2024/238

16.1.2024

COMMISSION REGULATION (EU) 2024/238

of 15 January 2024

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the introduction of restrictions on the use of 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 2000/13 (¹), 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 flavourings (2), 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 approved for use in and on foods and their conditions of use.
- (2) By Commission Implementing Regulation (EU) No 872/2012 (3) the list of flavouring substances was adopted and introduced in Part A of Annex I to Regulation (EC) No 1334/2008.
- (3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.
- (4) The Union list of flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008 contains, among others, a number of flavouring substances for which, at the time of adoption of the list by Regulation (EU) No 872/2012, the European Food Safety Authority ('the Authority') had not been able to rule out a safety risk to the health of the consumer on the basis of the data available and had, therefore, considered that additional data was necessary to complete their evaluation. Those substances were included in the Union list of flavouring substances but on the condition that safety data addressing the concerns expressed by the Authority was submitted before the expiry of specific deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008.
- (5) Among the substances included in the Union list of flavourings and source materials but identified by way of a footnote reference requiring the Authority to complete the evaluation, there are the following three substances of the Flavouring Group Evaluation 216 (FGE.216): 2-Phenylcrotonaldehyde (FL No 05.062), 5-Methyl-2-phenylhex-2-enal (FL No 05.099) and 4-Methyl-2-phenylpent-2-enal (FL No 05.100). For those substances the Authority requested additional scientific data that were subsequently submitted by the applicants.

⁽¹⁾ OJ L 354, 31.12.2008, p. 34.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

EN OJ L, 16.1.2024

(6) In its scientific opinion of 29 June 2022 (*), the Authority evaluated the submitted data and concluded that the representative substance of the group, 2-Phenylcrotonaldehyde (FL No 05.062), induced an aneugenicity mode of action. As the available *in vivo* micronucleus studies were inconclusive, an *in vivo* potential aneugenicity cannot be ruled out for 2-Phenylcrotonaldehyde (FL No 05.062), 5-Methyl-2-phenylhex-2-enal (FL No 05.099) and 4-Methyl-2-phenylpent-2-enal (FL No 05.100).

- (7) Following this opinion and in order to further evaluate the safety of those three substances the interested business operators committed to provide further data that would allow a thorough assessment of the *in vivo* aneugenicity for these three substances (5).
- (8) It is also appropriate, pending the re-evaluation by the Authority of the additional data from the interested business operators and following on from the scientific opinion of 29 June 2022, to limit the conditions of use of 2-Phenylcrotonaldehyde (FL No 05.062), 5-Methyl-2-phenylhex-2-enal (FL No 05.099) and 4-Methyl-2-phenylpent-2-enal (FL No 05.100) to their current use.
- (9) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (10) Foods not complying with the new conditions set out, to which any of the substances concerned have been added and which have been placed on the market in the Union or which have been dispatched from third countries and were in transit to the Union before the entry into force of this Regulation should be allowed to be marketed in the Union until their date of minimum durability or use-by date. This transitional measure should not apply to preparations to which any of the substances concerned has been added and which are not intended to be consumed as such, as the manufacturers of food products that use those preparations as ingredients know their composition when they use them.
- (11) For reasons of harmonisation with Regulation (EC) No 1333/2008 of the European Parliament and the Council (6) and in order to account for the restrictions that correspond to the food categories used by the Authority during the exposure assessment, the food categories listed in Section 1 of Part A of Annex I to Regulation (EC) No 1334/2008 should be replaced by the food categories listed in Part D of Annex II to Regulation (EC) No 1333/2008.
- (12) A new footnote should be added to column 8 in the Union list, under Section 1 of Part A of Annex I to Regulation (EC) No 1334/2008 to indicate the need for additional data where additional data are expected in order to fully complete the assessment of the Authority.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1334/2008

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

⁽⁴⁾ Scientific Opinion on Flavouring Group Evaluation 216 Revision 2 (FGE.216Rev2): consideration of the genotoxicity potential of α,β-unsaturated 2-phenyl-2-alkenals from subgroup 3.3 of FGE.19. EFSA Journal 2022;20(8):7420, doi:10.2903/j.efsa.2022.7420. Available online: https://www.efsa.europa.eu/en/efsajournal/pub/7420

⁽⁵⁾ IOFI EFFA Letter DG Sante – EFSA Opinion 216 Rev2 (EFSA Journal (2022; 20(8) 7420)) – follow-up IOFI/EFFA letter: confirmation of follow-up testing and anticipated timings. Ares(2022)8489668

⁽e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

OJ L, 16.1.2024 EN

Article 2

Transitional measures

1. Foods to which any of the flavouring substances listed in the Annex to this Regulation have been added, which do not comply with the conditions set out in that Annex and which have been lawfully placed on the market before the entry into force of this Regulation may be marketed until their date of minimum durability or use-by date.

- 2. Foods to which any of the flavouring substances listed in the Annex to this Regulation have been added, which do not comply with the conditions set out in that Annex and which have been imported into the Union from a third country may be marketed until their date of minimum durability or use-by date where the importer of such foods can demonstrate that they were dispatched from the third country concerned and were in transit to the Union before the entry into force of this Regulation.
- 3. The transitional measures provided for in paragraphs 1 and 2 shall not apply to preparations, not intended to be consumed as such, to which any of the flavouring substances listed in the Annex to this Regulation has been added.
- 4. For the purposes of this Regulation, preparations shall be understood as mixtures of one or more flavourings to which other food ingredients such as food additives, enzymes or carriers may be also incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

Article 3

Entry into force

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, 15 January 2024.

For the Commission The President Ursula VON DER LEYEN

ELI: http://data.europa.eu/eli/reg/2024/238/oj

EN OJ L, 16.1.2024

ANNEX

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

- (1) Section 1 is amended as follows:
 - (a) the table containing the list of food categories is replaced with the following:

'Category number	Food Category							
0.	All categories of foods							
01.	Dairy products and analogues							
01.1	Unflavoured pasteurised and sterilised (including UHT) milk							
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation							
01.3	Unflavoured fermented milk products, heat-treated after fermentation							
01.4	Flavoured fermented milk products including heat-treated products							
01.5	Dehydrated milk as defined by Directive 2001/114/EC							
01.6	Cream and cream powder							
01.6.1	Unflavoured pasteurised cream (excluding reduced fat creams)							
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20 %							
01.6.3	Other creams							
01.7	Cheese and cheese products							
01.7.1	Unripened cheese excluding products falling in category 16							
01.7.2	Ripened cheese							
01.7.3	Edible cheese rind							
01.7.4	Whey cheese							
01.7.5	Processed cheese							
01.7.6	Cheese products (excluding products falling in category 16)							
01.8	Dairy analogues, including beverage whiteners							
01.9	Edible caseinates							
02.	Fats and oils and fat and oil emulsions							
02.1	Fats and oils essentially free from water (excluding anhydrous milkfat)							
02.2	Fat and oil emulsions mainly of type water-in-oil							
02.2.1	Butter and concentrated butter and butter oil and anhydrous milkfat							
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No $1234/2007$ and liquid emulsions							
02.3	Vegetable oil pan spray							
03.	Edible ices							
04.	Fruit and vegetables							

OJ L, 16.1.2024 EN

04.1	Unprocessed fruit and vegetables
04.1.1	Entire fresh fruit and vegetables
04.1.2	Peeled, cut and shredded fruit and vegetables
04.1.3	Frozen fruit and vegetables
04.2	Processed fruit and vegetables
04.2.1	Dried fruit and vegetables
04.2.2	Fruit and vegetables in vinegar, oil, or brine
04.2.3	Canned or bottled fruit and vegetables
04.2.4	Fruit and vegetable preparations, excluding products covered by 5.4
04.2.4.1	Fruit and vegetable preparations excluding compote
04.2.4.2	Compote, excluding products covered by category 16
04.2.5	Jam, jellies and marmalades and similar products
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EC
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC
04.2.5.3	Other similar fruit or vegetable spreads
04.2.5.4	Nut butters and nut spreads
04.2.6	Processed potato products
05.	Confectionery
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC
05.2	Other confectionery including breath refreshening microsweets
05.3	Chewing gum
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4
06.	Cereals and cereal products
06.1	Whole, broken, or flaked grain
06.2	Flours and other milled products and starches
06.2.1	Flours
06.2.2	Starches
06.3	Breakfast cereals
06.4	Pasta
06.4.1	Fresh pasta
06.4.2	Dry pasta
06.4.3	Fresh pre-cooked pasta
06.4.4	Potato gnocchi
06.4.5	Fillings of stuffed pasta (ravioli and similar)
06.5	Noodles
06.6	Batters
	l

EN OJ L, 16.1.2024

06.7	Pre-cooked or processed cereals
07.	Bakery wares
07.1	Bread and rolls
07.1.1	Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt
07.1.2	Pain courant français; Friss búzakenyér, fehér és félbarna kenyerek
07.2	Fine bakery wares
08.	Meat
08.1	Fresh meat, excluding meat preparations as defined by Regulation (EC) No 853/2004
08.2	Meat preparations as defined by Regulation (EC) No 853/2004
08.3	Meat products
08.3.1	Non-heat-treated meat products
08.3.2	Heat-treated meat products
08.3.3	Casings and coatings and decorations for meat
08.3.4	Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates
08.3.4.1	Traditional immersion cured products (Meat products cured by immersion in a curing solution containing nitrites and/or nitrates, salt and other components)
08.3.4.2	Traditional dry cured products. (Dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation)
08.3.4.3	Other traditional and traditionally cured products (including immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking)
09.	Fish and fisheries products
09.1	Unprocessed fish and fisheries products
09.1.1	Unprocessed fish
09.1.2	Unprocessed molluscs and crustaceans
09.2	Processed fish and fishery products including mollusks and crustaceans
09.3	Fish roe
10.	Eggs and egg products
10.1	Unprocessed eggs
10.2	Processed eggs and egg products
11.	Sugars, syrups, honey and table-top sweeteners
11.1	Sugars and syrups as defined by Directive 2001/111/EC
11.2	Other sugars and syrups
11.3	Honey as defined in Directive 2001/110/EC
11.4	Table-top sweeteners
11.4.1	Table-top sweeteners in liquid form
11.4.2	Table-top sweeteners in powder form
11.4.3	Table-top sweeteners in tablets
12.	Salts, spices, soups, sauces, salads and protein products
· · · · · · · · · · · · · · · · · · ·	

OJ L, 16.1.2024 EN

14. 14.1	Beverages Non-alcoholic beverages
13.4	Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009 (4)
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants
13.1.5	Dietary foods for infants and young children for special medical purposes as defined by Commission Directive 1999/21/EC (3) and special formulae for infants
13.1.4	Other foods for young children
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC (²)
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC
13.1.1	Infant formulae as defined by Commission Directive 2006/141/EC (¹)
13.1	Foods for infants and young children
13.	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC
12.9	Protein products, excluding products covered in category 1.8
12.8	Yeast and yeast products
12.7	Salads and savoury based sandwich spreads
12.6	Sauces
12.5	Soups and broths
12.4	Mustard
12.3	Vinegars and diluted acetic acid (diluted with water to 4–30 % by volume)
12.2.2	Seasonings and condiments
12.2.1	Herbs and spices
12.2	Herbs, spices, seasonings
12.1.2	Salt substitutes
12.1.1	Salt

EN OJ L, 16.1.2024

14.1.1	Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products
14.1.4	Flavoured drinks
14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products
14.1.5.1	Coffee, coffee extracts
14.1.5.2	Other
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts
14.2.1	Beer and malt beverages
14.2.2	Wine and other products defined in Part II of Annex VII to Regulation (EU) No 1308/2013
14.2.3	Cider and perry
14.2.4	Fruit wine and made wine
14.2.5	Mead
14.2.6	Spirit drinks as defined in Regulation (EU) 2019/787
14.2.7	Aromatised wine products as defined by Regulation (EU) No 251/2014
14.2.7.1	Aromatised wines
14.2.7.2	Aromatised wine-based drinks
14.2.7.3	Aromatised wine-product cocktails
14.2.8	Other alcoholic beverages including mixtures of alcoholic beverages with non-alcoholic beverages and other alcoholic beverages based on distilled alcohol with alcoholic strength by volume less than 15 %
15.	Ready-to-eat savouries and snacks
15.1	Potato-, cereal-, flour- or starch-based snacks
15.2	Processed nuts
16.	Desserts excluding products covered in categories 1, 3 and 4
17.	Food supplements as defined in Directive 2002/46/EC
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children
18.	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children

⁽¹) OJ L 401, 30.12.2006, p. 1. (²) OJ L 339, 6.12.2006, p. 16. (³) OJ L 91, 7.4.1999, p. 29. (⁴) OJ L 16, 21.1.2009, p. 3.'

(b) under Column 8 (footnotes), the following footnote is added:

'(5) additional scientific data shall be submitted in a timeframe agreed with the Commission Services, for the evaluation to be completed by the Authority.'

(2) in Table 1 in Section 2, entries 05.062, 05.099 and 05.100 are replaced by the following:

05.062	2-Phenylcrotonaldehyde	4411-89-6	1474	670	In category 1.4 – not more than 0,50 mg/kg	5	EFSA
					In category 1.7 – not more than 1,40 mg/kg		
					In category 1.8 – not more than 1,30 mg/kg		
					In category 2.1, 2.2, 2.3 – not more than 1,60 mg/kg		
					In category 3.0 – not more than 1,15 mg/kg		
					In category 4.2 – not more than 0,05 mg/kg		
					In category 4.2.2 – not more than 0,20 mg/kg		
					In category 4.2.5 – not more than 0,30 mg/kg		
					In category 5.1 – not more than 2,00 mg/kg		
					In category 5.2 – not more than 2,00 mg/kg		
					In category 5.3 – not more than 2,00 mg/kg		
					In category 5.4 – not more than 1,10 mg/kg		
					In category 6.3 – not more than 2,00 mg/kg		
					In category 6.4 – not more than 0,04 mg/kg		
					In category 6.6 – not more than 0,30 mg/kg		
					In category 6.7 – not more than 0,60 mg/kg		
					In category 7.1 – not more than 2,00 mg/kg		
					In category 7.2 – not more than 2,00 mg/kg		
					In category 8.2, 8.3 – not more than 0,80 mg/kg		
					In category 9.2, 9.3 – not more than 0,50 mg/kg		
					In category 10.2, – not more than 0,20 mg/kg		
					In category 11.2 – not more than 1,5 mg/kg		
					In category 12.2 – not more than 0,60 mg/kg		
					In category 12.3 – not more than 1,80 mg/kg		
					In category 12.4 – not more than 0,20 mg/kg		
					In category 12.5 – not more than 0,40 mg/kg		
			1		In category 12.6 – not more than 1,90 mg/kg		

E

OJ L, 16.1.2024

In category 14.2.6 – not more than 5,00 mg/kg In category 15.0 – not more than 5,00 mg/kg In category 16 – not more than 5,00 mg/kg In category 17 – not more than 5,00 mg/kg	mg/kg	
Un category 18.0 – not more than 2,30 mg/kg 4-Methyl-2-phenylpent- 2-enal 26643-91-4 1473 10366 In category 1.4 – not more than 0,60 mg/kg In category 1.7 – not more than 5,00 mg/kg In category 1.8 – not more than 0,50 mg/kg	5	EFS.

OJ L, 16.1.2024

EN

ELI: http://data.europa.eu/eli/reg/2024/238/oj

			In category 5.1 – not more than 2,00 mg/kg	
			In category 5.2 – not more than 5,00 mg/kg	
			In category 5.3 – not more than 5,00 mg/kg	
			In category 5.4 – not more than 5,00 mg/kg	
			In category 6.3 – not more than 5,00 mg/kg	
			In category 6.4 – not more than 1,50 mg/kg	
			In category 6.6 – not more than 3,00 mg/kg	
			In category 6.7 – not more than 0,20 mg/kg	
			In category 7.1 – not more than 5,00 mg/kg	
			In category 7.2 – not more than 5,00 mg/Kg	
			In category 8.2, 8.3 – not more than 1,50 mg/kg	
			In category 9.2, 9.3 – not more than 1,50 mg/kg	
			In category 10.2 – not more than 1,50 mg/kg	
			In category 11.2 – not more than 0,10 mg/kg	
			In category 12.2 – not more than 0,90 mg/kg	
			In category 12.3 – not more than 1,50 mg/kg	
			In category 12.4 – not more than 1,50 mg/kg	
			In category 12.5 – not more than 0,80 mg/kg	
			In category 12.6 – not more than 1,50 mg/kg	
			In category 12.7 – not more than 1,50 mg/kg	
			In category 12.9 – not more than 5,00 mg/kg	
			In category 13.2, 13.3, 13.4 – not more than 5,00 mg/kg	
			In category 14.2.1 – not more than 0,08 mg/kg	
			In category 14.2.2 – not more than 0,08 mg/kg	
			In category 14.2.5 – not more than 0,08 mg/kg	
			In category 14.2.6 – not more than 0,08 mg/kg	
			In category 15.0 – not more than 1,8 mg/kg	
			In category 16 – not more than 4,00 mg/kg	
			In category 17 – not more than 0,60 mg/kg'	

E