Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Seventy-third meeting
Geneva, 8–17 June 2010

SUMMARY AND CONCLUSIONS

Issued 24 June 2010

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Geneva, Switzerland, from 8 to 17 June 2010. The purpose of the meeting was to evaluate certain food additives and contaminants.

Dr A. Mattia, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, served as Chairperson, and Mrs I. Meyland, National Food Institute, Technical University of Denmark, served as Vice-Chairperson.

Dr A. Wennberg, Nutrition and Consumer Protection Division, Food and Agriculture Organization of the United Nations, and Dr A. Tritscher, Department of Food Safety and Zoonoses, World Health Organization, served as Joint Secretaries.

The present meeting was the seventy-third in a series of similar meetings. The tasks before the Committee were (a) to elaborate principles governing the evaluation of food additives and contaminants, (b) to evaluate certain food additives and contaminants and (c) to review and prepare specifications for selected food additives.

The report of the meeting will be published in the WHO Technical Report Series. Its presentation will be similar to that of previous reports—namely, general considerations, comments on specific substances, and recommendations for future work. An annex will include detailed tables (similar to the tables in this report) summarizing the main conclusions of the Committee in terms of acceptable or tolerable daily intakes and other toxicological and safety recommendations. Information on the specifications for the identity and purity of certain food additives examined by the Committee will also be included.

The participants in the meeting are listed in Annex 1. Further information required or desired and future work for the Committee are listed in Annex 2. Items of a general nature that the Committee would like to disseminate quickly are included in Annex 3.

Toxicological and dietary exposure monographs on most of the substances that were considered will be published in WHO Food Additives Series No. 64. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs 10.

More information on the work of JECFA is available at:

http://www.fao.org/ag/agn/agns/jecfa_index_en.asp
and
http://www.who.int/ipcs/food/jecfa/en/index.html

Toxicological information 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 Agents[1]

A. Alicyclic primary alcohols, aldehydes, acids and related esters

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
Structural class I			
cis-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
(±)-*cis*- and *trans*-1,2-Dihydroperillaldehyde	1902	N	No safety concern
d-Limonen-10-ol	1903	N	No safety concern
p-Menthan-7-ol	1904	N	No safety concern
p-Menth-1-en-9-ol	1905	N	No safety concern
1,3-*p*-Menthadien-7-al	1906	N	No safety concern
Structural class II			
Methyl dihydrojasmonate	1898	N	No safety concern
cis- and *trans*-2-Heptylcyclopropanecarboxylic acid	1907	N	No safety concern
(±)-*cis*- and *trans*-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
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**
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)-(2*Z*)-propenoate	1915	N	No safety concern
Ethyl 3-(methylthio)-(2*E*)-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

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
Subgroup iii: Cyclic sulfides			
Structural class II			
2-Oxothiolane	1923	N	No safety concern
Structural class III			
(±)-*cis*- and *trans*-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**
Subgroup iv: Simple thiols			
Structural class I			
Dodecanethiol	1924	N	No safety concern
Subgroup v: Thiols with oxidized side-chains			
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**
Subgroup vii: Simple disulfides			
Structural class I			
Diisoamyl disulfide	1930	N	No safety concern
Butyl propyl disulfide	1932	N	No safety concern
di-*sec*-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
Subgroup ix: Trisulfides			
Structural class I			
Diisoamyl trisulfide	1934	N	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
Subgroup xi: Thioesters			
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
cis-3-Hexenyl acetoacetate	1974	N	No safety concern
Propyleneglycol diacetate	1976	N	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
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
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 isopropylideneglyceryl 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

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
Structural class III			
4-Hydroxy-2-butenoic 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
3-(Methylthio)propylamine	2004	N	No safety concern
Structural class III			
N-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
(±)-*N*-Lactoyl tyramine	2007	N	**Additional data required to complete evaluation**
N-(2-(Pyridin-2-yl)ethyl)-3-*p*-menthanecarboxamide	2008	N	No safety concern
N-*p*-Benzeneacetonitrile menthanecarboxamide	2009	N	No safety concern
N-(2-Hydroxyethyl)-2,3-dimethyl-2-isopropylbutanamide	2010	N	**Additional data required to complete evaluation**
N-(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

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
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 carbinyl crotonate	2025	N	No safety concern
Dimethylbenzyl carbinyl 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
(±)-2-Hydroxypiperitone	2038	N	No safety concern

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
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
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-(*trans*-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

Flavouring agent	No.	Specifications[a]	Conclusion based on current estimated dietary exposure
Structural class III			
(−)-8,9-Dehydrotheaspirone	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
o-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.

Contaminants evaluated toxicologically

Cadmium

Since cadmium was last considered by the Committee, there have been a number of new epidemiological studies that have reported cadmium-related biomarkers in urine following environmental exposure. The Committee noted that a large meta-analysis of studies that measured the dose–response relationship between the excretion of β_2-microglobulin and cadmium in urine was available. As the apparent half-life of cadmium in human kidneys is about 15 years, steady state would be achieved after 45–60 years of exposure. Therefore, data relating β_2-microglobulin excretion in urine to cadmium excretion in urine for individuals who are 50 years of age and older provided the most reliable basis on which to determine a critical concentration of cadmium in the urine. An analysis of the group mean data from individuals who were 50 years of age and older showed that the urinary excretion of less than 5.24 (confidence interval 4.94–5.57) µg of cadmium per gram creatinine was not associated with an increased excretion of β_2-microglobulin. Higher urinary cadmium levels were associated with a steep increase in β_2-microglobulin excretion.

To determine a corresponding dietary exposure that would result in a urinary cadmium concentration at the breakpoint of 5.24 (confidence interval 4.94–5.57) µg of cadmium per gram creatinine, a one-compartment toxicokinetic model was used. The lower bound of the 5th percentile dietary cadmium exposure (on a population level) that equates to the breakpoint was estimated to be 0.8 µg/kg body weight per day or 25 µg/kg body weight per month.

The Committee noted that the existing health-based guidance value for cadmium was expressed on a weekly basis (provisional tolerable weekly intake, or PTWI), but, owing to cadmium's exceptionally long half-life, considered that a monthly value was more appropriate. **The Committee therefore withdrew the PTWI of 7 µg/kg body weight.**

In view of the long half-life of cadmium, daily ingestion in food has a small or even a negligible effect on overall exposure. In order to assess long- or short-term risks to health due to cadmium exposure, dietary intake should be assessed over months, and tolerable intake should be assessed over a period of at least 1 month. To encourage this view, the Committee decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI). **The Committee established a PTMI of 25 µg/kg body weight.**

The estimates of exposure to cadmium through the diet for all age groups, including consumers with high exposure and subgroups with special dietary habits (e.g. vegetarians), examined by the Committee at this meeting are below the PTMI.

Lead

Exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. For children, the weight of evidence is greatest, and evidence across studies is most consistent, for an association of blood lead levels with impaired neurodevelopment, specifically reduction of intelligence quotient (IQ). Moreover, this effect has generally been associated with lower blood lead concentrations than those associated with the effects observed in other organ systems. For adults, the adverse effect associated with lowest blood lead concentrations for which the weight of evidence is greatest and most consistent is a lead-associated increase in systolic blood pressure. Therefore, the Committee concluded that the effects on neurodevelopment and increase in systolic blood pressure provided the appropriate bases for dose–response analyses.

Based on the dose–response analyses, the Committee estimated that the previously established PTWI of 25 µg/kg body weight is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. While such effects may be insignificant at the individual level, these changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population. **The Committee therefore concluded that the PTWI could no longer be considered health protective and withdrew it.**

Furthermore, as the dose–response analyses do not provide any indication of a threshold for the key adverse effects of lead, the Committee concluded that it was not possible to establish a new PTWI that would be health protective. The dose–response analyses conducted by the Committee should be used as guidance to identify the magnitude of effect associated with identified levels of dietary lead exposure in different populations.

The mean dietary exposure estimates of children aged about 1–4 years range from 0.03 to 9 µg/kg body weight per day. The health impact at the lower end of this range (0.03 µg/kg body weight per day) is considered negligible by the Committee, because it is below the exposure level of 0.3 µg/kg body weight per day calculated to be associated with a population decrease of 0.5 IQ points. The higher end of the exposure range (9 µg/kg body weight per day) is higher than the level of 1.9 µg/kg body weight per day calculated to be associated with a population decrease of 3 IQ points, which is deemed by the Committee to be of concern. For adults, the mean dietary lead exposure estimates range from 0.02 to 3.0 µg/kg body weight per day. The lower end of this range (0.02 µg/kg body weight per day) was considerably below the exposure level of 1.2 µg/kg body weight per day, calculated by the Committee to be associated with a population increase in systolic blood pressure of 1 mmHg (0.1 kPa). The Committee considered that any health risk that would be expected to occur at this exposure level is negligible. At the higher end of the range (3.0 µg/kg body weight per day), a population increase of approximately 2 mmHg (0.3 kPa) in systolic blood pressure would be expected to occur. In a large meta-analysis, an increase of this magnitude has been associated with modest increases in the risks of ischaemic heart disease and cerebrovascular stroke. The Committee considered this to be of some concern, but less so than that for the neurodevelopmental effects observed in children.

The Committee stressed that these estimates are based on dietary exposure (mainly food) and that other sources of exposure to lead also need to be considered.

The Committee concluded that, in populations with prolonged dietary exposures to lead that are in the higher end of the ranges identified above, measures should be taken to identify major contributing sources, including foods, and to identify methods of reducing dietary exposure, if appropriate.

Annex 1

Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives

Geneva, 8–17 June 2010

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Annex 2

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.

Annex 3

General considerations

An edited version of this section will appear in the report of the seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It is reproduced here so that the information can be disseminated quickly. This draft will be subject to editing.

Further consideration of combined intakes of flavouring agents

At the sixty-eighth meeting, the Committee decided that the safety assessment of possible combined intakes of flavouring agents should be based on the combined exposure to a common metabolite (on a molecular weight basis) or to a homologous series. For each common metabolite or homologous series, the intake estimates for about four or five flavouring agents with the highest intakes are summed. Following the introduction of the single portion exposure technique (SPET) for dietary exposure assessment of flavouring agents, the Committee concluded at the sixty-ninth meeting that the maximized survey-derived intake (MSDI) values should be used for calculating the combined intake.

The calculated combined intake is compared with the threshold of concern for the structural class of the common metabolite or the highest structural class relevant to the homologous series. When considering the combined intake for additional flavouring agents evaluated at the present meeting, the Committee recognized the amount of work required to develop data on combined intake and recommended that screening assessments should be used to determine whether such data are necessary. The Committee recommends that the following screening assessments should be used:

1. Many of the MSDIs for additional groups of flavouring agents are very low. Evaluation of combined intake is not necessary if the highest MSDI value in the additional group is <20 µg/day, because the combined intake for the highest four or five intakes would not exceed the lowest threshold of concern (90 µg/day for class III).
2. When an additional group contains compounds with low MSDIs compared with flavouring agents in the same group evaluated previously, consideration of combined intake is not necessary because it can be concluded that the additional flavouring agents would not contribute significantly to the combined intake of the flavouring group.
3. If the highest MSDI value in an additional group of flavouring agents is >20 µg/day, then identification of a common metabolite or homologous series should be undertaken, but calculation of the combined intake would not be necessary if the highest MSDI is <20% of the relevant threshold of concern, because the combined intake for the highest four or five intakes would not exceed the relevant threshold of concern.