CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3(b) **CX/FA 24/54/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-fourth Session

PROPOSED DRAFT SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 96TH AND 97TH JECFA MEETINGS RESPECTIVELY

Codex members and Observers wishing to submit comments at Step 3 on the proposed draft Specifications for the Identity and Purity of Food Additives arising from the 96th and 97th JECFA Meetings (Annexes 1 and 2) should do so as instructed in CL 2024/19/-FA available on the Codex webpage/Circular Letters 2024: http://www.codexalimentarius.org/circular-letters/en/.

BACKGROUND

A. Proposed draft specifications for identity and purity of food additives arising from the 96th and 97th JECFA meetings

1. At the 96th meeting held in Geneva, from 27 June to 6 July 2023:

2. Revised specifications were prepared for the following food additives: aspartame (INS 951), lycopene, synthetic (INS 160d(i)), lycopene from *Blakeslea trispora* (INS 160d(iii)), pentasodium triphosphate (INS 451(i)) and steviol glycosides.

3. Full specifications for two groups of flavouring agents were developed: esters of aliphatic acyclic primary alcohols with branched-chain aliphatic acyclic acids and hydroxy- and alkoxy-substituted benzyl derivatives.

4. Revised specifications were prepared for eight flavouring agents.

5. The specifications to be discussed and considered by CCFA54 for adoption are listed in Annex 1.

6. The specification monographs are available (in English only) on the JECFA Online Edition of: "Combined Compendium of Food Additive Specifications" https://www.fao.org/food-safety/resources/publications/en/ as FAO JECFA Monographs 31, 2023.

7. At the 97th meeting held in Rome from 31 October to 9 November 2023:

8. Revised specifications for the food additive titanium dioxide (INS 171) were prepared.

9. Full specifications for three groups of flavouring agents were developed:

- aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups
- linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters, and
- saturated aliphatic acyclic linear primary alcohols, aldehydes and acids.

10. The Committee discussed the importance of receiving data in support of the establishment of specifications for flavouring agents. For future meetings, data should be provided by the sponsor in support of any parameter for which a numerical value is specified.

11. The full specifications to be discussed and considered by CCFA54 for adoption are listed in Annex 1.

12. The specification monographs will be available (in English only) on the JECFA Online Edition of: "Combined Compendium of Food Additive Specifications" https://www.fao.org/food-safety/resources/publications/en/ as FAO JECFA Monographs 32, 2024.

RECOMMENDATIONS

13. CCFA54 is requested to review the specifications designated as “Full” for the food additives listed in Annex 1 with a view to recommending their adoption by CAC47 as Codex Specifications, taking into account comments received.

B. Other specifications for identity and purity of food additives resulting from the 96th and 97th JECFA meetings (for information only)

14. Requests for corrections, submitted to the CCFA, were evaluated at the ninety-sixth meeting of JECFA and found to be necessary (Annex 2). 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. Corrections will be made only in the online database for flavouring specifications.

15. Specifications were formulated at the 97th meeting for the following flavouring agents and were designated as *Tentative* due to their incomplete safety evaluation: (+/-) acetaldehyde ethyl isopropyl acetal (2303), 1,1-dipropoxyethane (2306) and paraldehyde (2299).

16. Requests for corrections reported to the JECFA Secretariat, were evaluated at the ninety-seventh JECFA meeting and found to be necessary (Annex 2). Corrections will be made only in the online database for specifications.

Annex 1

PROPOSED DRAFT SPECIFICATIONS RESULTING FROM THE 96TH AND 97TH JECFA MEETINGS

FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS FULL (FAO JECFA Monographs 31, 2023[1]):

Aspartame (INS 951) (R)
Lycopene, synthetic (INS 160d(i)); and lycopene from *Blakeslea trispora* (INS 160d(iii)) (R)
Pentasodium triphosphate (INS 451(i)) (R)
Steviol glycosides (R)

FOOD ADDITIVES SPECIFICATIONS DESIGNATED AS FULL (FAO JECFA Monographs 32, 2024[2]):

Titanium dioxide (INS 171) (R)

NEW SPECIFICATIONS DESIGNATED AS FULL FOR FLAVOURING AGENTS (FAO JECFA Monographs 31, 2023[2]):

Esters of aliphatic acyclic primary alcohols with branched-chain aliphatic acyclic acids
Structural class I

Flavouring agent	No.	Specifications
4-Methylpentyl 4-methylvalerate	2280	N
5-Methylhexyl acetate	2281	N
4-Methylpentyl isovalerate	2282	N
Ethyl 4-methylpentanoate	2283	N
Ethyl 2-ethylbutyrate	2284	N
Ethyl 2-ethylhexanoate	2285	N

Hydroxy- and alkoxy-substituted benzyl derivatives
Structural class I

Flavouring agent	No.	Specifications
2-Ethoxy-4-(hydroxymethyl)phenol	2271	N
2-Phenoxyethyl 2-(4-hydroxy-3-methoxyphenyl)acetate	2272	N
3-Phenylpropyl 2-(4-hydroxy-3-methoxyphenyl)acetate	2273	N
Ethyl-2-(4-hydroxy-3-methoxyphenyl)acetate	2274	N
cis-3-Hexenyl salicylate	2275	N
4-Formyl-2-methoxyphenyl 2-hydroxypropanoate	2276	N
2-Hydroxy-4-methoxybenzaldehyde	2277	N
3,4-Dihydroxybenzoic acid	2278	N
3-Hydroxybenzoic acid	2279	N

[1] (N) new specifications; (R) revised specifications.
[2] (N) new specifications; (R) revised specifications.

Flavouring agents considered for specifications only

Flavouring agent	No.	Specifications
(E)-2-hexenal diethyl acetal	1383	R
3-Butylidenephthalide	1170	R
1,4-Cineole	1233	R
Octahydrocoumarin	1166	R
3-(l-Methoxy)-2-Methylpropane-1,2-diol	1411	R
p-Methane-3,8-diol	1416	R
p-Isopropylacetophenone	808	R
Acetanisole	810	R

NEW SPECIFICATIONS DESIGNATED AS FULL FOR FLAVOURING AGENTS (FAO JECFA Monographs 32, 2024[2]):

Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups
Structural class I

Flavouring agent	No.	Specifications
(±)-6-Methoxy-2,6-dimethylheptanal	2308	N
Ethyl 5-formyloxydecanoate	2309	N
Mixture of ricinoleic acid, linoleic acid and oleic acid	2310	N
Ethyl 3-methyl-2-oxopentanoate	2311	N

Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters
Structural class I

Flavouring agent	No.	Specifications
(4Z,7Z)-Trideca-4,7-dienal	2286	N
cis-5-Dodecenyl acetate	2287	N
trans-5-Dodecenal	2288	N
cis-6-Dodecenal	2289	N
cis-9-Dodecenal	2290	N
(E)-3-Methyl-4-dodecenoic acid	2291	N
trans-5-Octenal	2292	N
trans-Tetradec-4-enal	2293	N
2,6-Dimethylheptenyl formate	2294	N
(Z)-9-Dodecenoic acid	2295	N
cis-Tridec-5-enal	2296	N
(Z)-8-Pentadecenal	2297	N

Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

Flavouring agent	No.	Specifications
Pentadecanoic acid	2300	N
Tridecanal	2301	N
Tridecanoic acid	2302	N
Acetaldehyde di-isobutyl acetal	2304	N
Acetaldehyde ethyl isobutyl acetal	2305	N

Annex 2

OTHER SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES RESULTING FROM THE 96TH and 97TH JECFA MEETINGS

(for information only)

SPECIFICATIONS DESIGNATED AS TENTATIVE (T) (FAO JECFA MONOGRAPHS 32, 2024)

Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

Flavouring agent	No.	Specifications
(+/-) Acetaldehyde ethyl isopropyl acetal (Safety evaluation not completed	2303	T
1,1-Dipropoxyethane (Safety evaluation not completed)	2306	T
Paraldehyde (Safety evaluation not completed)	2299	T

PUBLICATION OF AN ERRATA TO EXISTING SPECIFCIATIONS (FAO JECFA MONOGAPHS 31, 2023)

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, 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 (alpha and beta) (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, 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 (Annex 1, reference 166).
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,	CAS No. 23832-18-0 corresponds to 2-mercaptopinane; CAS No. 72361-41-2

		72361-41-2 and 6588-78-9	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 (*cis* and *trans* 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 *cis* isomer; CAS No. 56922-80-6 for the *trans* isomer; and CAS No. 2315-09-5, which is not specific to double bond geometry.
trans-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 *trans* 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: I 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 (*cis*- and *trans-)* CAS No.: 94293-57-9	Revision of name to match the flavouring evaluated at the Fifty-third JECFA meeting (Annex 1, reference 143) and replacement of incorrect CAS number.

PUBLICATION OF AN ERRATA TO EXISTING SPECIFCIATIONS (FAO JECFA MONOGAPHS 32, 2024)

Substance	Original text	Revised text	Additional information
Modified starches	Table on page 3 of specifications *(1)* Page 13 CAS numbers 601464-73-0 (Amylopectin, acetate) Page 22 Increase temperature to 250 °C at a rate of 14.5 °C/s. Hold at 250 °C for 1 min Page 22 Split/splitless injector settings Injector temperature: 250 °C Injection mode: splitless for 0.8 min	See revised table below CAS numbers 60164-73-0 (Amylopectin, acetate) Increase temperature to 250 °C at a rate of 14.5 °C/min, hold at 250 °C for 1 min Split/splitless injector settings Injector temperature: 250 °C Injection mode: splitless for 0.8 min Recommended liner of at least: 870 µL	Revised table is in alignment with specifications
Pullulan	Chemical formula: $(C_6H_{10}O_5)_x$ Characteristics: Mono-, di- and oligosaccharides Not more than 10% (expressed as glucose) Purity tests: Mono-, di- and oligosaccharides Procedure – Weigh accurately 0.8 g sample and dissolve in water to make 100 ml (stock solution). Method of assay: P(%) = 100 – (L+C) where L is loss on drying; and C is taken from the calculation for mono-, di- and oligosaccharides.	Chemical formula: $(C_{36}H_{60}O_{30})_n$ Characteristics: Mono-, di- and oligosaccharides Not more than 10% (expressed as glucose), on the dried basis Purity tests: Mono-, di- and oligosaccharides Procedure – Weigh accurately 0.8 g sample previously dried and dissolve in water to make 100 ml (stock solution). Method of assay: P(%) = [100 – C] where C is taken from the calculation for mono-, di- and oligosaccharides.	
Spirulina extract (INS 134)	Method of assay: Calculate the allophycocyanin content (percent, w/w) as follows: TaPC = [(0.180 x A620) – (0.042 x A650) x V1 x 100] / W1	Method of assay: Calculate the allophycocyanin content (percent, w/w) as follows: TaPC = [(0.180 x A650) – (0.042 x A620) x V1 x 100] / W1	

Modified starches *(1)*; revised table

Summary table							
GENERAL REQUIREMENTS							
IDENTIFICATION				**PURITY**			
Solubility	**Microscopy**	**Iodine Stain**	**Copper Reduction**	**Loss on Drying**	**Lead**	**Microbiological Criteria**	**Sulfur dioxide**
Insoluble in cold water, **if not pre-gelatinised.**	Granular structure typical of the starch source	Colour from dark blue to orange-red after addition of iodine TS	Red precipitate after addition of hot alkaline cupric tartrate to a test sample refluxed under acidic condition	Cereal starch ≤15.0%; Potato starch: ≤21.0%; Other starches: ≤18.0%	≤0.2mg/kg d.w. Pb (≤0.1 mg/kg) for starch sodium octenylsuccinate for infant formula	Aerobic Plate Count: ≤100,000 CFU/g; Yeasts and molds: ≤1,000 CFU/g; Total Coliforms: ≤100 CFU/g;	Modified cereal starches: ≤50 mg/kg d.w.; Other modified starches ≤10 mg/kg d.w.

SPECIFIC REQUIREMENTS			
Modified Starch	Annex	**IDENTIFICATION**	**PURITY**
Dextrin roasted starch (INS 1400)	1	Dispersion test	No additional
Acid treated starch (INS 1401)	1	Dispersion test	No additional
Alkaline treated starch (INS 1402)	1	Dispersion test	No additional
Bleached starch (INS 1403)	2	No additional	Carboxyl groups (≤0.1% d.w.); Residual oxidizing substances < 180 mg/kg calculated as H_2O_2
Oxidized starch (INS 1404)	5	Hypochlorite oxidized starch	Carboxyl groups (≤1.3% d.w.); Residual oxidizing substances < 180 mg/kg calculated as H_2O_2
Enzyme-treated starch (INS 1405)	1	Dispersion ~~index (Information Required); Reducing sugars (Information Required)~~ **test**	No additional
Monostarch phosphate (INS 1410)	3	Phosphate groups	Phosphate (≤0.5% d.w. for potato or wheat starches; ≤0.4% d.w for other starches)
Distarch phosphate (INS 1412)	3	Crosslinking	Phosphate (≤0.5% d.w. for potato or wheat starches; ≤0.4% d.w. for other starches)
Phosphated distarch phosphate (INS 1413)	3	Crosslinking	Phosphate (≤0.5% d.w. for potato or wheat starches; ≤0.4% d.w. for other starches)
Acetylated distarch phosphate (INS 1414)	3, 4	Acetyl group; Ester group; Crosslinking	Phosphate (≤0.14% d.w. for potato or wheat starches; ≤0.04% d.w. for other starches) Acetyl groups (≤2.5% d.w.); ~~Ester groups (≤0.5% d.w.)~~
Starch acetate (INS 1420)	4	Acetyl group; Ester group	Acetyl groups (≤2.5% d.w.); ~~Ester groups (≤0.5% d.w.)~~
Acetylated distarch adipate (INS 1422)	4, 8	Acetyl group; Ester group; Crosslinking	Acetyl groups (≤2.5% d.w.); Vinyl acetate (≤0.1 mg/kg); ~~Ester groups (≤0.5%d.w.)~~ Adipate groups (≤0.135% d.w.); Residual free adipic acid (≤0.025% d.w.)
Hydroxypropyl starch (INS 1440)	7	Hydroxypropyl ether groups	Hydroxypropyl groups (≤7.0% d.w.); Propylene chlorohydrins (≤1 mg/kg d.w.)
Hydroxypropyl distarch phosphate (INS 1442)	3, 7	Hydroxypropyl ether groups; Crosslinking	Phosphate (≤0.14% d.w. for potato or wheat starches; ≤0.04% d.w. for other starches) Hydroxypropyl groups (≤7.0% d.w.); Propylene chlorohydrins (≤1 mg/kg d.w.)
Starch sodium octenylsuccinate (INS 1450)	6	No additional	Octenylsuccinyl groups (≤3% d.w.); Residual free octenylsuccinic acid (≤0.3% d.w.);
Acetylated oxidized starch (INS 1451)	4, 5	Acetyl group	Acetyl groups (≤2.5% d.w.); Vinyl acetate (≤0.1 mg/kg); ~~Ester groups (≤0.5% d.w.)~~ Carboxyl groups (≤1.3% d.w.); Residual oxidizing substances < 180 mg/kg calculated as H_2O_2

Reference

1. Online edition. Modified starches Monograph 27; 2021 (https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/, accessed 15 November 2023).