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Subject: COMMISSION REGULATION (EU) No .../..of XXX amending and correcting Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances

Delegations will find attached Commission document D027721/03.

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Brussels, **XXX**
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[...] (2013) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending and correcting Annex I to Regulation (EC) No 1334/2008 of the European
Parliament and of the Council as regards certain flavouring substances**

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of XXX

amending and correcting Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13¹, and in particular Article 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials for use in food and their conditions of use.
- (2) Part A of the Union list contains both evaluated flavouring substances, which are assigned no footnotes and flavourings substances under evaluation, which are identified by footnote references 1 to 4 in the that list.
- (3) The European Food Safety Authority has completed the assessment of 23 substances which are currently listed as flavouring substances under evaluation. Those flavouring substances were assessed by EFSA in the following flavouring group evaluations: evaluation FGE.06rev4³ (substances FL-no 02.229, 05.137, 09.562 and 09.854), evaluation FGE.07rev4⁴ (substances FL-no 02.145, 02.194, 02.211, 07.198 and 07.204), evaluation FGE.08rev5⁵ (substance FL-no 15.134), evaluation FGE.09rev4⁶ (substances FL-no 07.202 and 07.255), evaluation FGE.12rev3⁷ (substance FL-no 05.182), evaluation FGE.20rev4⁸ (substances FL-no 05.026, 05.028, 05.029 and

¹ OJ L 354, 31.12.2008, p. 34.

² OJ L 354, 31.12.2008, p. 1.

³ EFSA Journal 2013; 11(2):3091.

⁴ EFSA Journal 2012; 10(10):2899.

⁵ EFSA Journal 2012; 10(7):2837.

⁶ EFSA Journal 2012; 10(7):2836.

⁷ EFSA Journal 2012; 10(12):2993.

⁸ EFSA Journal 2012; 10(12):2994.

09.858), evaluation in FGE.23rev4⁹ (substance FL-no 13.170), evaluation in FGE.63rev1¹⁰ (substances FL-no 02.252, 07.190 and 09.936), evaluation FGE.94rev1¹¹ (substance FL-no 16.095) and evaluation FGE.304¹² (substance FL-no 16.123). EFSA concluded that those flavouring substances do not give rise to safety concerns at the estimated levels of dietary intakes.

- (4) Therefore, the flavouring substances assessed in those flavouring group evaluations should be listed as evaluated substances by deleting footnote references 1 to 4 in the relevant entries of the Union list.
- (5) After publication of the Union list, certain errors have been identified in that list. Those errors are related to names, CAS-numbers, JECFA-numbers or secondary components of the followings substances: FL-no 02.093, 02.110, 05.085, 08.004, 09.016, 09.131, 09.132, 09.266, 09.578, 09.596, 09.880, 12.075, 12.086, 12.273, 13.028, 13.190, 14.067 and 17.015. The errors should be corrected.
- (6) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended and corrected accordingly.
- (7) 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

Part A of Annex I to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

⁹ EFSA Journal 2013; 11(2):3092.
¹⁰ EFSA Journal 2012; 10(10):2900.
¹¹ EFSA Journal 2012; 10(6):2747.
¹² EFSA Journal 2012; 10(10):2903.

ANNEX

Part A of Annex I to Regulation (EC) No 1334/2008 is amended as follows:

(1) The entry concerning FL-no 02.093 is replaced by the following:

"

02.093	(Z)-Non-6-en-1-ol	35854-86-5	324	10294				JECFA
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"

(2) The entry concerning FL-no 02.110 is replaced by the following:

"

02.110	2,6-Dimethylhept-6-en-1-ol	36806-46-9	348		At least 90%; secondary component 5-10% 2,6-dimethyl-5-hepten-1-ol			JECFA
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"

(3) The entry concerning FL-no 02.145 is replaced by the following:

"

02.145	2,6-Dimethylocta-1,5,7-trien-3-ol	29414-56-0						EFSA
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"

(4) The entry concerning FL-no 02.194 is replaced by the following:

"

02.194	Octa-1,5-dien-3-ol	83861-74-9						EFSA
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"

(5) The entry concerning FL-no 02.211 is replaced by the following:

"

02.211	Undeca-1,5-dien-3-ol	56722-23-7						EFSA
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"

(6) The entry concerning FL-no 02.229 is replaced by the following:

"

02.229	(-)-3,7-Dimethyl-6-octen-1-ol	7540-51-4			At least 90% cis-isomer; secondary components 2- 6% di-unsaturated and saturated C10 alcohols, 2- 4% citronellyl acetate and 2-3% citronellal			EFSA
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"

(7) The entry concerning FL-no 02.252 is replaced by the following:

"

02.252	4,8-Dimethyl-3,7-nonadien-2-ol	67845-50-5	1841					EFSA
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"

(8) The entry concerning FL-no 05.026 is replaced by the following:

"

05.026	o-Tolualdehyde	529-20-4						EFSA
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"

(9) The entry concerning FL-no 05.028 is replaced by the following:

"

05.028	m-Tolualdehyde	620-23-5						EFSA
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"

(10) The entry concerning FL-no 05.029 is replaced by the following:

"

05.029	p-Tolualdehyde	104-87-0						EFSA
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"

(11) The entry concerning FL-no 05.085 is replaced by the following:

"

05.085	(Z)-Hept-4-enal	6728-31-0	320	2124	At least 93% of Z-form of hept-4-enal; secondary component 2-5% of E-form of hept-4-enal.			JECFA
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"

(12) The entry concerning FL-no 05.137 is replaced by the following:

"

05.137	Dec-4(cis)-enal	21662-09-9			At least 90%; secondary component at least 5% trans-isomer			EFSA
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"

(13) The entry concerning FL-no 05.182 is replaced by the following:

"

05.182	2,6,6-Trimethylcyclohex-2-ene-1-carboxaldehyde	432-24-6						EFSA
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"

(14) The entry concerning FL-no 07.190 is replaced by the following:

"

07.190	Octa-1,5-dien-3-one	65213-86-7	1848		Mixture of stereoisomers: 60-90 % E-form and 10-40% Z-form			EFSA
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"

(15) The entry concerning FL-no 07.198 is replaced by the following:

"

07.198	Pseudo-ionone	141-10-6		11191				EFSA
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"

(16) The entry concerning FL-no 07.202 is replaced by the following:

"

07.202	2,6,6-Trimethylcyclohex-2-en-1-one	20013-73-4						EFSA
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"

(17) The entry concerning FL-no 07.204 is replaced by the following:

"

07.204	3,3,6-Trimethylhepta-1,5-dien-4-one	546-49-6						EFSA
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"

(18) The entry concerning FL-no 07.255 is replaced by the following:

"

07.255	l-Piperitone	4573-50-6	1856					EFSA
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"

(19) The entry concerning FL-no 08.004 is replaced by the following:

"

08.004	Lactic acid	50-21-5	930	4				EFSA
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"

(20) The entry concerning FL-no 09.016 is replaced by the following:

"

09.016	Menthyl acetate	16409-45-3	431	206				JECFA
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"

(21) The entry concerning FL-no 09.131 is replaced by the following:

"

09.131	DL-Isobornyl propionate	2756-56-1	1391	412				EFSA
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"

(22) The entry concerning FL-no 09.132 is replaced by the following:

"

09.132	Benzyl propionate	122-63-4	842	413				EFSA
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"

(23) The entry concerning FL-no 09.266 is replaced by the following:

"

09.266	Hexyl 2-butenate	19089-92-0	1807	10688				EFSA
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"

(24) The entry concerning FL-no 09.562 is replaced by the following:

"

09.562	trans-3-Hexenyl formate	56922-80-6						EFSA
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"

(25) The entry concerning FL-no 09.578 is replaced by the following:

"

09.578	Hexyl (E)-but-2-enoate	1617-25-0		10688				EFSA
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"

(26) The entry concerning FL-no 09.596 is replaced by the following:

"

09.596	Isopentyl-(Z)-but-2-enoate	10482-55-0						EFSA
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"

(27) The entry concerning FL-no 09.854 is replaced by the following:

"

09.854	cis-3-Hexenyl 2-methylbutanoate	53398-85-9						EFSA
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"

(28) The entry concerning FL-no 09.858 is replaced by the following:

"

09.858	Phenylmethyl 2-methyl-2-butenate	67674-41-3			Mixture of stereoisomers: 60-90 % E-form and 10- 40% Z-form			EFSA
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"

(29) The entry concerning FL-no 09.880 is replaced by the following:

"

09.880	(Z)-Hept-4-en-2-yl butanoate	94088-12-7						EFSA
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"

(30) The entry concerning FL-no 09.936 is replaced by the following:

"

09.936	4,8-Dimethyl-3,7-nonadien-2-yl acetate	91418-25-6	1847					EFSA
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"

(31) The entry concerning FL-no 12.075 is replaced by the following:

"

12.075	Methyl prop-1-enyl disulfide	5905-47-5	569	11712	At least 90%; secondary components 3-4% dimethyl disulfide and 3-4% di-1-propenyl disulfide			JECFA
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"

(32) The entry concerning FL-no 12.086 is replaced by the following:

"

12.086	S-Methyl 2-methylbutanethioate	42075-45-6	486					JECFA
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"

(33) The entry concerning FL-no 12.273 is replaced by the following:

"

12.273	3-(Methylthio)heptanal	51755-70-5	1692		At least 92%; secondary component 5-7% (E)-hept-2-enal			EFSA
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"

(34) The entry concerning FL-no 13.028 is replaced by the following:

"

13.028	2-Butyl-5 or 6-keto-1,4-dioxane	65504-95-2	1484	2206				EFSA
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"

(35) The entry concerning FL-no 13.170 is replaced by the following:

"

13.170	2S-cis-Tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran	3033-23-6						EFSA
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"

(36) The entry concerning FL-no 13.190 is replaced by the following:

"

13.190	3-((2-methyl-3-furyl)thio)-2-butanone	61295-44-1	1525					EFSA
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"

(37) The entry concerning FL-no 14.067 is replaced by the following:

"

14.067	2-Ethoxy-3-methylpyrazine	32737-14-7	793	11921	At least 82% 2-ethoxy-3-methylpyrazine. Secondary components 15% 2-ethoxy-5-methylpyrazine (CAS no 67845-34-5) or 2-ethoxy-6-methylpyrazine (CAS no 53163-97-6)			EFSA
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"

(38) The entry concerning FL-no 15.134 is replaced by the following:

"

15.134	2,5-Dihydroxy-1,4-dithiane	40018-26-6	550		Mixture of diastereoisomers: 25-30 % of (2S,5S and 2R,5R) and 70-75% (2S,5R and 2R,5S)			EFSA
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"

(39) The entry concerning FL-no 16.095 is replaced by the following:

"

16.095	Cyclopropanecarboxamide, N-[(2E)-3,7-dimethyl-2,6-octadien-1-yl]-	744251-93-2	1779					EFSA
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"

(40) The entry concerning FL-no 16.123 is replaced by the following:

"

16.123	(1R,2S,5R)-N-(4-Methoxyphenyl)-5-methyl-2-(1-methylethyl)cyclohexanecarboxamide	68489-09-8						EFSA
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"

(41) The entry concerning FL-no 17.015 is replaced by the following:

"

17.015	DL-Methylmethioninesulphonium chloride	3493-12-7	1427	761				EFSA
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"