, the table of derogations is replaced by the following table:

'Surfactants in total concentrations < 20 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
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

(*) This derogation is applicable provided that surfactants comply with Criterion 3(a) and they are anaerobically degradable.
(**) 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 %.';

(2) in Criterion 4, point (b) the following paragraph is added to the *Assessment and verification* text:

'For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.'.

COMMISSION DECISION

of 28 May 2014

establishing the criteria for the award of the EU Ecolabel for water-based heaters

(notified under document C(2014) 3452)

(Text with EEA relevance)

(2014/314/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 Ecolabelling Board,

Whereas:

(1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to products which have 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 Commission has drawn up a preliminary report on the technical, environmental, economic and legal aspects of the product group 'water-based heaters' typically used in the Union and made it publicly available for comment. The study on which this report is based (hereinafter 'the study') was devised together with stakeholders and interested parties from the Union and third countries.

(4) The results of the study, presented in the preliminary report, have shown that energy consumption in the use phase contributes most significantly to the overall environmental impact of water-based heaters. Therefore, the use of energy-efficient and low greenhouse gas-emitting water-based heaters should be promoted and, in addition, such heaters using more environmental friendly technologies and proven to be safe for consumers should be supported.

(5) It is appropriate to establish EU Ecolabel criteria for the product group 'water-based heaters'.

(6) 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.

(7) 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

1. The product group 'water-based heaters' shall comprise products that are used to generate heat as part of a water-based central heating system, where the heated water is distributed by means of circulators and heat emitters in order to reach and maintain the indoor temperature of an enclosed space such as a building, a dwelling, or a room, at a desired level. The heat generator generates heat by means of one or more of the following processes and technologies:

(a) combustion of gaseous, liquid or solid fossil fuels;

(b) combustion of gaseous, liquid or solid biomass;

(c) use of the Joule effect in electric resistance heating elements;

[1] OJ L 27, 30.1.2010, p. 1.

(d) capture of ambient heat from air, water or ground source, and/or waste heat;

(e) cogeneration (the simultaneous generation in one process of heat and electricity);

(f) solar energy (auxiliary).

2. The maximum output power of the water-based heaters shall be 400 kW.

3. Combination heaters are included in the scope of this product group, provided that their primary function is to provide space heat.

4. The following products are excluded from the scope of this product group:

(a) heaters whose primary function is to provide hot drinking or sanitary water;

(b) heaters for heating and distributing gaseous heat transfer media such as vapour or air;

(c) cogeneration space heaters with a maximum electrical capacity of 50 kW or above;

(d) space heaters that combine both indirect heating, using water-based central heating system, and direct heating, by direct emission of heat into the room or space where the appliance is installed.

Article 2

For the purpose of this Decision, the following definitions shall apply:

1. 'heater' means a space heater or combination heater;

2. 'space heater' means a device that

   (a) provides heat to a water-based central heating system in order to reach and maintain at a desired level the indoor temperature of an enclosed space such as a building, a dwelling or a room; and

   (b) is equipped with one or more heat generators;

3. 'combination heater' means a water-based space heater that is designed to also provide heat to deliver hot drinking or sanitary water at given temperature levels, quantities and flow rates during given intervals, and is connected to an external supply of drinking or sanitary water;

4. 'package of space heater, temperature control and solar device' means a package offered to the end-user containing one or more space heaters combined with one or more temperature controls and/or one or more solar devices;

5. 'package of combination heater, temperature control and solar device' means a package offered to the end-user containing one or more combination heaters combined with one or more temperature controls, and/or one or more solar devices;

6. 'solar device' means a solar-only system, a solar collector, a solar hot water storage tank or a pump in the collector loop, which are placed on the market separately;

7. 'water-based central heating system' means a system using water as a heat transfer medium to distribute centrally generated heat to heat emitters for the space heating of buildings, or parts thereof;

8. 'heat generator' means the part of a heater that generates the heat using one or more of the following processes:

   (a) combustion of fossil fuels and/or biomass fuels;

   (b) use of the Joule effect in electric resistance heating elements;

   (c) capture of ambient heat from an air source, water source or ground source, and/or waste heat;

9. 'gas heater' means a space heater or combination heater equipped with one or more heat generators fuelled with gaseous fuels of fossil origin or from biomass;

10. 'liquid fuel heater' means a space heater or combination heater equipped with one or more heat generators fuelled with liquid fuels of fossil origin or from biomass;

11. 'solid fuel heater' means a space heater or combination heater equipped with one or more heat generators fuelled with solid fuels of fossil origin or from biomass;

12. 'boiler space heater' means a space heater that generates heat using the combustion of fossil fuels and/or biomass fuels, and/or using the Joule effect in electric resistance heating elements;

13. 'gas boiler space heater' means a boiler space heater equipped with one or more heat generators using the combustion of gaseous fuels of fossil origin or from biomass;

14. 'liquid fuel boiler space heater' means a boiler space heater equipped with one or more heat generators using the combustion of liquid fuels of fossil origin or from biomass;

15. 'solid fuel boiler space heater' means a boiler space heater equipped with one or more heat generators using the combustion of solid fuels of fossil origin or from biomass;

16. 'solid biomass boiler space heater' means a boiler space heater equipped with one or more heat generators using the combustion of solid fuels from biomass;

17. 'electric boiler space heater' means a boiler space heater that generates heat using the Joule effect in electric resistance heating elements only;

18. 'electric boiler combination heater' means a boiler combination heater that generates heat using the Joule effect in electric resistance heating elements only;

19. 'heat pump space heater' means a space heater using ambient heat from an air source, water source or ground source, and/or waste heat for heat generation; a heat pump space heater may be equipped with one or more supplementary heaters using the Joule effect in electric resistance heating elements or the combustion of fossil and/or biomass fuels;

20. 'heat pump combination heater' means a heat pump space heater that is designed to also provide heat to deliver hot drinking or sanitary water at given temperature levels, quantities and flow rates during given intervals, and is connected to an external supply of drinking or sanitary water;

21. 'fuel-driven heat pump heater' means a heat pump heater equipped with one or more heat generators fuelled with gas or liquid fuel of fossil origin or from biomass;

22. 'electrically-driven heat pump heater' means a heat pump heater equipped with one or more heat generators using electricity as a fuel;

23. 'cogeneration space heater' means a space heater simultaneously generating heat and electricity in a single process;

24. 'temperature control' means equipment that interfaces with the end-user regarding the values and timing of the desired indoor temperature, and communicates relevant data, such as actual indoor and/or outdoor temperature(s), to an interface of the heater such as a central processing unit, thus helping to regulate the indoor temperature(s);

25. 'seasonal space heating energy efficiency' (η_s) means the ratio between the space heating demand for a designated heating season, supplied by a heater and the annual energy consumption required to meet this demand, expressed in percentage %;

26. 'water heating energy efficiency' (η_{wh}) means the ratio between the useful energy in the drinking or sanitary water provided by a combination heater and the energy required for its generation, expressed in percentage %;

27. 'rated heat output' means the declared heat output of a heater when providing space heating and, if applicable, water heating at standard rating conditions, expressed in kW; for heat pump space heaters and heat pump combination heaters the standard rating conditions for establishing the rated heat output are the reference design conditions, as set out in Commission Regulation (EU) No 813/2013 ([1]);

28. 'standard rating conditions' means the operating conditions of heaters under average climate conditions for establishing the rated heat output, seasonal space heating energy efficiency, water heating energy efficiency, sound power level, nitrogen oxide (NOx) emissions, carbon monoxide (CO) emissions, organic gaseous carbon (OGC) emissions and particulate matter;

([1]) Commission Regulation (EU) No 813/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters (OJ L 239, 6.9.2013, p. 136).

29. 'average climate conditions' mean the temperature conditions characteristic for the city of Strasbourg;

30. 'seasonal space heating emissions' means:

— for automatically stoked solid fuel boilers, a weighted average of the emissions at rated heat output and the emissions at 30 % of the rated heat output, expressed in mg/m^3,

— for manually stoked solid fuel boilers that can be operated at 50 % of the rated heat output in continuous mode, a weighted average of the emissions at rated heat output and the emissions at 50 % of the rated heat output, expressed in mg/m^3,

— for manually stoked solid fuel boilers that cannot be operated at 50 % or less of the rated heat output in continuous mode, the emissions at rated heat output, expressed in mg/m^3,

— for solid fuel cogeneration space heater, the emissions at rated heat output, expressed in mg/m^3;

31. 'global warming potential' means global warming potential as defined in Article 2(4) of Regulation (EC) No 842/2006 of the European Parliament and of the Council ([1]);

32. 'Nm ([1])' means normal cubic metre (at 101,325 kPa, 273,15 K).

Article 3

The criteria for awarding the EU Ecolabel for a product falling within the product group 'water-based heaters' defined in Article 1 of this Decision, as well as the related assessment and verification requirements, are set out in the Annex to this Decision.

Article 4

The criteria for the product group 'water-based heaters' and the related assessment and verification requirements set out in the Annex shall be valid for four years from the date of adoption of this Decision.

Article 5

For administrative purposes the code number assigned to the product group 'water-based heaters' shall be '045'.

Article 6

1. Applications for the EU Ecolabel for heat pumps which provide heat to a water based central heating system falling within the product group 'electrically driven, gas driven or gas absorption heat pumps' submitted within two months from the date of adoption of this Decision may be based either on the criteria set out in Commission Decision 2007/742/EC ([2]), or on the criteria set out in this Decision. Applications shall be evaluated in accordance with the criteria on which they are based.

2. EU Ecolabel licences awarded to heat pumps which provide heat to water based central heating system in accordance with the criteria set out in Decision 2007/742/EC may be used for 12 months from the date of adoption of this Decision.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 28 May 2014.

For the Commission

Janez POTOČNIK

Member of the Commission

([1]) Regulation (EC) No 842/2006 of the European Parliament and of the Council of 17 May 2006 on certain fluorinated greenhouse gases (OJ L 161, 14.6.2006, p. 1).

([2]) Commission Decision 2007/742/EC of 9 November 2007 establishing the ecological criteria for the award of the Community eco-label to electrically driven, gas driven or gas absorption heat pumps (OJ L 301, 20.11.2007, p. 14).

ANNEX

EU ECOLABEL CRITERIA AND ASSESSMENT REQUIREMENTS

Criteria for awarding the EU Ecolabel to water-based heaters are set for each of the following aspects:

1. Minimum energy efficiency
   (a) Minimum seasonal space heating energy efficiency
   (b) Minimum water heating energy efficiency
2. Greenhouse gas emission limits
3. Refrigerant and secondary refrigerant
4. Nitrogen oxide (NO_x) emission limits
5. Carbon monoxide (CO) emission limits
6. Organic gaseous carbon (OGC) emission limits
7. Particulate matter (PM) emission limits
8. Noise emission limits
9. Hazardous substances and mixtures
10. Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([1])
11. Plastic parts
12. Product design for sustainability
13. Installation instructions and user information
14. Information appearing on the EU Ecolabel

Table 1 presents the applicability of the different criteria to each heat generator technology. In the case of a package of space heater, it shall comply with all the criteria applicable to each of the heat generator technologies it is made of. Those criteria, for which there is a specific methodology aimed at the packages of space heaters, shall be applicable to the package of space heaters as a whole.

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, these may originate from the applicant or his supplier or both.

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

Test methods for each criterion, unless specified otherwise, shall be those described in the relevant Standards as indicated in **Table 2** and **Table 3** (where applicable). Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence. The methodology to calculate the seasonal space heating emissions is indicated in **Table 4**.

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

([1]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Table 1

Applicability of the different criteria to each of the heat generator technologies

Heat generator technology / Criteria	Gas boiler heaters	Liquid fuel boiler heaters	Solid fuel boiler heaters	Electric boiler heaters	Fuel-driven heat pump heaters	Electrically-driven heat pump heaters	Cogeneration space heaters
1(a) — Minimum seasonal space heating energy efficiency	x	x	x	x	x	x	x
1(b) — Minimum water heating energy efficiency (applicable to combination heaters only)	x	x		x	x	x	x
2 — Greenhouse gas emission limits	x	x	x	x	x	x	x
3 — Refrigerant and secondary refrigerant					x	x	
4 — Nitrogen oxide (NO_x) emission limits	x	x	x		x		x
5 — Carbon monoxide (CO) emission limits	x	x	x		x		x
6 — Organic carbon (OGC) emission limits			x				
7 — Particulate matter (PM) emission limits		x	x				x
8 — Noise emission limits					x	x	x
9 — Hazardous substances and materials	x	x	x	x	x	x	x
10 — Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006	x	x	x	x	x	x	x
11 — Plastic parts	x	x	x	x	x	x	x
12 — Product design for sustainability	x	x	x	x	x	x	x
13 — Installation instructions and user information	x	x	x	x	x	x	x
14 — Information appearing on the EU Ecolabel	x	x	x	x	x	x	x

Table 2

Relevant standards for test methods

Number	Title
Gas boiler heaters	
EN 676	Automatic Forced draught burners for gaseous fuels
EN 15502-1	Gas-fired heating boilers — Part 1: General requirements and tests
Liquid fuel boiler heaters	
EN 267	Automatic forced draught burners for liquid fuels
EN 303-1	Heating boilers — Part 1: Heating boilers with forced draught burners — Terminology, general requirements, testing and marking
EN 303-2	Heating boilers — Part 2: Heating boilers with forced draught burners — Special requirements for boilers with atomizing oil burners
EN 303-4	Heating boilers — Part 4: Heating boilers with forced draught burners — Special requirements for boilers with forced draught oil burners with outputs up to 70 kW and a maximum operating pressure of 3 bar — Terminology, special requirements, testing and marking
EN 304	Heating boilers — Test code for heating boilers for atomizing oil burners
Solid fuel boiler heaters	
EN 303-5	Heating boilers — Part 5: Heating boilers for solid fuels, manually and automatically stoked, nominal heat output of up to 500 kW — Terminology, requirements, testing and marking
EN 14918	Solid biofuels — Determination of calorific value
Electric boiler heaters	
EN 60335-2-35	Household and similar electrical appliances — Safety — Part 2-35: Particular requirements for instantaneous water heaters
Fuel-driven heat pump heaters	
EN 12309 series	Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW
DIN 4702, Part 8	Central heating boiler; determination of the standard efficiency and the standard emissivity
Electrically-driven heat pump heaters	
EN 14511 series	Air conditioners, liquid chilling packages and heat pumps with electrically driven compressors for space heating and cooling
EN 14825	Air conditioners, liquid chilling packages and heat pumps, with electrically driven compressors, for space heating and cooling — Testing and rating at part load conditions and calculation of seasonal performance

Number	Title
Cogeneration space heaters	
EN 50465	Gas appliances — Fuel cell gas heating appliances — Fuel cell gas heating appliance of nominal heat input inferior or equal to 70 kW ([1])
ISO 3046-1	Reciprocating internal combustion engines — Performance — Part 1: Declarations of power, fuel and lubricating oil consumptions, and test methods — Additional requirements for engines for general use

([1]) An updated version of the standard is expected to cover cogeneration space heaters as well (see Draft prEN 50465:2011 Gas appliances — Combined Heat and Power appliance of nominal heat input inferior or equal to 70 kW).

Table 3

Additional relevant standards for test methods of air emissions

Number	Title
Nitrogen oxide emissions	
EN 14792	Stationary source emissions — Determination of mass concentration of nitrogen oxides (NOx) — Reference method: Chemiluminescence
Carbon monoxide emissions	
EN 15058	Stationary source emissions — Determination of the mass concentration of carbon monoxide (CO) — Reference method: Non-dispersive infrared spectrometry
Organic gaseous carbon emissions	
EN 12619	Stationary source emissions — Determination of the mass concentration of total gaseous organic carbon at low concentrations in flue gases — Continuous flame ionisation detector method
Particulate matter emissions	
EN 13284-1	Stationary source emissions — Determination of low range mass concentration of dust — Part 1: Manual gravimetric method
Noise emissions	
EN ISO 3744	Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane (ISO 3744:2010)
EN ISO 3746	Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)
EN 12102	Air conditioners, liquid chilling packages, heat pumps and dehumidifiers with electrically driven compressors for space heating and cooling — Measurement of airborne noise — Determination of the sound power level

Table 4

Methodology to calculate the seasonal space heating emissions

Type of solid fuel boiler	Formula
Manually stoked solid fuel boilers that can be operated at 50 % of the rated heat output in continuous mode, and automatically stoked solid fuel boilers	$E_s = 0{,}85 \times E_{s,p} + 0{,}15 \times E_{s,r}$

Type of solid fuel boiler	Formula
Manually stoked solid fuel boilers that cannot be operated at 50 % or less of the rated heat output in continuous mode, and solid fuel cogeneration space heaters	$E_S = E_{S,R}$

Where:

E_s are the seasonal space heating emissions.

$E_{s,p}$ are the emissions of respectively particulate matter, organic gaseous compounds, carbon monoxide and nitrogen oxides measured at 30 % or 50 % of rated heat output, as applicable.

$E_{s,r}$ are the emissions of respectively particulate matter, organic gaseous compounds, carbon monoxide and nitrogen oxides measured at rated heat output.

Criterion 1 — Minimum energy efficiency

(a) — *Minimum seasonal space heating energy efficiency*

The seasonal space heating energy efficiency η_s of the water-based heater shall not fall below the limit values set out in **Table 5**.

Table 5

Minimum requirements for seasonal space heating energy efficiency by heat generator technology

Heat generator technology	Minimum seasonal space heating energy efficiency
All heaters except solid biomass boiler heaters	$\eta_s \geq 98$ %
Solid biomass boiler heaters	$\eta_s \geq 79$ %

(i) The seasonal space heating energy efficiency shall be calculated in accordance with the procedures set out in Annex III to Regulation (EU) No 813/2013 and in Annex VII to Commission Delegated Regulation (EU) No 811/2013 ([1]), including, where applicable, the harmonised standards the reference numbers of which have been published for this purpose in the *Official Journal of the European Union*, or other reliable, accurate and reproducible methods that take into account the generally recognised state-of-the-art methods and that meet the conditions and technical parameters set out in Annex III of Regulation (EU) No 813/2013.

(ii) For solid fuel boiler heaters, η_s shall be calculated in accordance with the procedures referred to in point (i), taking into account the following additional requirements:

(a) the calculation of η_s shall be based on the gross calorific value of the wet fuel (as received) GCV_{ar}, which corrects for the moisture content in the fuel but includes in the energy content the latent heat energy stored in hydrogen that is oxidised to water in the combustion process. The principles laid down in Standard EN 303-5 shall apply to estimate η_s, while GCV_{ar} instead of the net calorific value of the wet fuel (as received) NCV_{ar} shall be used for the calculation of η_s.

(b) for determining the calorific value of solid biomass, the principles laid down in Standard EN 14918 shall apply.

(c) The gross calorific value of the wet fuel at constant volume $GCV_{ar,V}$ can be derived as follows:

$$GCV_{ar,V} = GCV_{dry,V} \times (100 - m)/100 \text{ [MJ/kg]}$$

where:

m is the moisture content of the wet fuel (percentage by mass)

$GCV_{dry,V}$ is the gross calorific value of the dry fuel (moisture-free) at constant volume

([1]) Commission Delegated Regulation (EU) No 811/2013 of 18 February 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to the energy labelling of space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device (OJ L 239, 6.9.2013, p. 1).

(d) The gross calorific value of the dry fuel at constant volume $GCV_{dry,V}$ can be derived as follows:

$GCV_{dry,V} = NCV_{dry,P} + 0{,}2122 \times H_{dry} + 0{,}0008 \times (O_{dry} + N_{dry})$ [MJ/kg]

where:

$NCV_{dry,P}$ is the net calorific value of the dry fuel (including ash) at constant pressure

H_{dry} is the hydrogen content of the dry fuel (percentage by mass)

O_{dry} is the oxygen content of the dry fuel (percentage by mass)

N_{dry} is the nitrogen content of the dry fuel (percentage by mass)

(e) The net calorific value of the dry fuel at constant pressure $NCV_{dry,P}$ can be derived as follows:

$NCV_{dry,P} = NCV_{ar,P} \times 100/(100 — m) + 2{,}443 \times m/(100 — m)$ [MJ/kg]

where:

$NCV_{ar,P}$ is the net calorific value of the wet fuel at constant pressure

(f) It shall be noted that with combining (c), (d) and (e), $GCV_{ar,V}$ can be derived from $NCV_{ar,P}$ as follows:

$GCV_{ar,V} = NCV_{ar,P} + [0{,}2122 \times H_{dry} + 0{,}0008 \times (O_{dry} + N_{dry})] \times (100 — m)/100 + 0{,}02443 \times m$ [MJ/kg]

Assessment and verification:

The applicant shall declare that the product complies with this criterion and provide test results conducted in accordance with the testing procedure indicated in the EN standards (including transitional methods where applicable) applicable to the given type of product (see **Table 2**). Measurements and calculations of the seasonal space heating energy efficiency shall be made using the methodology of seasonal space heating energy efficiency of packages and in accordance with the procedures referred to in point (i). For solid fuel boiler heaters, the seasonal space heating energy efficiency shall be calculated in accordance with point (ii).

(b) — *Minimum water heating energy efficiency*

(i) The water heating energy efficiency η_{wh} of combination heaters or package of space heaters containing one or more combination heaters shall not fall below 65 %. This criterion shall not apply to solid fuel boiler heaters.

(ii) The water heating energy efficiency shall be calculated in accordance with the procedures set out in Annex III to Regulation (EU) No 813/2013 and in Annex VII to Delegated Regulation (EU) No 811/2013.

Assessment and verification:

The applicant shall declare that the product complies with this criterion and provide test results conducted in accordance with the testing procedure indicated in the EN standards (including transitional methods where applicable) applicable to the given type of product (see **Table 2**). Measurements and calculations shall be made using the methodology of water heating energy efficiency of packages in accordance with the procedures referred to in point (ii).

Criterion 2 — Greenhouse gas (GHG) emission limits

The greenhouse gas (GHG) emissions of the water-based heater, expressed in grams of CO_2-equivalent per kWh of heating output calculated using the Total Equivalent Warming Impact (TEWI) formulas set out in Table 7, shall not exceed the values set out in **Table 6**.

Table 6

GHG emission limits by heat generator technology

Heat generator technology	GHG emission limits
All heaters, except heat pump heaters	200 g CO_2-equivalent/kWh heating output
Heat pump heaters	150 g CO_2-equivalent/kWh heating output

The GHG emissions shall be calculated following the TEWI formulae as set out in **Table 7** (the formula depends on the heat generator technology). Each TEWI formula may consist of two parts, one depending solely on the heater efficiency (expressed in terms of the seasonal space heating energy efficiency, η_s) and the fuel carbon intensity (represented by the β parameter), and the second part (only applicable to heat pump heaters) depending on the greenhouse gas emissions due to refrigerant leakage. The GHG emissions from the refrigerant leakage depend on the global warming potential (GWP_{100}) of the refrigerant and the refrigerant leakage during the use phase (expressed as an annual leakage rate, ER, in percentage of the total mass of the refrigerant per year) and at end-of-life (expressed as a percentage of the total mass of the refrigerant, α).

Table 7

TEWI formulae by heat generator technology

Heat generator technology	TEWI formula (g CO_2-equivalent/kWh heating output)
Boiler heaters	$\frac{\beta_{fuel}}{\eta_s}$
Heat pump heaters	$\delta \times \frac{\beta_{fuel}}{\eta_s} + (1-\delta) \times \frac{\beta_{elec}}{2{,}5 \times \eta_s} + \frac{GWP_{100} \times m \times (ER \times n \times \alpha)}{P \times h \times n}$
Cogeneration space heaters	$\frac{\beta_{fuel}}{\eta_{thermal}} - \frac{\eta \times \beta_{elec}}{\eta_{thermal}}$
Package of space heaters	$(1-S_{HP}) \times \frac{\beta_{fuel(1)}}{\eta_{s,B}} + S_{HP} \times (\delta \times \frac{\beta_{fuel(2)}}{\eta_{s,HP}} + (1-\delta) \times \frac{\beta_{elec}}{2{,}5 \times \eta_{s,HP}}) + \frac{GWP_{100} \times m \times (ER \times n \times \alpha)}{P \times h \times n}$

The main parameters in the TEWI formulae set out in Table 7 are described in **Table 8**.

Table 8

Main parameters for computing the TEWI formulae

Parameter	Description of parameter	Units	Constant value or test to be performed in order to obtain the parameter
β_{elec}	GHG emission intensity of electricity	[g CO_2-equivalent/kWh_{elec}]	384
β_{fuel}	GHG emission intensity of the fuel used by the heater	[g CO_2-equivent/kWh]	See Table 9
η_s	Seasonal space heating energy efficiency	[-]	To be tested and declared by the applicant (Criterion 1)
$\eta_{s,B}$	Seasonal space heating energy efficiency of the boiler heater part for average climate conditions	[-]	To be tested and declared by the applicant; this corresponds to the seasonal space heating energy efficiency of the package minus supplementary heat pump, as stated in the product fiche of packages

Parameter	Description of parameter	Units	Constant value or test to be performed in order to obtain the parameter
$\eta_{s,HP}$	Seasonal space heating energy efficiency of the heat pump heater part for average climate conditions	[-]	To be tested and declared by the applicant; this corresponds to the seasonal space heating energy efficiency of the supplementary heat pump, as stated in the product fiche of packages
$\eta_{thermal}$	Thermal efficiency	[-]	See Table 10
η_{el}	Electrical efficiency	[-]	See Table 10
δ	Proxy	[-]	= 0 if electrically-driven heat pump heater = 1 if fuel-driven heat pump heater
GWP_{100}	Global warming potential (effect over 100 years)	[g CO_2-equivalent/g refrigerant, over 100 year period]	Value declared by the applicant according Criterion 3
m	Refrigerant mass	[g]	To be declared by the applicant
ER	Refrigerant loss per year	[%/yr]	A value of ER = 3,5 %/yr shall be used.
n	Lifetime	[yr]	A value of n = 15 shall be used.
α	Refrigerant loss at end of life (disposal loss)	[%]	A value of α = 35 % shall be used.
P	Design load	[kW]	To be declared by the applicant.
h	Full load operating hours	[h/yr]	2 000
s_{HP}	Share of heat output from the heat pump heater part over the total heat output	[-]	= (16 — T_{HP})/26 where T_{HP} is the temperature (° C) at which the (primary) heat pump efficiency equals the primary boiler efficiency. It is assumed that below this temperature the boiler fulfils the heat demand, while above this temperature the heat pump supplies the heat demand.

Table 9 describes how to evaluate parameter β_{fuel} in the TEWI formulae depending on the fuel used by the heater. In case the boiler is designed for a fuel not listed in the table, the closest match of fuel shall be selected, based on the origin (fossil or biomass) and form (gaseous, liquid or solid) of the fuel used.

Table 9

Parameter β_{fuel} (GHG emission intensity) to compute the TEWI formulae

Fuel used by the heater	GHG emission intensity	Value (g CO_2-equivalent/kWh)
Gaseous fossil fuels	$\beta_{fuel} = \beta_{gas}$	202
Liquid fossil fuels	$\beta_{fuel} = \beta o_{il}$	292
Solid fossil fuels	$\beta_{fuel} = \beta_{coal}$	392
Gaseous biomass	$\beta_{fuel} = \beta_{bio\text{-}gas}$	98
Liquid biomass	$\beta_{fuel} = \beta_{bio\text{-}oil}$	149
Wood logs	$\beta_{fuel} = \beta_{bio\text{-}log}$	19
Wood chips	$\beta_{fuel} = \beta_{bio\text{-}chip}$	16
Wood pellets	$\beta_{fuel} = \beta_{bio\text{-}pellet}$	39
Blends of fossil fuels and biomass	β_{fuel} = weighted average derived from the sum of the weight fractions of the individual fuels multiplied by their GHG emission parameter	Σ (Fuel X % × $\beta_{fuel\ X}$) + (Fuel Y % × $\beta_{fuel\ Y}$) + … (Fuel N % × $\beta_{fuel\ N}$)

Table 10 describes how to evaluate parameters $\eta_{thermal}$ and η_{el} in the TEWI formula for cogeneration space heaters.

Table 10

Parameters $\eta_{thermal}$ and η_{el} to compute the TEWI formula for cogeneration space heaters

Parameter	Expression
$\eta_{thermal}$	$\eta_{thermal} = \eta_s - 2{,}5 \times \eta_{el}$
η_{el}	For cogeneration space heaters not equipped with supplementary heaters $\eta_{el} = \eta_{el,CHP100+Sup0}$
	For cogeneration space heaters equipped with supplementary heaters $\eta_{el} = 0{,}85 \times \eta_{el,CHP100+Sup0} + 0{,}15 \times \eta_{el,CHP100+Sup100}$

Where:

η_s means the seasonal space heating energy efficiency as defined in Regulation (EU) No 813/2013

η_{el} means the electrical efficiency as defined in Regulation (EU) No 813/2013

$\eta_{el,CHP100+Sup0}$ means the electrical efficiency at rated heat output of cogeneration space heater with supplementary heater disabled, as defined in Regulation (EU) No 813/2013

$\eta_{el,CHP100+Sup100}$ means the electrical efficiency at rated heat output of cogeneration space heater with supplementary heater enabled, as defined in Regulation (EU) No 813/2013

Assessment and verification:

A certificate signed by the manufacturer declaring compliance with this criterion shall be submitted to the awarding competent body, together with the relevant documentation. The applicant shall provide the calculated GHG emissions following the proposed TEWI formulae and detail all the parameters used to calculate the GHG emissions.

Criterion 3 — Refrigerant and secondary refrigerant

Refrigerant

The global warming potential over a 100 year period (GWP_{100}) of the refrigerant shall not exceed a value of 2000. GWP_{100} values shall be those set out in Annex I to Regulation (EC) No 842/2006. Sources of references for the GWP_{100} values should be those defined in Annex I.1(7) to Commission Regulation (EU) No 206/2012 ([1]).

Secondary refrigerant

In the case of space heaters using a secondary refrigerant, the design of these heaters shall not be based on secondary refrigerant, brine or additives classified as environmentally hazardous or constituting a health hazard within the meaning of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) and Council Directive 67/548/EEC ([3]), and installation instructions shall clearly indicate that substances classified as environmentally hazardous or constituting a health hazard shall not be used as a secondary refrigerant.

Assessment and verification:

Refrigerant

The names of refrigerant(s) used in the product shall be submitted with the application, along with their GWP_{100} values as defined in Regulation (EC) No 842/2006. The GWP_{100} values of refrigerants shall be calculated in terms of the 100-year warming potential of one kilogram of a gas relative to one kilogram of CO_2. Sources of references for the GWP_{100} values should be those defined in Annex I.1(7) to Regulation (EU) No 206/2012.

For the secondary refrigerant(s) only

The name(s) of the secondary refrigerant(s) used shall be submitted with the application.

Criterion 4 — Nitrogen oxide (NO_x) emission limits

The nitrogen oxide (NO_x) content of the exhaust gas shall not exceed the limit values indicated in **Table 11** (not applicable to electrical heaters). NO_x emissions shall be measured as the sum of nitrogen monoxide and nitrogen dioxide and at the following operating conditions:

— Gas and liquid heaters, at standard rating conditions and rated heat output

— Solid fuel heaters, as seasonal space heating emissions according **Table 4**.

The unit of measurement shall be given in mg/kWh GCV energy input or in mg/Nm³, as appropriate.

Table 11

NO_x emission limits by heat generator technology

Heat generator technology	NO_x emission limit
Gas heaters	Equipped with internal combustion engine: 170 mg/kWh GCV energy input Equipped with external combustion: 36 mg/kWh GCV energy input
Liquid fuel heaters	Equipped with internal combustion engine: 380 mg/kWh GCV energy input Equipped with external combustion: 100 mg/kWh GCV energy input
Solid fuel heaters	150 mg/Nm³ at 10 % O_2

([1]) Commission Regulation (EU) No 206/2012 of 6 March 2012 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for air conditioners and comfort fans (OJ L 72, 10.3.2012, p. 7).

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([3]) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

Assessment and verification:

A certificate signed by the manufacturer declaring compliance with this criterion shall be submitted to the awarding competent body, together with the relevant documentation.

The NO_x emissions in the exhaust gas shall be determined as standard emission factors according to the relevant standards included in **Table 2** and **Table 3** (where applicable).

Criterion 5 — Carbon monoxide (CO) emission limits

The carbon monoxide (CO) content of the exhaust gas shall not exceed the limit values indicated in **Table 12** (not applicable to electrical heaters). CO emissions shall be measured at the following operating conditions:

— Gas and liquid heaters, at standard rating conditions and rated heat output

— Solid fuel heaters, as seasonal space heating emissions according **Table 4**.

The unit of measurement shall be given in mg/kWh GCV energy input or in mg/Nm³, as appropriate.

Table 12

CO emission limits by heat generator technology

Heat generator technology	CO emission limit
Gas heaters	Equipped with internal combustion engine: 150 mg/Nm³ at 5 % O_2 Equipped with external combustion: 25 mg/kWh GCV energy input
Liquid fuel heaters	Equipped with internal combustion engine: 200 mg/Nm³ at 5 % O_2 Equipped with external combustion: 50 mg/kWh GCV energy input
Solid fuel heaters	Automatically stoked: 175 mg/Nm³ at 10 % O_2 Manually stoked: 250 mg/Nm³ at 10 % O_2

Assessment and verification:

A certificate signed by the manufacturer declaring compliance with this criterion shall be submitted to the awarding competent body, together with the relevant documentation.

The CO emissions in the exhaust gas shall be determined as standard emission factors according to the relevant standards included in **Table 2** and **Table 3** (where applicable).

Criterion 6 — Organic gaseous carbon (OGC) emission limits

The organic gaseous carbon (OGC) of the exhaust gas also understood as organically bound carbon content shall not exceed the limit values indicated in **Table 13** (only applicable to solid fuel boiler heaters). OGC emissions shall be measured as seasonal space heating emissions according **Table 4**. The unit of measurement shall be given in mg/Nm³.

Table 13

OGC emission limits by heat generator technology

Heat generator technology	OGC emission limit
Solid fuel boiler heaters	7 mg/Nm³ at 10 % O_2

Assessment and verification:

A certificate signed by the manufacturer declaring compliance with this criterion shall be submitted to the awarding competent body, together with the relevant documentation.

The OGC emissions in the exhaust gas shall be determined as standard emission factors according to the relevant standards included in **Table 2** and **Table 3** (where applicable).

Criterion 7 — Particulate matter (PM) emission limits

The particle matter (PM) content of the exhaust gas shall not exceed the limit values indicated in **Table 14**. PM emissions shall be measured at the following operating conditions:

— Liquid heaters, at standard rating conditions and rated heat output

— Solid fuel heaters, as seasonal space heating emissions according **Table 4**.

The unit of measurement shall be given in mg/Nm^3.

Table 14

PM emission limits by heat generator technology

Heat generator technology	PM emission limit
Liquid fuel heaters	Equipped with internal combustion engine: 1 mg/Nm^3 at 5 % O_2 Equipped with external combustion: no limit
Solid fuel heaters	20 mg/Nm^3 at 10 % O_2

Assessment and verification:

A certificate signed by the manufacturer declaring compliance with this criterion shall be submitted to the awarding competent body, together with the relevant documentation.

The PM emissions in the exhaust gas shall be determined as standard emission factors according to the relevant standards included in **Table 2** and **Table 3** (where applicable).

Criterion 8 — Noise emission limits

The noise emissions shall not exceed the limit values indicated in **Table 15**. Noise emissions shall be measured at standard rating conditions and rated heat output. The unit of measurement shall be given in dB(A) or dB(C), as appropriate.

Table 15

Noise emission limits by heat generator technology

Heat generator technology	Measurement	Noise emission limit
Heat pump heaters equipped with external combustion and electrically-driven heat pumps	A-weighted sound power level limit value ($L_{WAd,\ lim}$)	$17 + 36 \times \log(P_N + 10)$ dB(A)
Heat pump heaters equipped with internal combustion engine	A-weighted sound pressure level limit value ($L_{PAd,\ lim}$)	$30 + 20 \times \log (0{,}4 \times P_N + 15)$ dB(A)
	C-weighted sound pressure level limit value ($L_{PCd,\ lim}$)	$L_{PAd,\ lim}$ + 20 dB(C)
Cogeneration space heaters equipped with internal combustion engine	A-weighted sound pressure level limit value ($L_{PAd,\ lim}$)	$30 + 20 \times \log (P_E + 15)$ dB(A)
	C-weighted sound pressure level limit value ($L_{PCd,\ lim}$)	$L_{PAd,\ lim}$ + 20 dB(C)

Note: P_N means the nominal (full load) or declared heat output; P_E means the electricity output.

Assessment and verification:

A certificate signed by the manufacturer declaring compliance with this criterion shall be submitted to the awarding competent body, together with the relevant documentation.

Testing shall be performed in accordance with EN 12102 for heat pump heaters equipped with external combustion and electrically-driven heat pumps, and EN ISO 3744 or EN ISO 3746 for heat pump and cogeneration space heaters equipped with internal combustion engines. The test report shall be submitted with the application.

Criterion 9 — Hazardous substances and mixtures

In accordance with Article 6(6) of Regulation (EC) No 66/2010, the product or any article of it shall not contain substances referred to in Article 57 of Regulation (EC) No 1907/2006 nor substances or mixtures meeting the criteria for classification in the hazard classes or categories listed in **Table 16** in accordance with Regulation (EC) No 1272/2008 or with Directive 67/548/EEC.

Table 16

List of hazard statements and risk phrases

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

Hazard statement (1)	Risk Phrase (2)
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	R50/50-53
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 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

(1) As provided for in Regulation (EC) No 1272/2008.
(2) As provided for in Directive 67/548/EEC.

The use of substances or mixtures in the final product which upon processing change their properties in a way that the identified hazard no longer applies is exempted from the above requirement.

Concentration limits for substances or mixtures meeting the criterion for classification in the hazard classes or categories listed in table 16, and for substances meeting the criteria of Article 57(a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008. Where specific concentration limits are determined, they shall prevail against the generic ones.

Concentration limits for substances meeting the criteria of Article 57(d), (e) or (f) of Regulation (EC) No 1907/2006 shall not exceed 0,1 % weight by weight.

The substances or mixtures listed in **Table 17** are specifically exempted from the prohibition set out in Article 6(6) of Regulation (EC) No 66/2010.

Table 17

Derogations from the prohibition set out in Article 6(6) of Regulation (EC) No 66/2010

Derogated substances, parts or articles	Derogations
Articles with weight below 25 g	All hazard statements and risk phrases
Homogeneous parts of complex articles with weight below 25 g	All hazard statements and risk phrases
Nickel in stainless steel	H351/372 and R40/48/23

Assessment and verification:

For each article and/or homogeneous part of complex articles with weight over 25 g, the applicant shall provide a declaration of compliance with this criterion, together with the related documentation, such as declarations of compliance signed by the suppliers of substances and copies of relevant Safety Data Sheets in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits for substances and mixtures shall be specified in the Safety Data Sheets in accordance with Article 31 of Regulation (EC) No 1907/2006.

Criterion 10 — Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the prohibition set out in Article 6(6) of Regulation (EC) No 66/2010 may be granted concerning substances identified as substances of very high concern and included in the list referred to in Article 59 of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogenous part of a complex article in concentrations higher than 0,1 % w/w. Specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall apply where the concentration is lower than 0,1 % w/w.

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 a declaration of compliance with this criterion, together with the related documentation, such as declarations of compliance signed by the suppliers of substances and copies of relevant Safety Data Sheets in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits for substances and mixtures shall be specified in the Safety Data Sheets in accordance with Article 31 of Regulation (EC) No 1907/2006.

Criterion 11 — Plastic parts

If any plasticiser substance in the manufacturing process is applied, it shall comply with the requirements on hazardous substances set out in Criteria 9 and 10.

Plastic parts of articles or homogeneous parts of complex articles with weight 25 g or more shall not have chlorine content greater than 50 % by weight.

Plastic parts with weight 50 g or more shall be marked according to the requirements of European Standard EN ISO 11469 to ensure that they are recycled, recovered, or disposed of in the correct manner during the end-of-life phase.

Assessment and verification:

The applicant shall provide a declaration of compliance with this criterion, together with the related documentation, such as declarations of compliance signed by the suppliers of substances and copies of relevant Safety Data Sheets. The applicant shall provide information on the plasticisers used in the product. The applicant shall provide information on the maximum chlorine content of the plastic parts. A declaration of compliance signed by the plastic suppliers and copies of relevant Safety Data Sheets about materials and substances shall also be provided to the awarding competent body. The applicant shall provide information on the intentionally added substances used as flame retardants.

Criterion 12 — Product design for sustainability

The product shall be designed in such a way that its exchangeable components can be replaced easily by service personnel. Information about which elements can be replaced shall be clearly indicated in the information sheet attached to the product. The applicant shall further ensure that genuine or equivalent spare parts are available for at least 10 years from the date of purchase.

Repair or replacement of the product shall be covered by the warranty terms for at least five years.

The applicant shall undertake to take the product back free of charge at end-of-life and shall ensure proper recycling or material recovery of the product, while non-recyclable product parts shall be disposed of in an environmentally acceptable manner. The product information shall provide the details of the take-back scheme in place.

Assessment and verification:

The applicant shall provide a declaration of compliance with this criterion, together with the relevant documentation, including a sample or samples of the product information sheet and warranty terms.

Criterion 13 — Installation instructions and user information

The product shall be accompanied by relevant installation instructions and user information, which shall give all the technical details needed for a proper installation and shall provide advice on the product's proper and environmentally friendly use as well as its maintenance. It shall bear the following information in print (on the packaging or on the documentation accompanying the product) or in electronic format:

(a) a statement informing that the product has been awarded the EU Ecolabel, together with a brief, specific explanation as to what this means in addition to the general information provided alongside the EU Ecolabel logo;

(b) general information on appropriate dimensions of heaters for different building characteristics/size;

(c) information on the energy consumption of the heater.

(d) proper installation instructions, including:

  (i) instructions specifying that the heater shall be installed by fully trained fitters;

  (ii) any specific precautions that shall be taken when the heater is assembled or installed;

  (iii) instructions specifying that the control settings of the heater ('heating curve') shall be adjusted properly after installation;

  (iv) if applicable, details on what air pollution emission values the flue gas shall have during the operating phase and how the heater should be adjusted to achieve it. In particular, the instructions shall state that:

    — the heater shall be adjusted with the aid of measuring gauges for measuring CO, O_2 or CO_2, NO_x, temperature and soot to ensure that none of the threshold values provided for in criteria 2, 4, 5, 6 and 7 are exceeded;

    — holes shall be made for measuring gauges in the same location as used in laboratory testing;

    — measurement results shall be recorded in a special form or diagram, one copy of which is retained by the end user;

  (v) for low flue gas temperature technology, instructions specifying that the system shall be equipped with corrosion-retarding technology;

  (vi) for condensing boiler technology, instructions specifying that the chimney shall be protected against condensate with low pH;

  (vii) information on who the fitter can approach for guidance on installation;

(e) operating instructions for service personnel;

(f) user information, including:

  (i) references to competent installers and service personnel;

  (ii) recommendations on the proper use and maintenance of the heater, including the correct fuels to be used and their appropriate storage for optimum combustion and the regular maintenance schedule to keep;

  (iii) advice on how rational use can minimise the environmental impact of the heater, in particular information on proper product's use to minimise energy consumption;

  (iv) if applicable, information on how the measurement results should be interpreted and how they can be improved.

  (v) information about which spare parts can be replaced;

(g) recommendations on appropriate disposal at product's end-of-life.

Assessment and verification:

The applicant shall declare that the product complies with this criterion and provide the competent body with a sample or samples of the user information or a link to a manufacturer's website containing this information as part of the application.

Criterion 14 — Information appearing on the EU Ecolabel

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

— Increased energy efficiency

— Reduced greenhouse gas emissions

— Reduced air emissions

The guidelines for the use of the optional label with the text box can be found in the 'Guidelines for the use of the EU Ecolabel logo' on the website:

http://ec.europa.eu/environment/ecolabel/promo/pdf/logo %20guidelines.pdf

Assessment and verification:

The applicant shall provide a sample of the printed paper product showing the label, together with a declaration of compliance with this criterion.

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