

## COMMISSION DECISION

of 18 May 2005

## amending Decision 1999/217/EC as regards the register of flavouring substances used in or on foodstuffs

(notified under document number C(2005) 1437)

(Text with EEA relevance)

(2005/389/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>, and in particular Article 3(2) and Article 4(3) 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. That register was adopted by Commission Decision 1999/217/EC<sup>(2)</sup>.
- (2) In addition, Regulation (EC) No 2232/96 provides for a programme for the evaluation of flavouring substances in order to check whether they comply with the general criteria for the use of flavouring substances set out in the Annex to that Regulation.
- (3) The European Food Safety Authority (the Authority) concluded in its opinion of 13 July 2004 on para-hydroxybenzoates, that propyl 4-hydroxybenzoate (FL 09.915) had effects on sex hormones and the male reproductive organs in juvenile rats. The Authority was unable to recommend an acceptable daily intake (ADI) for this substance because of the lack of clear no-observed-adverse-effect-level (NOAEL). The use of propyl 4-hydroxybenzoate as a flavouring substance in food is not acceptable, 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. As a consequence, propyl 4-hydroxybenzoate should be deleted from the register.

- (4) The Authority concluded in its opinion of 7 December 2004 on aliphatic dialcohols, diketones and hydroxyketones, that pentane-2,4-dione (FL 07.191) is genotoxic *in vitro* and *in vivo*. Accordingly, its use as a flavouring substance is not acceptable, because 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. As a consequence, pentane-2,4-dione should be deleted from the register.
- (5) 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 the 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>(3)</sup>, for a number of substances, the notifying Member States requested that they should be registered in such a way as to protect the intellectual property rights of the manufacturer.
- (6) Protection for these substances, listed in Part B of the register, is limited to a maximum period of five years following the date of receipt of the notification. That period has now expired for 28 substances which should consequently be transferred to Part A of the register.
- (7) Decision 1999/217/EC should therefore be amended accordingly.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

<sup>(1)</sup> OJ L 299, 23.11.1996, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 84, 27.3.1999, p. 1. Decision as last amended by Decision 2004/357/EC (OJ L 113, 20.4.2004, p. 28).

<sup>(3)</sup> OJ L 127, 29.4.1998, p. 32.

HAS ADOPTED THIS DECISION:

*Article 1*

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

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 18 May 2005.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

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## ANNEX

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

1. Part A is amended as follows:

(a) The rows set out in the table for the substances attributed with FL-numbers 07.191 (pentane-2,4-dione) and 09.915 (propyl 4-hydroxybenzoate) are deleted.

(b) The following rows are inserted in the table:

FL No	Chemical group	CAS	Name	Fema	Einecs	Synonyms	Comments
01.070	31	111-66-0	1-Octene		203-893-7		
01.071	31	111-67-1	2-Octene		203-894-2		
01.072	31	544-76-3	Hexadecane		280-878-9		
07.251	21	577-16-2	Methylacetophenone				CAS No corresponds to 2-methylacetophenone
01.073	31	592-99-4	4-Octene				
01.074	31	593-45-3	Octadecane		209-790-3		
16.084	30	627-67-8	3-Methyl-1-nitrobutane		211-008-0		
01.075	31	629-78-7	Heptadecane		211-108-4		
12.260	20	4131-76-4	Methyl-2-methyl-3-mercaptopropionate		223-949-4		
12.261	20	6725-64-0	Methanedithiol				
01.076	31	20996-35-4	3,7-Decadiene				
16.085	20	27959-66-6	4,4-Dimethyl-1,3-oxathiane				
12.262	20	29414-47-9	(Methylthio)methanethiol				
05.210	04	30390-51-3	4-Dodecenal		250-174-9		
05.211	02	30689-75-9	6-Methyloctanal				
14.166	30	32536-43-9	Indole acetic acid				
07.252	05	33665-27-9	4-Octen-2-one				
02.244	04	54393-36-1	4-Octen-1-ol				
10.070	09	57681-53-5	4-Hydroxy-2-heptenoic acid lactone		260-902-7		
05.212	04	76261-02-4	6-Dodecenal				
05.213	04	90645-87-7	5-Nonenal				
15.124	29	103527-75-9	3-Methyl-2-butenylthiophene			Rose thiophene	
05.214	04	121052-28-6	8-Dodecenal				
05.215	03	134998-59-7	2,6-Decadienal (c,c)				
05.216	03	134998-60-0	2,6-Decadienal (t,t)				
12.263	20		3-Mercapto-3-methylbutanal				
12.264	20	92585-08-5	4,2-Thiopentanone				
03.021	16	142-96-1	Dibutyl ether		205-575-3		

2. 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
CN065	26.1.2001	
CN074	18.4.2003	6
CN075	18.4.2003	6
CN076	18.4.2003	6