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# **COVER NOTE**

From:	European Commission
date of receipt:	17 March 2016
To:	General Secretariat of the Council
Subject:	Annex to the Commission Decision XXX 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

Delegations will find attached document D043371/02 - Annex 1 to 4.

Encl.: D043371/02 - Annex 1 to 4

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# EN ANNEXES 1 to 4

# 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:

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

<sup>(\*)</sup> This derogation is applicable provided that they are ready degradable and anaerobically degradable.

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- (\*\*) 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)  $\le 100$ .
- (\*\*\*) 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 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 Commission Decision 2014/313/EU:

	H400: Very toxic to aquatic life	R50
Subtilisin	11400. Very toxic to aquatic inc	K50
	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

<sup>(\*)</sup> This derogation is applicable provided that they are ready degradable and anaerobically degradable.

## 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), six paragraph, with the following table that takes into account the changes introduced by Commission 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	H331: Toxic if inhaled	R23
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
between 2 and 12 and	H317: May cause allergic skin reaction	R43

<sup>(\*\*)</sup> 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)  $\le 100$ .

<sup>(\*\*\*)</sup> Including stabilisers and other auxiliary substances in the preparations.

<sup>(\*\*\*\*)</sup> 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 %.

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maximum 0,10 % w/w of active material)	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

<sup>(\*)</sup> Derogation is only for criterion 3(b). Biocides shall comply with criterion 3(d).

## 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), six 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	H331: Toxic if inhaled	R23
purposes (**)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42

<sup>(\*\*)</sup> Including stabilisers and other auxiliary substances in the preparations.

<sup>(\*\*\*)</sup> 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 %

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(only for liquids with pH	H317: May cause allergic skin reaction	R43
between 2 and 12 and maximum 0,10 % w/w of active material)	H400: Very toxic to aquatic life	R50
To Childs	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
Bleach catalysts (***)	H400: Very toxic to aquatic life	R50
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

<sup>(\*)</sup> This derogation is applicable provided that surfactants comply with criterion 3(a) and they are anaerobically degradable.

<sup>(\*\*)</sup> Derogation is only for criterion 4(b). Biocides shall comply with criterion 4(e).

<sup>(\*\*\*)</sup> Including stabilisers and other auxiliary substances in the preparations.

<sup>(\*\*\*\*)</sup> 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 %.