

## II

(Acts whose publication is not obligatory)

## COMMISSION

## COMMISSION DECISION

of 7 April 2004

amending Decision 1999/217/EC as regards the register of flavouring substances

(notified under document number C(2004) 1273)

(Text with EEA relevance)

(2004/357/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs <sup>(1)</sup>, as amended by Regulation (EC) No 1882/2003 <sup>(2)</sup>, and in particular Article 3(2) thereof,

Whereas:

(1) Regulation (EC) No 2232/96 lays down the procedure for the establishment of rules in respect of flavouring substances used or intended to be used in foodstuffs. That Regulation provides for the adoption of a register of flavouring substances ('the register') following notification by the Member States of a list of the flavouring substances which may be used in or on foodstuffs marketed in their territory and on the basis of scrutiny by the Commission of that notification.

(2) In addition, Regulation (EC) No 2232/96 provides for a programme of evaluation of the flavouring substances contained in the register ('the evaluation programme') in order to check if those substances comply within the general criteria for their use set out in the Annex to that Regulation. Regulation (EC) No 2232/96 provides that the persons responsible for placing the flavouring substances on the market are to forward data necessary

for their evaluation to the Commission. That Regulation also provides that following completion of the evaluation programme, the list of flavouring substances the use of which is to be authorised to the exclusion of others, is to be adopted.

(3) Pursuant to Regulation (EC) No 2232/96, Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 <sup>(3)</sup>, as last amended by Decision 2002/113/EC <sup>(4)</sup>, adopted a register of flavouring substances used in or on foodstuffs.

(4) Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council <sup>(5)</sup>, provides for certain information to be submitted by the person responsible for placing certain flavouring substances contained in the register on the market in order to enable the evaluation of the substance to be carried out.

(5) Commission Regulation (EC) No 622/2002 of 11 April 2002 establishing deadlines for the submission of information for the evaluation of chemically defined flavouring substances used in or on foodstuffs <sup>(6)</sup>, established time limits for the submission of information for the evaluation of flavouring substances as required

<sup>(1)</sup> OJ L 299, 23.11.1996, p. 1.

<sup>(2)</sup> OJ L 284, 31.10.2003, p. 1.

<sup>(3)</sup> OJ L 84, 27.3.1999, p. 1.

<sup>(4)</sup> OJ L 49, 20.2.2002, p. 1.

<sup>(5)</sup> OJ L 180, 19.7.2000, p. 8.

<sup>(6)</sup> OJ L 95, 12.4.2002, p. 10.

- pursuant to Regulation (EC) No 1565/2000. However, for a number of substances for which the deadline of 31 December 2002 had been established, no information has been submitted nor has the Commission been informed about any intention to still submit information. Therefore, these substances cannot be evaluated in respect of their compliance with the general criteria for the use of flavouring substances set out in Regulation (EC) No 2232/96 before the completion of the evaluation programme. Accordingly, it is appropriate to delete these substances from the register.
- (6) Scrutiny of the flavouring substances listed in the register revealed inconsistencies concerning the names of certain substances (FL No 06.100, and FL No 06.131) and also concerning certain chemical numbers (FL No 02.027, FL No 07.033, FL No 07.153, and FL No 09.578). In addition, cases were identified where the same substance appeared under different chemical names in the register (FL No 02.228 and FL No 02.027; FL No 07.221 and FL No 07.033). Those inconsistencies should be rectified.
- (7) Scrutiny by the Commission also revealed that of the different forms of quinine only quinine hydrochloride (FL No 14.011), quinine monohydrochloride dihydrate (FL No 14.155) and quinine sulphate (FL No 14.152) are used as flavouring substances. The other forms of quinine (FL No 14.146 and FL No 14.154) should therefore be deleted from the register.
- (8) The Scientific Committee on Food concluded in its opinion of 26 February 2002 that N-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide (capsaicin, FL No 16.014) is genotoxic. Capsaicin is naturally present in *Capsicum* species (e.g. chilli, cayenne pepper, red pepper). High consumption of chillies has been reported to be a risk factor for cancer. Although the maximum daily intake in the European Union is much lower than the intake levels associated with cancer, the addition of capsaicin as such to food should be avoided, as it does not comply with the general criteria for the use of flavouring substances set out in the Annex to Regulation (EC) No 2232/96. Accordingly, that substance should be deleted from the register.
- (9) For two substances listed in the register (CN060 and CN061), the notifying Member State has withdrawn its notification. Those substances should therefore be deleted from the register.
- (10) It is not appropriate to maintain the confidential code of substances that otherwise have been notified with their full name and were on the market at the moment the register was elaborated.
- (11) The industry has now provided information concerning certain substances which are indicated with the number 4 in the column 'comments' of part A of the Annex to Decision 1999/217/EC and for which additional information was required under that Decision. In particular, evidence was provided that those substances are flavouring substances. Accordingly, that Annex should be amended to delete the reference to number 4.
- (12) It is appropriate to make a correction to the register by giving a Flavis number to some substances that were on the market at the moment the register was elaborated to ensure that they are correctly taken up in the evaluation programme.
- (13) Member States have notified new flavouring substances to be included in the evaluation programme and they should therefore be incorporated into the register.
- (14) For some newly notified substances, in application of Regulation (EC) No 2232/96 and Commission Recommendation 98/282/EC of 21 April 1998 on the ways in which the Member States and signatory States to the Agreement on the European Economic Area should protect intellectual property in connection with the development and manufacture of flavouring substances referred to in Regulation (EC) No 2232/96 of the European Parliament and of the Council<sup>(1)</sup>, the notifying Member State requested designation in such a way as to protect the intellectual property rights of their manufacturer. Those substances should therefore be listed in part B of the Annex to Decision 1999/217/EC.
- (15) Decision 1999/217/EC should therefore be amended accordingly.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

#### Article 1

The Annex to Decision 1999/217/EC is amended in accordance with the Annex to this Decision.

<sup>(1)</sup> OJ L 127, 29.4.1998, p. 32.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 7 April 2004.

*For the Commission*  
David BYRNE  
*Member of the Commission*

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## ANNEX

The Annex to Decision 1999/217/EC is amended as follows:

1. in the list in the third paragraph of the introductory part of the Annex which precedes part A, the following point 6 is added:

'6. Substance which may not be used in and on food, unless lawfully placed on the market in the Member State(s) concerned.'

2. part A is amended as follows:

- (a) the entries for the substances attributed with the FL-Nos referred to in points (i) to (vi) are amended as follows:

- (i) for FL No 02.027, the entry '141-25-3' in the column 'CAS' is replaced by the entry '6812-78-8' and the entry '205-473-9' in the column 'Einecs' shall be replaced by '229-887-4';
- (ii) for FL No 06.100, the entry 'Acetaldehyde dipentyl acetal' in the column 'Name' is replaced by the entry '1,1-dipentyloxyethane';
- (iii) for FL No 06.131, the entry '1-Ethoxy-3-methyl-1-isopentyloxybutane' in the column 'Name' is replaced by the entry '1-ethoxy-1-(3-methylbutoxy)-3-methylbutane';
- (iv) for FL No 07.033, the entry '95-41-0' in the column 'CAS' is replaced by the entry '11050-62-7';
- (v) for FL No 07.153, the entry '1803-39-0' in the column 'CAS' is replaced by the entry '20489-53-6';
- (vi) for FL No 09.578, the entry '19089-92-0' in the column 'CAS' is replaced by the entry '1617-25-0';
- (vii) for FL No 12.201, the entry '57074-34-7' in the column 'CAS' is replaced by the entry '94293-57-9';

- (b) the rows set out in the table for the substances attributed with the following FL-numbers are deleted:

'02.046	02.143	02.158	02.161	02.169	02.179	02.220	02.225
02.228	02.241	05.086	05.138	05.145	05.151	05.161	05.162
05.163	05.165	05.168	05.181	05.206	06.056	06.093	06.110
06.112	07.006	07.037	07.073	07.155	07.166	07.186	07.197
07.209	07.218	07.221	07.222	07.227	08.077	08.084	08.091
08.105	08.106	08.118	08.122	08.124	08.125	09.172	09.175
09.190	09.224	09.226	09.320	09.322	09.336	09.338	09.343
09.344	09.359	09.361	09.366	09.373	09.376	09.378	09.393
09.497	09.577	09.591	09.597	09.610	09.622	09.627	09.628
09.630	09.653	09.828	09.849	09.856	09.863	09.868	09.883
09.889	09.890	12.011	12.090	12.091	12.105	12.119	12.131
12.133	12.140	12.144	12.160	12.184	12.185	12.190	12.204
12.213	12.215	12.219	12.220	12.225	12.229	14.146	14.154
16.014	16.077	17.004	17.011	17.016	17.030'		

- (c) for the substances attributed with the following FL-Nos, the number '4' in the column 'comments' in the table is deleted:

'02.004	02.121	02.216	02.217	09.016	09.034	09.367	09.712
16.009	16.017'						

(d) the following rows are inserted in the table:

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
02.243	04	56805-23-3	(E)-3-(Z)-6-Nonadien-1-ol	3884	278-518-3		6
04.095	25	527-60-6	2,4,6-Trimethyl phenol		208-419-2		6
04.096	18	579-60-2	2-Methoxy-6-(2-propenyl)phenol		209-444-1		6
05.207	04	105683-99-6	6-Decenal, cis				6
05.208	04	169054-69-7	Z-8-Tetradecenal				6
05.209	04	147159-48-6	6-Decenal, trans				6
06.132	23	63253-24-7	Vanillin butan-2,3-diol acetal (mixture of stereo isomers)	4023		Vanillin erythro and threo-butan-2,3-diol acetal	6
05.217	04	21662-08-8	5-Decenal				
05.218	04	56554-87-1	16-Octadecenal				
07.239	05	2278-53-7	[R-(E)]-5-Isopropyl-8-methylnona-6,8-dien-2-one		218-907-7		6
07.240	05	13019-20-0	2-Methylheptan-3-one	4000	235-877-0		6
07.241	05	1635-02-5	3,4-Dimethylhex-3-en-2-one		216-656-8		6
07.242	21	5355-63-5	3-Hydroxy-4-phenylbutane-2-one				6
07.243	21	99-93-4	4-Hydroxy acetophenone		202-802-8		6
07.244	05	20859-10-3	Trans-6-Methyl-3-hepten-2-one	4001			6
07.245	08	71048-82-3	Trans-delta-damascone		275-156-8	(1alpha(E),2beta) - 1-(2,6,6-trimethyl-cyclohex-3-en-1-yl)but-2-en-1-one	6
07.246	08	25304-14-7	Dimethyl cyclohexyl methyl ketone		246-799-1		6
07.247	05	30086-02-3	Octadien-2-one/3,5- (E,E)	4008			6

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
07.248	10	585-25-1	Octan-2,3-dione		209-552-9		6
07.249	05	927-49-1	Undecan-6-one	4022	213-150-9		6
07.253	05	30086-02-3	3,5-Octadiene-2-one				
09.917	04	1576-85-8	4-Pentenyl acetate	4011	216-413-6		6
09.918	04	67452-27-1	Cis-4-decanyl acetate	3967			6
09.919	09	139564-43-5	Ethyl 3-acetoxy-2-methylbutyrate				6
09.920	08	156324-82-2	2-Isopropyl-5-methylcyclohexyl oxycarbonyloxy-2-hydroxypropane	3992	417-420-9		6
09.921	04	54653-25-7	Ethyl 5-hexenoate	3976			6
09.922	04	39924-27-1	Ethyl cis-4-heptenoate	3975	254-702-9		6
09.923	05	39026-94-3	Hept-2-yl butyrate	3981			6
09.924	05	5921-83-5	(+/-)-3-Heptyl acetate	3980	203-932-8		6
09.925	05	60826-15-5	Nonan-3-yl acetate	4007	262-444-3		6
09.926	05	84434-65-1	Octan-3-yl formate	4009	282-866-1		6
09.927	04	141-15-1	Rhodinyl butyrate	2982	205-462-9		6
09.928	04	3681-82-1	Trans-3-hexenyl acetate		222-962-2		6
10.069	09	67663-01-8	3-Methyl gamma-decalactone	3999			6
10.070	09	1073-11-6	4-Methyl-5-hexen-1,4-olide		214-024-6		6
12.238	20	227456-27-1	3-Mercapto-2-methylpentan-1-ol	3996			6
12.239	20	227456-28-2	3-Mercapto-2-methylpentanal	3994			6
12.240	20	6540-86-9	2,4,6-Trithiaheptane				6

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
12.241	20	258823-39-1	2-Mercapto-2-methylpentan-1-ol	3995			6
12.242	20	29414-47-9	Methylthiomethylmercaptan				
12.243	20	6725-64-0	Dimercaptomethane				6
12.244	20	14109-72-9	1-Methylthio-2-propanone	3882			6
12.245	20	7529-06-8	1,3-Dimercapto-2-thiapropane				6
12.246	20		1-(Methylthio) hexan-3-one				6
12.247	20	61837-77-2	1-(Methylthio) octan-3-one				6
12.248	20	5862-47-5	2-(Methylthio) ethyl acetate				6
12.249	20	227456-27-1	3-Mercapto-2-methylpentanol (mixture of stereo isomers)	3996			6
12.250	20	51755-72-7	3-Mercaptohexanal				6
12.251	20	136954-22-8	3-Mercaptohexyl hexanoate	3853			6
12.252	20	31539-84-1	4-Mercapto-4-methyl-2-pentanol				6
12.253	20	72437-68-4	Amyl methyl disulfide				6
12.254	20	63986-03-8	Butyl ethyl disulfide				6
12.255	20	156472-94-5	Ethyl 3-mercaptopbutyrate	3977			6
12.256	20	31499-70-4	Ethyl propyl trisulfide				6
12.257	20	104228-51-5	Ethyl 4-(acetylthio) butyrate	3974			6
12.259	20	29725-66-4	p-menthan-3-one, 1 mercapto				6
13.191	14	376595-42-5	O-Ethyl S-(2-furylmethyl)thiocarbonate				6
13.192	14	109537-55-5	Furfuryl 2-methyl-3-furyldisulfide				6

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
13.193	14	26486-21-5	2,5-Dimethyltetrahydro-3-furanthiol	3971			6
13.194	14	252736-39-3	2,5-Dimethyltetrahydro-3-furyl thioacetate	3972			6
13.195	30	26131-91-9	2-Isobutyl-4,5-dimethyl oxazole				6
13.196	14	180031-78-1	4-(Furfurylthio) pentan-2-one	3840			6
13.197	14	252736-36-0	Furyl propyldisulfide	3979			6
14.162	28	98-79-3	L-2-Pyrrolidone-5-carboxylic acid				6
14.163	28	1192-58-1	1-Methylpyrrole-2-carboxaldehyde		214-755-0		6
14.164	28	622-39-9	2-Propylpyridine		210-732-4		6
14.165	28	2168-14-8	N-ethyl-2-formylpyrrole				6
15.123	20	53897-58-5	2,4,6-Triethyl-1,3,5-trithiane				6
16.082	30	21018-84-8	Amarogentin				6'



3. the table of part B is replaced by the following:

**'Flavouring substances notified in application of Article 3(2) of Regulation (EC) No 2232/96, for which the protection of the intellectual property rights of the manufacturer has been requested**

Code	Date of receipt of the notification by the Commission	Comments
CN003	17.10.1998	
CN004	17.10.1998	
CN009	17.10.1998	
CN010	17.10.1998	
CN012	17.10.1998	
CN013	17.10.1998	
CN014	17.10.1998	
CN016	17.10.1998	
CN019	17.10.1998	
CN022	17.10.1998	
CN023	17.10.1998	
CN030	17.10.1998	
CN033	17.10.1998	
CN035	17.10.1998	
CN036	17.10.1998	
CN037	17.10.1998	
CN042	17.10.1998	
CN045	17.10.1998	
CN048	17.10.1998	
CN049	17.10.1998	
CN050	17.10.1998	
CN052	17.10.1998	
CN053	17.10.1998	
CN054	17.10.1998	
CN057	17.10.1998	
CN058	30.10.1998	
CN059	18.9.1998	
CN064	3.2.1999	
CN065	26.1.2001	
CN074	18.4.2003	6
CN075	18.4.2003	6
CN076	18.4.2003	6'