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JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Ninety-sixth meeting (Safety evaluation of certain food additives)
27 June–6 July 2023

SUMMARY AND CONCLUSIONS

Issued on 14 July 2023

The Ninety-sixth meeting of the Joint FAO/WHO Executive Committee on Food Additives was held in Geneva from 27 June to 6 July 2023. The purpose of the meeting was to evaluate the safety of certain food additives and flavourings. The present meeting was the Ninety-sixth in a series of similar meetings. The tasks before the Committee were to (a) further elaborate principles governing the evaluation of food additives; (b) undertake safety evaluations of certain food additives; (c) review and prepare specifications for certain food additives; and (d) establish specifications for certain flavouring agents.

Dr D. Benford served as Chairperson and Dr R. Cantrill served as Vice-chairperson.

The Committee evaluated the safety of one food additive, revised the specifications for three food additives, evaluated the safety of two groups of flavouring agents and revised the specifications for eight flavouring agents.

The report of the meeting will be published in the WHO Technical Report Series (No. 1050). The report will summarize the main conclusions of the Committee in terms of acceptable daily intakes (ADIs) and other toxicological, dietary exposure and safety recommendations. Information on deliberations and conclusions with regards to the specifications for the identity and purity of certain food additives examined by the Committee and on specifications for the flavouring agents will also be included.

The participants are listed in Annex 1. Future work and recommendations arising from the summary report of the Ninety-sixth JECFA meeting are summarized in Annex 2. Finally, Annex 3 includes requests for corrections that were reported to the JECFA Secretariat, evaluated by the Committee and found to be necessary (note that these corrections will only be made in the electronic versions available in the online database).

Toxicological monographs summarizing the data that were considered by the Committee in establishing ADIs will be published in WHO Food Additives Series No. 87. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs No. 31.

More information on the work of JECFA is available at: <http://www.fao.org/food-safety/scientific-advice/jecfa/en/> and <https://www.who.int/foodsafety/en/>.

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Toxicological and dietary exposure information and conclusions

Food additive evaluated toxicologically, assessed for dietary exposure and specifications revised

Aspartame

At its twenty-fifth meeting, the Committee established an ADI of 0–40 mg/kg bodyweight (bw) for aspartame (1). This ADI was based on the no-observed-adverse-effect limit (NOAEL) of 4000 mg/kg bw per day, the highest dose tested, in a 104-week study in rats exposed to aspartame in the diet reported by Ishii et al. (2), and the application of a 100-fold uncertainty factor. At the present meeting, the Committee evaluated biochemical, toxicological and epidemiological studies on aspartame, its metabolites and degradation products that had become available since the previous Committee's evaluation. The Committee also assessed estimates of dietary exposure to aspartame for the first time.

Following oral exposure, aspartame is fully hydrolysed in the gastrointestinal tract of humans and animals into three metabolites: phenylalanine, aspartic acid and methanol. The Committee therefore reaffirmed that there is no systemic exposure to aspartame after dietary exposure. Phenylalanine, aspartic acid and methanol are also released from commonly consumed foods by enzymatically catalysed hydrolysis. After the pre-systemic hydrolysis of aspartame, these substances enter the systemic circulation at levels lower than those derived from consumption of common foods. The Committee noted that in oral aspartame exposure studies in humans at doses up to the current ADI, there were no increases in the plasma concentrations of the metabolites of aspartame.

The Committee concluded that there was no concern for genotoxicity of oral exposure to aspartame.

The Committee evaluated data from twelve oral carcinogenicity studies of aspartame and identified deficiencies with all of them. The Committee noted that all the studies apart from those by Soffritti et al. (3–6) showed negative results. The Committee considered the positive findings of Soffritti and colleagues, noting that there were limitations in the study design, execution, reporting and interpretation of these studies. In particular, this was because of the use of a test protocol in which most animals were allowed to reach natural death. As a result, the interpretation of these studies was complicated by the known increases in cancer occurrence with ageing. The Committee reached the view that the results of the Soffritti et al. studies are of uncertain relevance and therefore cannot be used for the risk assessment of aspartame. The Committee concluded that the carcinogenicity study by Ishii et al. (2) was close to meeting the current testing guidelines and showed negative results. The Committee reviewed several recently published studies that investigated possible mechanisms that may be relevant to the induction of cancer, including oxidative stress. The studies that reported changes in markers of oxidative stress had limitations in their design. The Committee noted that histopathological changes that would be expected from prolonged oxidative stress were not observed in other short- and long-term toxicity studies of aspartame.

Based on the negative results of the Ishii et al. study as well as the other negative carcinogenicity studies, no concern of genotoxicity, and a lack of a plausible mechanism by which oral exposure to aspartame could induce cancer, the Committee concluded that there was no concern for carcinogenicity in animals from oral exposure to aspartame.

The NOAEL in one- or two-generation reproductive and developmental toxicity studies in rats was 4000 mg/kg bw per day, the highest dose tested. The NOAEL for developmental toxicity in mice was 5700 mg/kg bw per day, the highest dose tested. The Committee therefore concluded that aspartame was not a reproductive or developmental toxicant in animals.

The Committee evaluated data from randomized controlled trials (RCTs) and epidemiological studies to examine the association between aspartame consumption and certain health effects, such as cancer, type 2 diabetes (T2D) and other non-cancer health end-points in humans.

The Committee noted that statistically significant increases were reported for some cancers, such as hepatocellular, breast and haematological (non-Hodgkin lymphoma and multiple myeloma) cancers, in some cohort studies conducted with aspartame or beverages containing aspartame as an intense sweetener. However, a consistent association between aspartame consumption and a specific cancer type was not observed. All studies have limitations with respect to their assessment of exposure and, in many studies, particularly with respect to aspartame versus intense sweeteners in general. Reverse causality, chance, bias and confounding by socioeconomic or lifestyle factors, or consumption of other dietary components cannot be ruled out. Overall, the Committee concluded that the evidence of an association between aspartame consumption and cancer in humans is not convincing.

Several studies assessing the effects of aspartame consumption on T2D and other non-cancer health end-points in humans showed inconsistent results. For example, RCTs showed reduced glycaemic responses after aspartame consumption, whereas in epidemiological studies aspartame consumption was associated with a greater T2D risk. The Committee noted that the results of the epidemiological studies may be biased by how T2D cases were identified (either specific medications and self-reported physician diagnosis). The Committee therefore concluded that the evidence of an association between aspartame consumption and the evaluated non-cancer health end-points is not convincing.

Overall, the Committee concluded that there was no convincing evidence from experimental animal or human data that aspartame has adverse effects after ingestion. This conclusion is underpinned by the information that aspartame is fully hydrolysed in the gastrointestinal tract into metabolites that are identical to those absorbed after consumption of common foods, and that no aspartame enters the systemic circulation. The Committee concluded that the data evaluated at the present meeting indicated no reason to change the previously established ADI of 0–40 mg/kg bw for aspartame. The Committee therefore reaffirmed the ADI of 0–40 mg/kg bw for aspartame at the present meeting.

The Committee determined that dietary exposure estimates to aspartame at the mean of up to 10 mg/kg bw per day for children and 5 mg/kg bw per day for adults, and for high dietary exposures up to 20 mg/kg bw per day for children and 12 mg/kg bw per day for adults, were appropriate for the present assessment.

The Committee noted that these dietary exposure estimates do not exceed the ADI. The Committee therefore concluded that dietary exposure to aspartame does not pose a health concern.

After review of the data submitted, the Committee made the following modifications to the specifications monograph for aspartame that was previously revised at the Eighty-second meeting (7): updated the description to include details on manufacturing; added flavour enhancer to the functional uses; replaced the method of assay with a high-performance liquid chromatography method; added a test and specification for “other related impurities”; and removed the test and specification for “other optical isomers”.

An addendum to the toxicology and dietary exposure monograph was prepared. The specifications were revised.

Aspartame references

1. Evaluation of certain food additives (Twenty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). Geneva: World Health Organization; 1981. WHO Technical Report Series, No. 669.
2. Ishii H, Koshimizu T, Usami S, Fujimoto T. Toxicity of aspartame and its diketopiperazine for Wistar rats by dietary administration for 104 weeks. *Toxicology*. 1981;21(2):91–4. doi:10.1016/0300-483x(81)90119-0
3. Soffritti M, Belpoggi F, Degli Esposti D, Lambertini L. Aspartame induces lymphomas and leukaemias in rats. *Eur J Oncol*. 2005;10:107–16.
4. Soffritti M, Belpoggi F, Degli Esposti D, Lambertini L, Tibaldi E, Rigano A. First experimental demonstration of the multipotential carcinogenic effects of aspartame administered in the feed to Sprague-Dawley rats. *Environ Health Perspect*. 2006;114:379–85. doi:10.1289/ehp.8711
5. Soffritti M, Belpoggi F, Tibaldi E, Esposti DD, Lauriola M. Life-span exposure to low doses of aspartame beginning during prenatal life increases cancer effects in rats. *Environ Health Perspect*. 2007;115:1293–7. doi:10.1289/ehp.10271
6. Soffritti M, Belpoggi F, Manservigi M, Tibaldi E, Lauriola M, Falcioni L, Bua L. Aspartame administered in feed, beginning prenatally through life span, induces cancers of the liver and lung in male Swiss mice. *Am J Ind Med*. 2010;53:1197–206. doi:10.1002/ajim.20896
7. Safety evaluation of certain food additives. Geneva: World Health Organization; 2017. WHO Food Additives Series, No. 73.

Food additives considered for specifications only

Food additive	Specification	Details
Lycopene (synthetic); and lycopene from <i>Blakeslea trispora</i>	R	Upon request from the CCFA, the Committee revised the specifications for lycopene (synthetic) (INS 160d(ii)) and lycopene from <i>Blakeslea trispora</i> (INS 160d(iii)) by replacing “freely soluble in chloroform” with “sparingly soluble in tetrahydrofuran (THF)” in the solubility test, and replacing the “solution in chloroform” test with a “solution in THF” test requirement.
Pentasodium triphosphate	R	At the request of the CCFA, the Committee revised the specifications for pentasodium triphosphate (INS 451(i)) by revising: the assay value for P ₂ O ₅ to not less than 56% and not more than 59% of P ₂ O ₅ ; the pH value to 9.1–10.2 (1% solution); and the level of lead from 4 mg/kg to not more than 2 mg/kg.
Steviol glycosides	R	The Committee was requested to change the list of non-toxicogenic nonpathogenic strains used to facilitate the transfer of glucose to steviol glycosides to: <i>Anoxybacillus caldiproteoliticus</i> , <i>Bacillus licheniformis</i> and <i>Bacillus subtilis</i> in Annex 4: Enzyme Modified Glucosylated Steviol Glycosides of the Ninety-fifth JECFA meeting report. The following text was also added: “The production strain of the enzyme used to facilitate the transfer of glucose to steviol glycosides was incorrectly identified as <i>Bacillus stearothermophilus</i> . The revised identification is <i>Anoxybacillus caldiproteoliticus</i> .”

CCFA: Codex Committee on Food Additives; R: revised specification.

Flavouring agents evaluated by the revised Procedure for the Safety of Evaluation of Flavouring Agents

A. Esters of aliphatic acyclic primary alcohols with branched-chain aliphatic acyclic acids

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
4-Methylpentyl 4-methylvalerate	2280	N	No safety concern
5-Methylhexyl acetate	2281	N	No safety concern
4-Methylpentyl isovalerate	2282	N	No safety concern
Ethyl 4-methylpentanoate	2283	N	No safety concern
Ethyl 2-ethylbutyrate	2284	N	No safety concern
Ethyl 2-ethylhexanoate	2285	N	No safety concern

N: new specifications.

B. Hydroxy- and alkoxy-substituted benzyl derivatives

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
2-Ethoxy-4-(hydroxymethyl)phenol	2271	N	No safety concern
2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate	2272	N	No safety concern
3-Phenylpropyl 2-(4-hydroxy-3-methoxyphenyl)acetate	2273	N	No safety concern
Ethyl-2-(4-hydroxy-3-methoxyphenyl)acetate	2274	N	No safety concern
cis-3-Hexenyl salicylate	2275	N	No safety concern
4-Formyl-2-methoxyphenyl 2-hydroxypropanoate	2276	N	No safety concern
2-Hydroxy-4-methoxybenzaldehyde	2277	N	No safety concern

3,4-Dihydroxybenzoic acid	2278	N	No safety concern
3-Hydroxybenzoic acid	2279	N	No safety concern

N: new specifications.

Favouring agents considered for specifications only

Food additive	No.	Specification
(E)-2-hexenal diethyl acetal	1383	R
3-Butylidenephthalide	1170	R
1,4-Cineole	1233	R
Octahydrocoumarin	1166	R
3-(/i-Methoxy)-2-Methylpropane-1,2-diol	1411	R
<i>p</i> -Methane-3,8-diol	1416	R
<i>p</i> -Isopropylacetophenone	808	R
Acetanisole	810	R

R: revised specification.

Annex 1. List of participants

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Annex 2. Recommendations and future work

Withdrawal of specifications without full safety review

The Committee noted that several flavourings have full specifications but are not accompanied by a full safety evaluation. The Ninety-sixth Committee recommends the compilation of a list of such flavourings with a view to withdrawing their specifications.

Annex 3. Corrigenda

The Committee discussed the tentative errata. One request was for the amendment of the CAS number for the flavouring agent ethyl levulinate propyleneglycol ketal (No. 1973) for which specifications were prepared at the Seventy-third JECFA meeting, but a full safety evaluation was not completed. The Committee did not consider the request to revise the CAS number and instead withdrew the specifications for No. 1973 as information to allow the completion of the safety review of the flavouring agent has not been provided to the Committee in a timely manner. A recommendation for future work was made to compile a list of flavourings for which a full safety evaluation has not been completed with a view to withdraw such specifications.

The following requests for corrections, submitted to the CCFA, were evaluated at the Ninety-sixth meeting of JECFA and found to be necessary. Corrections will be made only in the online database for flavouring specifications.

Flavouring	Original text	Revised text	Additional information
S-Methyl hexanethioate (No. 489)	CAS No.: 20756-86-9 Chemical formula: $C_7H_{14}O_2S$ Molecular weight: 162.24	CAS No.: 2432-77-1 Chemical formula: $C_7H_{14}OS$ Molecular weight: 146.25	Correction to CAS number, chemical formula and molecular weight.
Isopulegol (No. 755)	CAS No.: 89-79-2	CAS No.: 7786-67-6 and CAS No.: 89-79-2	According to the specifications from the Fifty-fifth JECFA meeting, ^a No. 755 is a mixture of isomers. CAS No. 89-79-2 is specifically for the L isomer. CAS No. 7786-67-6 does not specify stereochemistry, and represents the mixture of isomers. Both CAS numbers will be included in the updated specification.
Farnesene (α and β) (No. 1343)	CAS No.: 502-61-4	CAS Nos: 502-61-4 (alpha); 18794-84-8 (beta); 688330-26-9 (mixture)	According to specifications from the Sixty-third JECFA meeting, ^b No. 1343 is a mixture of 3,7,11-trimethyldodeca-1,3,6,10-tetraene and 3-methylene-7,11-dimethyldodeca-1,6,10-triene. CAS No. 688330-26-9 is for a mixture of the two compounds. CAS No. 502-61-4 only represents 3,7,11-trimethyldodeca-1,3,6,10-tetraene. CAS No. 18794-84-8 represents 3-methylene-7,11-dimethyldodeca-1,6,10-triene. All three CAS numbers will be included in the updated specification.
1-Butanethiol (No. 511)	CAS No. 61122-71-2	CAS No. 109-79-5	Original CAS number is incorrect and not related to 1-butanethiol. The correct CAS number is 109-79-5.
8-Ocimenyl acetate (No. 1226)	Missing CAS number	CAS No. 197098-61-6	CAS number missing from specifications. Correct CAS number (197098-61-6) was originally included in table 4 of the report from the Sixty-first JECFA meeting. ^c
Methylthio 2-(propionyloxy) propionate (No. 493)	Missing CAS number	CAS No.: 827024-53-3	Added missing CAS number.
2, 3, or 10-Mercaptopinane (No. 520)	Missing CAS number	CAS Nos: 23832-18-0, 72361-41-2 and 6588-78-9	CAS No. 23832-18-0 corresponds to 2-mercaptopinane; CAS No. 72361-41-2 corresponds to 3-mercaptopinane; CAS No. 6588-78-9 corresponds to 10-mercaptopinane
Methyl 3-methyl-1-butenyl disulfide (No. 571)	Missing CAS number	CAS No.: 233666-09-6	Added missing CAS number.
Potassium 2-(1'-ethoxy) ethoxypropanoate (No. 933)	Missing CAS number Chemical formula: $C_7H_{13}O_4$	CAS No.: 100743-68-8 Chemical formula: $C_7H_{13}O_4K$	Added missing CAS number and revised formula to include potassium.
(-)-Menthol 1- and 2-propylene glycol carbonate (No. 444)	CAS No.: 156329-82-2	CAS No.:	The original CAS No. (156329-82-2) is no longer in the CAS registry. A proposal was made to JECFA to replace it with CAS No. 30304-82-6. However, CAS No. 30304-82-6 does not match the flavouring reviewed by JECFA.

Lactic acid (No. 930)	CAS No.: 598-82-3	CAS Nos: 10326-41-7, 79-33-4 and 50-21-5	The original CAS No. (598-82-3) is no longer valid. The following CAS numbers have been added: CAS No. 10326-41-7 for D-lactic acid; CAS No. 79-33-4 for L-lactic acid; CAS No. 50-21-5 for the mixture of isomers.
Allyl 10-undecenoate (No. 9)	CAS No.: 7439-76-7	CAS No.: 7493-76-7	Typographical error
Geranyl formate (No. 54)	CAS No.: 1005-86-2	CAS No.: 105-86-2	Typographical error
Allyl heptanoate (No. 4)	CAS No.: 142-91-8	CAS No.: 142-19-8	Typographical error
Allyl propionate (No. 1)	CAS No.: 2408-70-0	CAS No.: 2408-20-0	Typographical error
3-Hexenyl formate (<i>cis</i> and <i>trans</i> mixture) (No. 1272)	CAS No.: 151824	CAS Nos: 33467-73-1, 56922-80-6 and 2315-09-5	The original CAS number is no longer valid. The following CAS numbers were added: CAS No. 33467-73-1 for the <i>cis</i> isomer; CAS No. 56922-80-6 for the <i>trans</i> isomer; and CAS No. 2315-09-5, which is not specific to double bond geometry.
<i>trans</i> -3-Heptenyl acetate (No. 135)	CAS No.: 34942-91-1	CAS No.: 1576-77-8	The original CAS number is not specific to the double bond geometry. CAS number 1576-77-8 is specific for the <i>trans</i> isomer.
Methyl 4-methylvalerate (No. 216)	CAS No.: 2412-24-1	CAS No.: 2412-80-8	Typographical error
2,6-Dimethyloctanal (No. 273)	CAS No.: 1321-89-7 Synonyms: l isodecylaldehyde; isodecanal; 2,6-dimethyl octanoic aldehyde	CAS No.: 7779-07-9 Synonyms: 2,6- dimethyl octanoic aldehyde	Replacement of incorrect CAS number. Removal of two incorrect synonyms.
Menthone-8-thioacetate (No. 506)	Flavouring name: menthone-8- thioacetate CAS No.: 109-79-5	Flavouring name: menthone-8- thioacetate (<i>cis</i> - and <i>trans</i> -) CAS No.: 94293-57-9	Revision of name to match the flavouring evaluated at the Fifty-third JECFA meeting ^d and replacement of incorrect CAS number.

^a Evaluation of certain food additives and contaminants (Fifty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). Geneva: World Health Organization; 2001. WHO Technical Report Series, No. 901.

^b Evaluation of certain food additives (Sixty-third report of the Joint FAO/WHO Expert Committee on Food Additives). Geneva: World Health Organization; 2005. WHO Technical Report Series, No. 928.

^c Evaluation of certain food additives and contaminants (Sixty-first report of the Joint FAO/WHO Expert Committee on Food Additives). Geneva: World Health Organization; 2004. WHO Technical Report Series, No. 922.

^d Evaluation of certain food additives and contaminants (Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives). Geneva: World Health Organization; 2000. WHO Technical Report Series, No. 896.