

ANNEX 1: SUMMARY OF RECOMMENDATIONS FROM THE 69TH JECFA**Toxicological recommendations and information on specifications***Food additives considered for specifications only*

Food additive	Specifications ^a
Activated carbon	R
Annatto extract (oil-processed bixin)	W
Cassia gum	R
Indigotine	R
Steviol glycosides	R
Sucrose esters of fatty acids	R
Sucrose monoesters of lauric, palmitic or stearic acid	N, T
Titanium dioxide	R

^a N, new specifications; R, existing specifications revised; T, tentative specifications; W, existing specifications withdrawn.

Flavouring agents evaluated by the Procedure for the Safety Evaluation of Flavouring Agents¹***A. Alicyclic primary alcohols, aldehydes, acids and related esters***

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
<i>cis</i> -4-(2,2,3-Trimethylcyclopentyl)butanoic acid	1899	N	No safety concern
(2,4)-, (3,5)- and (3,6)-Dimethyl-3-cyclohexenylcarbaldehyde	1900	N	No safety concern
(±)- <i>cis</i> - and <i>trans</i> -1,2-Dihydroperillaldehyde	1902	N	No safety concern
<i>d</i> -Limonen-10-ol	1903	N	No safety concern
<i>p</i> -Menthan-7-ol	1904	N	No safety concern
<i>p</i> -Menth-1-en-9-ol	1905	N	No safety concern
1,3- <i>p</i> -Menthadien-7-al	1906	N	No safety concern
Structural class II			
Methyl dihydrojasmonate	1898	N	No safety concern
<i>cis</i> - and <i>trans</i> -2-Heptylcyclopropanecarboxylic acid	1907	N	No safety concern
(±)- <i>cis</i> - and <i>trans</i> -2-Methyl-2-(4-methyl-3-pentenyl)cyclopropanecarbaldehyde	1908	N	No safety concern

¹ The flavouring agent 2-aminoacetophenone (No. 2043) was on the agenda to be evaluated in the group of aromatic substituted secondary alcohols, ketones and related esters. Although the compound fulfils some of the structural requirements for this group, the main toxicologically relevant structural feature is the amino group; hence, the compound was not evaluated and should be evaluated in the future in the group of aliphatic and aromatic amines and amides. The flavouring agent (±)-2-phenyl-4-methyl-2-hexenal (No. 2069) was on the agenda to be evaluated in the group of benzyl derivatives. However, as this compound did not meet the structural requirements for this group, the compound was not evaluated at this meeting.

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class III		N	
Perillaldehyde propyleneglycol acetal	1901	N	No safety concern

^a N, new specifications.

B. Simple aliphatic and aromatic sulfides and thiols

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
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Subgroup i: Simple sulfides

Structural class I

Methyl octyl sulfide	1909	N	No safety concern
Methyl 1-propenyl sulfide	1910	N	No safety concern
Di-(1-propenyl)-sulfide (mixture of isomers)	1911	N	No safety concern

Structural class III

Butanal dibenzyl thioacetal	1939	N	Additional data required to complete evaluation
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Subgroup ii: Acyclic sulfides with oxidized side-chains

Structural class I

Ethyl 2-hydroxyethyl sulfide	1912	N	No safety concern
2-(Methylthio)ethyl acetate	1913	N	No safety concern
Ethyl 3-(methylthio)-(2Z)-propenoate	1915	N	No safety concern
Ethyl 3-(methylthio)-(2E)-propenoate	1916	N	No safety concern
Ethyl 3-(methylthio)-2-propenoate (mixture of isomers)	1917	N	No safety concern
4-Methyl-2-(methylthiomethyl)-2-pentenal	1918	N	No safety concern
4-Methyl-2-(methylthiomethyl)-2-hexenal	1919	N	No safety concern
5-Methyl-2-(methylthiomethyl)-2-hexenal	1920	N	No safety concern
Butyl β-(methylthio)acrylate	1921	N	No safety concern
Ethyl 3-(ethylthio)butyrate	1922	N	No safety concern
Methional diethyl acetal	1940	N	No safety concern
3-(Methylthio)propyl hexanoate	1941	N	Additional data required to complete evaluation

Structural class III

1-(3-(Methylthio)-butyryl)-2,6,6-trimethylcyclohexene	1942	N	No safety concern
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Subgroup iii: Cyclic sulfides

Structural class II

2-Oxothiolane	1923	N	No safety concern
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Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class III			
(±)- <i>cis</i> - and <i>trans</i> -2-Pentyl-4-propyl-1,3-oxathiane	1943	N	Additional data required to complete evaluation
2-Pentenyl-4-propyl-1,3-oxathiane (mixture of isomers)	1944	N	Additional data required to complete evaluation
<i>Subgroup iv: Simple thiols</i>			
Structural class I			
Dodecanethiol	1924	N	No safety concern
<i>Subgroup v: Thiols with oxidized side-chains</i>			
Structural class I			
2-Hydroxyethanethiol	1925	N	No safety concern
4-Mercapto-4-methyl-2-hexanone	1926	N	No safety concern
3-Mercapto-3-methylbutyl isovalerate	1927	N	No safety concern
(±)-Ethyl 3-mercapto-2-methylbutanoate	1928	N	No safety concern
3-Mercaptohexanal	1929	N	No safety concern
3-Mercaptopropionic acid	1936	N	No safety concern
2-Ethylhexyl 3-mercaptopropionate	1938	N	No safety concern
Structural class III			
3-(Methylthio)propyl mercaptoacetate	1914	N	Additional data required to complete evaluation
<i>Subgroup vii: Simple disulfides</i>			
Structural class I			
Diisoamyl disulfide	1930	N	No safety concern
Butyl propyl disulfide	1932	N	No safety concern
di- <i>sec</i> -Butyl disulfide	1933	N	No safety concern
Structural class III			
Bis(2-methylphenyl) disulfide	1931	N	Additional data required to complete evaluation
Methyl 2-methylphenyl disulfide	1935	N	No safety concern
<i>Subgroup ix: Trisulfides</i>			
Structural class I			
Diisoamyl trisulfide	1934	N	No safety concern
<i>Subgroup xi: Thioesters</i>			
Structural class I			
Methyl isobutanethioate	1937	N	No safety concern

^a N, new specifications.

C. Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
Hydroxyacetone	1945	N	No safety concern
Propyl pyruvate	1946	N	No safety concern
Methyl 3-hydroxybutyrate	1947	N	No safety concern
Dodecyl lactate	1948	N	No safety concern
(±)-Ethyl 3-hydroxy-2-methylbutyrate	1949	N	No safety concern
Hexadecyl lactate	1950	N	No safety concern
Methyl 3-acetoxy-2-methylbutyrate	1951	N	No safety concern
1-Hydroxy-4-methyl-2-pentanone	1952	N	No safety concern
Ethyl 2-acetylhexanoate	1953	N	No safety concern
3-Isopropenyl-6-oxoheptanoic acid	1954	N	No safety concern
Ethyl 3-hydroxyoctanoate	1955	N	No safety concern
Methyl 3-acetoxyoctanoate	1956	N	No safety concern
5-Oxooctanoic acid	1957	N	No safety concern
Ethyl 2-acetyloctanoate	1958	N	No safety concern
Ethyl 5-acetoxyoctanoate	1959	N	No safety concern
5-Oxodecanoic acid	1960	N	No safety concern
Ethyl 5-oxodecanoate	1961	N	No safety concern
Ethyl 5-hydroxydecanoate	1962	N	No safety concern
5-Oxododecanoic acid	1963	N	No safety concern
Dimethyl adipate	1964	N	No safety concern
Dipropyl adipate	1965	N	No safety concern
Diisopropyl adipate	1966	N	No safety concern
Diisobutyl adipate	1967	N	No safety concern
Dioctyl adipate	1968	N	No safety concern
Methyl levulinate	1970	N	No safety concern
Propyl levulinate	1971	N	No safety concern
Isoamyl levulinate	1972	N	No safety concern
<i>cis</i> -3-Hexenyl acetoacetate	1974	N	No safety concern
Propyleneglycol diacetate	1976	N	No safety concern
Mixture of 6-(5-decenoyloxy)decanoic acid and 6-(6-decenoyloxy)decanoic acid	1977	N	No safety concern
Propyleneglycol dipropionate	1978	N	No safety concern
Propyleneglycol monobutyrate (mixture of isomers)	1979	N	No safety concern
Propyleneglycol dibutyrate	1980	N	No safety concern
Propyleneglycol mono-2-methylbutyrate (mixture of isomers)	1981	N	No safety concern
Propyleneglycol di-2-methylbutyrate	1982	N	No safety concern
Propyleneglycol monohexanoate (mixture of isomers)	1983	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Propyleneglycol dihexanoate	1984	N	No safety concern
Propyleneglycol dioctanoate	1985	N	No safety concern
2-Oxo-3-ethyl-4-butanolide	1986	N	No safety concern
Ethyl 5-hydroxyoctanoate	1987	N	No safety concern
Structural class III			
Ethyl acetoacetate ethyleneglycol ketal	1969	N	No safety concern
Ethyl levulinate propyleneglycol ketal	1973	N	Additional data required to complete evaluation
Hydroxycitronellal propyleneglycol acetal	1975	N	No safety concern
Mixture of isopropylidenglyceryl 5-hydroxyoctanoate and δ -decalactone	1988	N	Additional data required to complete evaluation

^a N, new specifications.

D. Aliphatic lactones

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class II			
5-Pentyl-3H-furan-2-one	1989	N	No safety concern
5-Hydroxy-4-methylhexanoic acid δ -lactone	1990	N	No safety concern
Isoambrettolide	1991	N	No safety concern
7-Decen-4-olide	1992	N	No safety concern
9-Decen-5-olide	1993	N	No safety concern
8-Decen-5-olide	1994	N	No safety concern
Orin lactone	1995	N	No safety concern
9-Dodecen-5-olide	1996	N	No safety concern
9-Tetradecen-5-olide	1997	N	No safety concern
γ -Octadecalactone	1998	N	No safety concern
δ -Octadecalactone	1999	N	No safety concern
Structural class III			
4-Hydroxy-2-butenic acid γ -lactone	2000	N	No safety concern
2-Nonenoic acid γ -lactone	2001	N	No safety concern
4-Hydroxy-2,3-dimethyl-2,4-nonadienoic acid γ -lactone	2002	N	No safety concern

^a N, new specifications.

E. Aliphatic and aromatic amines and amides

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
Choline chloride	2003	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
3-(Methylthio)propylamine	2004	N	No safety concern
Structural class III			
<i>N</i> -Ethyl-2,2-diisopropylbutanamide	2005	N	Additional data required to complete evaluation
Cyclopropanecarboxylic acid (2-isopropyl-5-methyl-cyclohexyl)-amide	2006	N	No safety concern
(±)- <i>N</i> -Lactoyl tyramine	2007	N	Additional data required to complete evaluation
<i>N</i> -(2-(Pyridin-2-yl)ethyl)-3- <i>p</i> -menthanecarboxamide	2008	N	No safety concern
<i>N-p</i> -Benzeneacetonitrile menthanecarboxamide	2009	N	No safety concern
<i>N</i> -(2-Hydroxyethyl)-2,3-dimethyl-2-isopropylbutanamide	2010	N	Additional data required to complete evaluation
<i>N</i> -(1,1-Dimethyl-2-hydroxyethyl)-2,2-diethylbutanamide	2011	N	Additional data required to complete evaluation

^a N, new specifications.

F. Phenol and phenol derivatives

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
4-Propenylphenol	2012	N	No safety concern
2,4,6-Trimethylphenol	2013	N	No safety concern
Sodium 3-methoxy-4-hydroxycinnamate	2014	N	No safety concern
Guaicol butyrate	2015	N	No safety concern
Guaicol isobutyrate	2016	N	No safety concern
Guaicol propionate	2017	N	No safety concern
4-(2-Propenyl)phenyl-β-D-glucopyranoside	2018	N	No safety concern
Phenyl butyrate	2019	N	No safety concern
Hydroxy(4-hydroxy-3-methoxyphenyl)acetic acid	2020	N	No safety concern
Structural class II			
1-(4-Hydroxy-3-methoxyphenyl)-decan-3-one	2021	N	No safety concern
Structural class III			
3-(4-Hydroxy-phenyl)-1-(2,4,6-trihydroxy-phenyl)-propan-1-one	2022	N	No safety concern
Magnolol	2023	N	No safety concern
5,7-Dihydroxy-2-(3-hydroxy-4-methoxy-phenyl)-chroman-4-one	2024	N	No safety concern

^a N, new specifications.

G. Aliphatic acyclic and alicyclic terpenoid tertiary alcohols and structurally related substances

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
Dimethylbenzyl carbonyl crotonate	2025	N	No safety concern
Dimethylbenzyl carbonyl hexanoate	2026	N	No safety concern
Caryophyllene alcohol	2027	N	No safety concern
Cubebol	2028	N	No safety concern
(-)-Sclareol	2029	N	No safety concern
(+)-Cedrol	2030	N	No safety concern
α -Bisabolol	2031	N	No safety concern

^a N, new specifications.

H. Aliphatic acyclic and alicyclic α -diketones and related α -hydroxyketones

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class II			
3-Methyl-2,4-nonedione	2032	N	No safety concern
Mixture of 3-hydroxy-5-methyl-2-hexanone and 2-hydroxy-5-methyl-3-hexanone	2034	N	No safety concern
3-Hydroxy-2-octanone	2035	N	No safety concern
2,3-Octanedione	2036	N	No safety concern
4,5-Octanedione	2037	N	No safety concern
(\pm)-2-Hydroxypiperitone	2038	N	No safety concern
Structural class III			
Acetoin propyleneglycol ketal	2033	N	No safety concern
1,1'-(Tetrahydro-6a-hydroxy-2,3a,5-trimethylfuro[2,3-d]-1,3-dioxole-2,5-diyl)bis-ethanone	2039	N	No safety concern

^a N, new specifications.

I. Aromatic substituted secondary alcohols, ketones and related esters

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
4-Hydroxyacetophenone	2040	N	No safety concern
3-Hydroxy-4-phenylbutan-2-one	2041	N	No safety concern
2-Methoxyacetophenone	2042	N	No safety concern
2-Methylacetophenone	2044	N	No safety concern
2-Hydroxy-5-methylacetophenone	2045	N	No safety concern
Dihydrogalangal acetate	2046	N	Additional data required to complete evaluation
2,3,3-Trimethylindan-1-one	2047	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class III			
4-(3,4-Methylenedioxyphenyl)-2-butanone	2048	N	No safety concern

^a N, new specifications.

J. Alicyclic ketones, secondary alcohols and related esters

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
Cyclohexanone diethyl ketal	2051	N	No safety concern
3,3,5-Trimethylcyclohexyl acetate	2053	N	No safety concern
Structural class II			
2-(<i>trans</i> -2-Pentenyl)cyclopentanone	2049	N	No safety concern
2-Cyclopentylcyclopentanone	2050	N	No safety concern
2-Cyclohexenone	2052	N	No safety concern
2,6,6-Trimethyl-2-hydroxycyclohexanone	2054	N	No safety concern
Cyclotene propionate	2055	N	No safety concern
Cyclotene butyrate	2056	N	No safety concern
4-(2-Butenylidene)-3,5,5-trimethylcyclohex-2-en-1-one (mixture of isomers)	2057	N	No safety concern
4-Hydroxy-4-(3-hydroxy-1-butenyl)-3,5,5-trimethyl-2-cyclohexen-1-one	2058	N	No safety concern
Structural class III			
(-)-8,9-Dehydrotheaspiron	2059	N	No safety concern
(±)-2,6,10,10-Tetramethyl-1-oxaspiro[4.5]deca-2,6-dien-8-one	2060	N	No safety concern

^a N, new specifications.

K. Benzyl derivatives

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
Benzyl hexanoate	2061	N	No safety concern
<i>o</i> -Anisaldehyde	2062	N	No safety concern
Prenyl benzoate	2063	N	No safety concern
Benzyl levulinate	2064	N	No safety concern
4-Methylbenzyl alcohol	2065	N	No safety concern
Benzyl nonanoate	2066	N	No safety concern
Structural class II			
2-Ethylhexyl benzoate	2068	N	No safety concern
Structural class III			
4-Methylbenzaldehyde propyleneglycol acetal	2067	N	No safety concern

^a N, new specifications.

L. Aliphatic secondary alcohols, ketones and related esters and acetals

Flavouring agent	No.	Specifications ^a	Conclusion based on current estimated dietary exposure
Structural class I			
(±)-Octan-3-yl formate	2070	N	No safety concern
2-Pentyl 2-methylpentanoate	2072	N	No safety concern
3-Octyl butyrate	2073	N	No safety concern
Structural class II			
(R)-(-)-1-Octen-3-ol	2071	N	No safety concern
2-Decanone	2074	N	No safety concern
Structural class III			
6-Methyl-5-hepten-2-one propylene glycol acetal	2075	N	No safety concern
2-Nonanone propylene glycol acetal	2076	N	No safety concern

^a N, new specifications.

Flavouring agents considered for specifications only

No.	Flavouring agent	Specifications ^a
439	4-Carvomenthenol	R
952	5,6,7,8-Tetrahydroquinoxaline	R

^a R, revised specifications.

ANNEX 2: RECOMMENDATIONS AND FURTHER INFORMATION REQUIRED**Further information required or desired** **β -apo-8'-carotenal, β -apo-8'-carotenoic acid ethyl ester and β -carotene (synthetic)**

The revision of the specifications monographs of β -apo-8'-carotenal, β -apo-8'-carotenoic acid ethyl ester and β -carotene (synthetic) was deferred to a future meeting, pending submission of the data necessary for revision of purity tests for carotenoids and subsidiary colouring matter.

Sucrose monoesters of lauric, palmitic or stearic acid

A test method capable of distinguishing sucrose monoesters of lauric, palmitic or stearic acid from sucrose esters of fatty acids is needed. The tentative specifications for sucrose monoesters of lauric, palmitic or stearic acid will be withdrawn if the requested data are not received by the end of 2011.

Additional data required to complete the evaluation according to the Procedure for the Safety Evaluation of Flavouring Agents

Additional data are required to complete the toxicological evaluations of 13 flavouring agents (Nos 1914, 1931, 1939, 1941, 1943, 1944, 1973, 1988, 2005, 2007, 2010, 2011 and 2046).

HPLC methods for subsidiary dyes and isomers in food colours

The Committee noted the need for high-performance liquid chromatographic (HPLC) methods for the separation and quantification of subsidiary dyes and isomers in food colours to replace the paper chromatographic method in Volume 4 of the Combined Compendium of Food Additive Specifications (FAO, JECFA Monographs 1, 2006). To this end, producers of food colours, industries and organizations are encouraged to notify the FAO JECFA Secretariat of the availability of appropriate methods.

CORRIGENDA**COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS
FAO FOOD AND NUTRITION PAPER 52, Addendum 12, ROME, 2004.**

Page 93, Flavouring agent JECFA No. 1454: The name is corrected to **cis- and trans- Linalool oxide**, to correspond to the information in the report from the 63rd meeting of JECFA (WHO Technical Report Series No. 928, 2005, p. 108) and which was the substance that was evaluated. The Chemical Abstract Services (C.A.S.) number is corrected to 60047-17-8, and the C.A.S. numbers of the cis- and trans-form of linalool oxide are also given, 5989-33-3 and 34995-77-2, respectively. The synonyms are modified to read: Linalool oxide (furanoid form) and 2-Methyl-5-(1-hydroxy-1-methylethyl)-2-vinyltetrahydrofuran.

**COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS
FAO JECFA MONOGRAPHS 7, ROME, 2009.**

Page 47, In the revised specifications for Modified starches, the heading of Table 1 had been omitted in this revision and is reinserted above the subheadings Modification, Process limitations and End-product specifications.

FAO TECHNICAL PAPERS

FAO JECFA MONOGRAPHS

- 1 Combined compendium of food additive specifications – JECFA specifications monographs from the 1st to the 65th meeting. (E)
Vol. 1 Food additives A – D
Vol. 2 Food additives E – O
Vol. 3 Food additives P – Z
Vol. 4 Analytical methods, test procedures and laboratory solutions
- 2 Residue evaluation of certain veterinary drugs - Joint FAO/WHO Expert Committee on Food Additives 66th meeting 2006 (E)
- 3 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 67th meeting 2006 (E)
- 4 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 68th meeting 2007 (E)
- 5 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 69th meeting 2008 (E)
- 6 Residue evaluation of certain veterinary drugs - Joint FAO/WHO Expert Committee on Food Additives 70th meeting 2008 (E)
- 7 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 71st meeting 2006 (E)
- 8 Safety evaluation of certain contaminants in food - Joint FAO/WHO Expert Committee on Food Additives 72nd meeting 2010 (E)
Joint FAO/WHO publication WHO Food Additives Series No. 63/ FAO JECFA Monographs 8, in preparation.
- 9 Residue evaluation of certain vweterinary drugs
RESIDUE EVALUATION
Joint FAO/WHO Expert Committee on Food Additives Meeting 2010 – Evaluation of data on ractopamine residues in pig tissues (E)

Availability: 2010

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COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS

Joint FAO/WHO Expert Committee on Food Additives

73rd meeting 2010

This document contains food additive specifications monographs, analytical methods and other information, prepared at the seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which was held in Geneva, Switzerland, from 8 to 17 June 2010. The specifications monographs provide information on the identity and purity of food additives used directly in foods or in food production. The main three objectives of these specifications are to identify the food additive that has been subjected to testing for safety, to ensure that the additive is of the quality required for use in food or in processing, and to reflect and encourage good manufacturing practice. This publication and other documents produced by JECFA contain information that is useful to all those who work with or are interested in food additives and their safe use in food.

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ISBN 978-92-5-106662-1 ISSN 1817-7077



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I1782E/1/09.10