

COMMISSION DECISION (EU) 2016/1796**of 7 July 2016****amending Decisions 2011/263/EU, 2011/264/EU, 2012/720/EU and 2012/721/EU in order to take account of developments in the classification of substances***(notified under document C(2016) 4131)***(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 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) 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⁾.
- (2) 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.
- (3) Subtilisin is a hazardous substance with a harmonised classification according to Annex VI of Regulation (EC) No 1272/2008. This includes the following hazard classes: Respiratory sensitisation Category 1, Serious eye damage Category 1, Skin irritation Category 2 and Specific Target Organ Toxicity Single Exposure for respiratory tract Category 3.
- (4) Commission Decisions 2011/263/EU ⁽⁴⁾ and 2011/264/EU ⁽⁵⁾, as amended through Commission Decision 2012/49/EU ⁽⁶⁾ include already a derogation for the enzyme subtilisin, classified as H400: Very toxic to aquatic life, for established ecological criteria for the award of the EU Ecolabel for detergents for dishwashers and laundry detergents, as subtilisin had been recognised as an important ingredient of these detergents and had been

⁽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 2012/49/EU of 26 January 2012 amending Decisions 2011/263/EU and 2011/264/EU in order to take account of developments in enzymes classification in accordance with Annex I to Council Directive 67/548/EEC and Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (OJ L 26, 28.1.2012, p. 36).

previously derogated. Moreover, with the same intention of allowing subtilisin in EU Ecolabel products, Commission Decisions 2012/720/EU ⁽¹⁾ and 2012/721/EU ⁽²⁾ allowed enzymes classified as H400: Very toxic to aquatic life in for industrial and institutional automatic dishwasher detergents and industrial and institutional laundry detergents. Those derogations were granted recognizing the important function of subtilisin in the above mentioned detergent groups and its high level of degradation/inactivation in waste water treatment plants, and during detergents' use and transport to sewer systems. The derogations were needed because subtilisin was classified as Aquatic Acute 1 (M factor 1) (H400) by self-classification when it was registered under the Regulation (EC) No 1907/2006, which would have prevented its inclusion in products bearing the EU Ecolabel.

- (5) Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) No 286/2011 ⁽³⁾. The amendments to Regulation (EC) No 1272/2008 became applicable in respect of substances from 1 December 2012 and 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 toxicity and biodegradability data. On the basis of the new criteria, a recent study conducted by the REACH SIEF for subtilisin indicated that subtilisin has to be classified also as hazardous to the aquatic environment (chronic), Category 2. The substance is readily biodegradable and should not cause a risk to the environment because it is almost entirely deactivated in the sewage plants. As a result of this classification, subtilisin would be banned from the 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, 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.
- (6) Subtilisin enhances the cleaning performance of detergents by effectively breaking down proteinous stain components. The enzyme delivers excellent performance even at low temperatures with the required dosage that allows the respect of low temperature, compaction, and performance criteria under the EU Ecolabel scheme. At the moment, there is no alternative ingredient or technology. Other enzymes with different catalytic activities, e.g. alpha-amylase, lipase, pectate lyase can remove other types of deposits and stains, e.g. starch, fat and pectin stains, but they cannot remove proteinous stains.
- (7) The review of the criteria for the award of the EU Ecolabel for detergents for dishwashers and laundry detergents, set out in Decisions 2011/263/EU and 2011/264/EU, and 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 related amendments did not take into account the new criteria for environmental classification introduced by Regulation (EU) No 286/2011.
- (8) This amendment shall apply retroactively from 1 December 2012, in order to ensure the continuity of the validity of the EU Ecolabel criteria for detergents for dishwashers, laundry detergents, industrial and institutional automatic dishwasher detergents, and industrial and institutional laundry detergents.
- (9) Commission Decisions 2011/263/EU, 2011/264/EU, 2012/720/EU and 2012/721/EU should therefore be amended accordingly.
- (10) 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.

⁽¹⁾ 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).

⁽²⁾ 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).

⁽³⁾ 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).

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

Article 4

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

Article 5

This Decision shall apply from 1 December 2012.

Article 6

This decision is addressed to Member States.

Done at Brussels, 7 July 2016.

For the Commission
Karmenu VELLA
Member of the Commission

ANNEX I

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

For the sake of clarity and legal certainty, it is appropriate to replace the entire table of derogations in Criterion 2, point (b), fifth paragraph, with the following table that takes into account the changes introduced by Commission Decision 2014/313/EU ⁽¹⁾:

'Subtilisin	H400: Very toxic to aquatic life	R50
	H411: Toxic to aquatic life with long-lasting effects	R50-53
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 $\log P_{ow}$ (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) \leq 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 %.

⁽¹⁾ Commission Decision 2014/313/EU 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 (OJ L 164, 3.6.2014, p. 74).

ANNEX II

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

For the sake of clarity and legal certainty, it is appropriate to replace the entire table of derogations in Criterion 4, point (b), fifth paragraph, with the following table that takes into account the changes introduced by Decision 2014/313/EU:

'Subtilisin	H400: Very toxic to aquatic life	R50
	H411: Toxic to aquatic life with long-lasting effects	R50-53
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 $\log P_{ow}$ (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) \leq 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 %.

ANNEX III

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

For the sake of clarity and legal certainty, it is appropriate to replace the entire table of derogations Criterion 3, point (b), sixth paragraph, with the following table that takes into account the changes introduced by Decision 2014/313/EU:

'Subtilisin	H400: Very toxic to aquatic life	R50
	H411: Toxic to aquatic life with long-lasting effects	R50-53
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 %

ANNEX IV

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

For the sake of clarity and legal certainty, it is appropriate to replace the entire table of derogations in Criterion 4, point (b), sixth paragraph, is replaced by the following table:

'Subtilisin	H400: Very toxic to aquatic life	R50
	H411: Toxic to aquatic life with long-lasting effects	R50-53
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 %.