



Food and Agriculture
Organization of the
United Nations



World Health
Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Eighty-ninth meeting (Safety evaluation of certain food additives)
Virtual meeting, 1–12 June 2020

SUMMARY AND CONCLUSIONS

Issued on 10 July 2020

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held on a virtual online platform, on 1–12 June 2020. The purpose of the meeting was to evaluate the safety of certain food additives and flavourings. The present meeting was the 89th in a series of similar meetings. The tasks before the Committee were (a) to further elaborate principles governing the evaluation of food additives, (b) to undertake safety evaluations of certain food additives, (c) to review and prepare specifications for certain food additives and (d) to establish specifications for certain flavouring agents.

The 89th meeting of JECFA was originally scheduled for 2–11 June 2020 at WHO headquarters in Geneva, Switzerland. Because of the travel restrictions and lock-downs due to the COVID-19 pandemic in many countries, the joint FAO/WHO JECFA secretariat was unable to convene the meeting as scheduled. Therefore, the meeting was held as a video-conference.

In view of the countries of origin of the invited experts, the only possible time for a video-conference was restricted to a 4-h time slot (12:00–16:00 CEST) a day. This allowed approximately 40% of the usual daily time (8–10 h) of a JECFA 8-day face-to-face meeting.

As under the circumstances less meeting time had been available, compared to a normal JECFA meeting, the food additives natamycin (INS 234), natamycin (INS 235), β -glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*, collagenase from *S. violaceoruber* expressed in *S. violaceoruber*, phosphodiesterase from *Penicillium citrinum* and phospholipase A2 from *S. violaceoruber* expressed in *S. violaceoruber*, which were originally scheduled for discussion, had therefore not been considered. Furthermore, it became quickly apparent early in the meeting that the experts of the 89th JECFA would not have been able to complete the evaluations for alicyclic ketones, secondary alcohols and related esters and a toxicological evaluation of riboflavin from *Ashbya gossypii*. Therefore, these two evaluations have also been deleted from the meeting agenda. All compounds that had been deleted from the agenda of the 89th JECFA will be re-scheduled for evaluation at future JECFA meetings. More details can be found in Annex 4.

Dr Antonia Mattia served as Chairperson and Professor Cantrill as Vice-Chairperson.

Mr Kim Petersen, World Health Organization (WHO), and Dr Markus Lipp, Food and Agriculture Organization of the United Nations (FAO), served as joint secretaries.

The Committee evaluated the safety of six food additives, conducted an exposure assessment for one group of food additives and revised the specifications for three other food additives (including one group). The Committee also evaluated the safety of two groups of flavouring agents and revised the specifications for 12 flavouring agents. Tentative specifications were prepared for three, as the safety evaluations were not completed.

The report of the meeting will be published in the WHO Technical Report Series. The report will summarize the main conclusions of the Committee in terms of acceptable daily intakes and other toxicological, dietary exposure and safety recommendations. Information on deliberations and conclusion with regard to the specifications for the identity and purity of certain food additives examined by the Committee and on the specifications for the flavouring agents will also be included.

The participants are listed in Annex 1. Information of a general nature that the Committee wishes to disseminate quickly is provided in Annex 2. Future work and recommendations arising from the meeting

are summarized in Annex 3. Annex 4 details the selection of compounds and observations by experts with regard to the feasibility of holding these expert meetings online rather than in-person.

Toxicological monographs summarizing the data that were considered by the Committee in establishing ADIs will be published in WHO Food Additives Series No. 80. Monographs summarizing the data that were considered by the Committee in recommending MRLs will be published in FAO JECFA Monographs No. 25.

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 information on specifications

Food additives evaluated toxicologically and assessed for dietary exposure

Food additive	Specifications	Acceptable daily intakes (ADIs) and other conclusions on toxicology and dietary exposure
Adenosine 5'-monophosphate deaminase from <i>Streptomyces murinus</i>	N	<p>Negative results were observed in genotoxicity tests, and a NOAEL of 500 mg/kg bw per day (equal to 69 mg TOS/kg bw per day) was identified in a 13-week oral toxicity study. Comparison of the dietary exposure estimate of 0.075 mg TOS/kg bw per day with the NOAEL of 69 mg TOS/kg bw per day gives a margin of exposure (MOE) of 920.</p> <p>The Committee concluded that the AMP deaminase enzyme preparation from <i>S. murinus</i> would not pose a health concern when used in the applications specified, at the levels specified and in accordance with good manufacturing practice.</p>
D-Allulose 3-epimerase from <i>Arthrobacter globiformis</i> expressed in <i>Escherichia coli</i>	N	<p>Negative results were observed with D-allulose in genotoxicity tests. A NOAEL of 1100 mg TOS/kg bw per day was identified, the highest dose tested, in a short-term (90-day) oral toxicity study in rats. When the dietary exposure estimate for the highest consumers (90th percentile for infants and children) of 0.38 mg TOS/kg bw per day was compared with the NOAEL of 1100 mg TOS/kg bw per day, an MOE of nearly 3000 was calculated.</p> <p>The Committee established an ADI “not specified” for D-allulose 3-epimerase from <i>A. globiformis</i> M30 expressed in <i>E. coli</i> K-12 W3110 when the enzyme is used in the applications specified, at the levels specified and in accordance with good manufacturing practice.</p>
Carbohydrate-derived fulvic acid (CHD-FA)	No ^a	<p>The Committee concluded that the available data are inadequate for an evaluation of the safety of CHD-FA.</p> <p>The Committee assessed the chemical and technical information received and concluded that there was insufficient information to prepare specifications for CHD-FA.</p>
Jagua (genipin-glycine) blue (Jagua blue)	R ^b	<p>The Committee considered that the new toxicological data and additional characterization of the test compound provided adequate information for completing the safety evaluation of Jagua blue. The new 12-month study of rats exposed in utero was conducted for a longer exposure time and at higher doses of Jagua blue, as recommended by the Committee at its 84th meeting. Although no new toxicokinetics study was available, newly developed analytical methods for the dimers provided acceptable characterization of the test article, thus reducing the uncertainty of the safety assessment due to limited biochemical information.</p> <p>An ADI of 0–11 mg/kg bw was established by the Committee for Jagua blue, on a blue-polymer basis. This ADI was based on the absence of treatment-related long-term toxicity and of reproductive and developmental toxicity in the 12-month rat dietary study with in-utero exposure, in which the NOAEL was identified as 1127 mg/kg bw per day of the blue polymer, the highest dose tested. The ADI was established by applying an uncertainty factor of 100 to the NOAEL.</p> <p>The Committee noted that the upper end of the high-level dietary exposure estimate for Jagua blue, on a blue-polymer basis, for infants and toddlers of 11.5 mg/kg bw per day is in the region of the upper bound of the ADI. In view of the conservative nature of the dietary exposure assessments, in which it was assumed that all foods contained Jagua blue on a blue-polymer basis at the maximum use level, and because the ADI was based on a NOAEL that was the highest dose tested, the Committee concluded that the estimated dietary exposure to Jagua blue, on</p>

Lipase from <i>Mucor javanicus</i>	N	<p>a blue-polymer basis, does not represent a health concern.</p> <p>Negative results were obtained in genotoxicity tests, and no treatment-related adverse effects were seen at the highest dose tested (800 mg TOS/kg bw per day) in a 13-week study of oral toxicity in rats. A comparison of the estimated dietary exposure of 0.84 mg TOS/kg bw per day with the highest dose tested of 800 mg TOS/kg bw per day gives an MOE of at least 900.</p> <p>The Committee established an ADI “not specified” for the lipase enzyme preparation from <i>M. javanicus</i>, used in the applications specified and in accordance with good manufacturing practice.</p>
Phosphatidylinositol-specific phospholipase C expressed in <i>Pseudomonas fluorescens</i> (PI-PLC)	N	<p>Negative results were obtained in genotoxicity tests, and no treatment-related adverse effects were seen with PI-PLC enzyme concentrate at the highest dose tested (1871 mg TOS/kg bw per day) in the 13-week study of oral toxicity in rats. A comparison of the highest estimated dietary exposure of 0.01 mg TOS/kg bw per day with the highest dose tested of 1871 mg TOS/kg bw per day gives an MOE of at least 187 100.</p> <p>The Committee established an ADI “not specified” for the PI-PLC enzyme preparation expressed in <i>P. fluorescens</i>, used in the applications specified and in accordance with good manufacturing practice.</p>
Riboflavin from <i>Ashbya gossypii</i>	No ^c	Because of time constraints, the assessments of safety and dietary exposure were not completed.

N: new specifications; R: existing specifications revised;

^a No specifications were prepared. Information is required to prepare specifications (see Annex 3).

^b Specifications were revised and the tentative status removed.

^c As the evaluation had been postponed, specifications will be published at a later point (see Annex 3).

Food additive assessed only for dietary exposure

Food additive	Conclusions on dietary exposure
Sucrose esters of fatty acids (INS 473) (SEFs) and sucrose oligoesters type I and type II (INS 473a) (SOEs)	<p>At its 49th meeting, the Committee established a group ADI of 0–30 mg/kg bw for SEFs and sucroglycerides on the basis of their potential to induce laxative effects in adult volunteers at doses > 30 mg/kg bw per day, without applying an uncertainty factor. At its 71st meeting, the Committee noted that some of the components of SEFs may be present in significant amounts in SOEs and established a group ADI of 0–30 mg/kg bw for SEFs, SOEs and sucroglycerides.</p> <p>The high dietary exposure estimate of the sum of SEFs and SOEs of 113 mg/kg bw per day for children aged 3–9 years exceeds the group ADI of 0–30 mg/kg bw per day by a factor of about 4. The Committee also noted that the dietary exposure estimates for some other age groups also exceeded the ADI.</p> <p>The Committee noted that the high dietary exposure estimates are conservative, predominantly due to the assumptions that</p> <ul style="list-style-type: none"> • all foods that could contain SOEs and SEFs do in fact contain these food additives, whereas other food additives with the same functions in foods are available; and • when SEFs or SOEs are used, they are always present at the reported use levels. <p>Therefore, the Committee considered that more refined dietary exposure estimates should be provided.</p>

Food additives considered for specifications only

Food additive	Specifications
Magnesium stearate (INS 470(iii))	R ^a
Polyvinyl alcohol (INS 1203)	R ^b
Sorbitan esters of fatty acids (INS 491, INS 492, INS 495)	No ^c

R: existing specifications revised;

^a For the assay of magnesium, the ICP-AES method reference was replaced with a general term to read as 'use a method appropriate to the specified level'

^b The solubility criteria was changed to "practically insoluble or insoluble in ethanol" for additional remarks see annex 3.

^c No specifications were prepared. Information is required to prepare specifications (see Annex 3).

Flavouring agents evaluated by the revised Procedure for the Safety Evaluation of Flavouring Agents**A. Amino acids and related substances**

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Betaine	2265	N	No safety concern
<i>N</i> -Acetyl-glutamate	2269	N	No safety concern
L-Cysteine methyl ester hydrochloride	2270	N	No safety concern
Glutamyl-2-aminobutyric acid	2266	N	No safety concern
Glutamyl-norvaline	2268	N	No safety concern
Glutamyl-norvalyl-glycine	2267	N	No safety concern

B. Phenol and phenol derivatives

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
(±)-Homoeriodictyol sodium salt	2256	N	No safety concern
(±)-Naringenin	2257	N	No safety concern
(2 <i>R</i>)-3',5-Dihydroxy-4'-methoxyflavanone	2258	N	No safety concern
7,8-Dihydroxyflavone	2259	N	No safety concern
(2 <i>S</i>)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan	2260	N	Genotoxicity data for (2 <i>S</i>)-3',7-Dihydroxy-8-methyl-4'-methoxyflavan raise concerns for potential genotoxicity
(<i>R</i>)-5-Hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one	2261	N	No safety concern
3-(3-Hydroxy-4-methoxyphenyl)-1-(2,4,6-trihydroxyphenyl)propan-1-one	2262	N	No safety concern

Flavouring agents considered for specifications only

Food additive	No.	Specifications
4-Hydroxy-2,3-dimethyl-2,4-nonadienoic acid γ -lactone	2002	R ^a

β -Caryophyllene oxide	1575	R ^b
2-Acetyl-1-pyrroline	1604	R ^c
(2 <i>E</i> ,6 <i>E</i> / <i>Z</i> ,8 <i>E</i>)- <i>N</i> -(2-Methylpropyl)-2,6,8-decatrienamide	2077	R ^d
4-Hexen-3-one	1125	R ^e
d-Carvone	380.1	R ^f
2-Pentylfuran	1491	R ^g
3-(2-Furyl)acrolein	1497	R ^h
2-Phenyl-3-(2-furyl)prop-2-enal	1502	R ⁱ
2-Acetyl-5-methylfuran	1504	R ^j
3-Acetyl-2,5-dimethylfuran	1506	R ^k
4-(2-Furyl)-3-buten-2-one	1511	R ^l
Ethyl 3-(2-furyl) propanoate	1513	R ^m
Phenethyl 2-furoate	1517	R ⁿ

R: revised

^a The specific gravity was revised to 0.950-1.000 at 20 °C, and the assay minimum was maintained at 93%, with a change of the secondary component from 1-2% 3,4-Dimethyl 5-ketobutanoic acid gamma lactone to 2-3% of 3,4-dimethylfuran-2,5-dione.

^b The melting point was revised to 55–63 °C and the assay minimum to 95% (sum of isomers). Specifications for the isomeric composition were also established: 84-89% (1*R*, 4*R*, 6*R*, 10*S*) (CAS No. 1139-30-6), 7-9% (1*R*, 4*R*, 6*S*, 10*S*) (CAS No. 60594-22-1), 0.3-2% (1*R*, 4*S*, 6*S*, 10*S*) (CAS No. 103475-43-0) and 1-2% humulene-1,2-epoxide

^c The assay minimum was revised to 90%, with a secondary component of up to 5-6% of 5,6-dihydro-2-methyl-3-(4*H*)-pyridinone

^d The isomeric composition was updated to be 73-80% (2*E*,6*Z*,8*E*), 15-18% (2*E*,6*E*,8*E*), 3-7% (2*E*,6*Z*,8*Z*), 1-2% (2*Z*,6*Z*,8*E*), and 1-2% (2*Z*,6*E*,8*E*).

^e The assay minimum was set to 95% (sum of isomers) and the specifications for the isomeric composition were established as: *trans*-4-hexen-3-one (90-95%) and *cis*-4-hexene-3-one (1-5%).

^f The refractive index was revised to 1.496-1.502 and the specific gravity to 0.956-0.961

^g The refractive index was revised to 1.445-1.451 and the assay minimum to 95%

^h The melting point was revised to 42–54 °C

ⁱ The physical form and odour were revised.

^j The specific gravity was revised to 1.065-1.074, the assay minimum to 95%, as well as the physical form and odour were revised.

^k The specific gravity was revised to 1.034-1.048, as well as the physical form and odour.

^l the melting point was revised to 28–40 °C, as well as the physical form and odour.

^m The physical form and odour were revised, and specifications for the refractive index and the specific gravity were established as 1.455-1.462 and 1.051-1.058, respectively.

ⁿ The refractive index was revised to 1.540-1.550, the specific gravity to 1.138-1.150, and the physical form and odour were updated.

Annex 1**Eighty-ninth meeting of the
Joint FAO/WHO Expert Committee on Food Additives**
Virtual meeting, 1–12 June 2020**Members**

Dr S. Barlow, Brighton, East Sussex, United Kingdom
Dr J. Bend, Department of Pathology and Laboratory Medicine, Schulich Medicine and Dentistry, Western University, London, Ontario, Canada
Dr D. Benford, Cheddington, United Kingdom
Dr P.E. Boon, Department for Food Safety, Centre for Nutrition, Prevention and Health Services, National Institute for Public Health and the Environment, Bilthoven, the Netherlands
Dr R. Cantrill, Halifax, Nova Scotia, Canada (Vice-Chairperson)
Dr E. Dessipri, Department of Biological Standardisation, OMCL Network & HealthCare, European Directorate for the Quality of Medicines & HealthCare, Council of Europe, Strasbourg, France
Dr D.E. Folmer, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, Maryland, USA (Joint Rapporteur)
Ms Tracy Hambridge, Food Standards Australia New Zealand, Majura Park, Australian Capital Territory, Australia
Dr Madduri Veerabhadra Rao, Whitefields, Kondapur, Hyderabad, Telangana State, India
Dr A. Mattia, FDA/CFSAN Retired, USA (Chairperson)
Dr U. Mueller, Yarralumla, Australian Capital Territory, Australia (Joint Rapporteur)
Dr J. Schlatter, Zurich, Switzerland
Dr J. Smith, Bio|Food|Tech, Charlottetown, Prince Edward Island, Canada
Dr J.R. Srinivasan, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, Maryland, USA

Secretariat

Mr D. Arcella, European Food Safety Authority; Parma, Italy (FAO expert)
Professor Dr M. Beatriz. de Abreu Gloria, Departamento de Ciências do Consumo - Universidade Federal Rural de Pernambuco, Pernambuco, Brazil (FAO expert)
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- Dr A. Tada, Division of Food Additives, National Institute of Health Sciences, Kawasaki-ku, Kawasaki-shi, Kanagawa, Japan (FAO expert)
- Dr S.G. Walch, Chemisches und Veterinäruntersuchungsamt, Karlsruhe, Germany (FAO expert)
- Dr S. Takasu, Division of Pathology, Biological Safety Research Center, National Institute of Health Sciences, Kawasaki-ku, Kawasaki-shi, Kanagawa, Japan (WHO temporary adviser)
- Dr Y. (Janet) Zang, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, Maryland, USA (WHO temporary adviser)
- Ms L. Zhang, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (Codex Secretariat)

Annex 2

General considerations

An edited version of this section will appear in the report of the eighty-seventh 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.

Update of guidance on dose–response assessment and derivation of health-based guidance values (revision of Environmental Health Criteria (EHC) 240, Chapter 5)

Since the last update to the Committee in June 2019 (WHO Technical Report Series (TRS) No. 1020, 2019), revision of Chapter 5 of EHC 240, on dose–response assessment and derivation of health-based guidance values, has continued, and a draft of the chapter was sent for public consultation in December 2019. In response, the Secretariat received about 300 comments from 14 organizations or individuals, indicating a high level of interest. The comments included many helpful suggestions for further revision and clarification of the text. Most of the comments have now been considered and addressed, and the work will be completed soon. After editing, the text will be published online as an updated chapter of EHC 240.

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Update of guidance on evaluation of enzyme preparations (revision of EHC 240, Chapter 9.1.4.2)

The Committee was given an update on progress made in revising guidance on the evaluation of enzymes for use in food. An expert working group was established in 2018 to discuss the available information on the safety of enzymes used in food and current practices of the food enzyme industry. Several documents and definitions were amended and submitted for public comment late in 2019. The comments received were evaluated, and the text of a revised version of Chapter 9.1.4.2 of EHC 240 was edited further as necessary.

The working group made a series of recommendations to this Committee, which came to the following consensus.

- 1a. The Committee adopted the proposed definitions of “safe food enzyme production strain” and “presumed safe progeny strain” (Annex 2) with minor editorial changes.
- 1b. The Committee adopted the proposed revisions to Chapter 9.1.4.2 of EHC 240 pertaining to enzymes, including a revision of the classification of enzymes and their definitions. The text for Class I Type iii and Class II enzymes was modified to state that “an ADI may be established.”
- 1c. The Committee approved the proposed checklist of data requirements for the risk assessment of enzyme preparations in submissions for review by JECFA, with a change to one of the test requirements. The Committee debated the value of including on the checklist a request for information on “Bioinformatic analysis of the amino acid sequence for potential matches with known toxins” (checklist item #29). The Committee decided that it should remain on the checklist, and the usefulness of such information should be evaluated once sufficient experience has been gained.
- 1d. The Committee adopted the proposed list of terms and definitions related to submissions on enzyme preparations for use in food and added a definition of “total organic solids”.
2. The Committee recommended that allergenicity should be assessed only for enzyme preparations proposed for inclusion in Class I Type iii or Class II.
3. The Committee debated whether it would be appropriate to combine consideration of immobilized enzyme preparations that are in contact with foods only during processing with consideration of enzyme preparations added to foods but removed from the final products. Differing points of view were expressed, and the Committee was reminded that such consideration did not apply to other situations in which food-grade carriers and formulation ingredients are used. Furthermore, the Committee considered that the levels of residues of immobilizing agents in the final product would be extremely low; the levels of these substances or their contaminants permitted in the final product should be at the lowest levels that are technologically feasible. The Committee decided that the wider issue of food contact materials was not one of their current terms of reference, and their

consideration would have to be initiated by the Codex Alimentarius Commission or others before it could be taken up.

4. The Committee supported establishment of a separate online database for toxicological data and specifications for enzyme preparations for use in food evaluated by JECFA in order to simplify presentation of the data to users (similar to that currently used for flavourings).

5. The Committee supported establishment of a separate JECFA numbering system for identifying enzyme preparations for which JECFA had completed safety evaluations (similar to that used for flavourings).

6. The Committee supported development of an enzyme-specific template for the submission of information on analytical methods, including method performance characteristics (method validation data) and quality control data.

Update of guidance on evaluation of the genotoxicity of chemical substances in food

Since the last update provided to the Committee, in June 2019 (TRS 1020), on revision of Chapter 4.5 of EHC 240, guidance on evaluating the genotoxicity of chemical substances in food, a draft of the chapter was sent for public consultation in December 2019. In response, the Secretariat received about 300 comments from 14 organizations or individuals, indicating a high level of interest. The comments included many helpful suggestions for further revision and clarification of the text. Most of the comments have now been considered and addressed, and the work will be completed soon. After editing, the text will be published online as an updated chapter of EHC 240.

Withdrawal of the ADI for lipase from *Aspergillus oryzae*, var.

In evaluating lipase from *Mucor javanicus* at the present meeting (item 3.1.5), the Committee noted that the specifications for lipase from *Aspergillus oryzae*, var. had been withdrawn by the Committee at its 55th meeting (Annex 1, reference 149) but that it had not addressed the consequences of the withdrawal of specifications on its acceptable daily intake (ADI). The Committee at its current meeting decided to withdraw the ADI "not specified" for lipase from *Aspergillus oryzae*, var.

The Committee also noted that specifications for other food additives had been withdrawn at the 55th meeting without addressing the consequences for the respective ADIs. The Committee recommends reconsideration of the ADIs concerned at a future meeting.

Corrigenda

The following requests for corrections, reported to the JECFA Secretariat, were evaluated by JECFA at the current meeting and found to be necessary. The corrections will be made, however, only in the electronic versions and in the online database.

Food additive	Original text	Revised text	Additional information
Calcium disodium ethylenediamine-tetraacetate INS 385	CAS No. 662-33-9	CAS No. 62-33-9 (anhydrous) 6766-87-6 (dihydrate) 23411-34-9 (hydrated)	Correction to CAS No. (for the anhydrous form)
	Chemical formula C ₁₀ H ₁₂ CaN ₂ Na ₂ O ₈ · 2H ₂ O	Chemical formula C ₁₀ H ₁₂ CaN ₂ Na ₂ O ₈ (anhydrous) C ₁₀ H ₁₂ CaN ₂ Na ₂ O ₈ · H ₂ O (monohydrate) C ₁₀ H ₁₂ CaN ₂ Na ₂ O ₈ · 2H ₂ O (dihydrate)	CAS No. for hydrated forms; chemical formula and formula weight for anhydrous and monohydrate also included
	Formula weight	Formula weight	

	410.31	374.37 (anhydrous) 392.31 (monohydrate) 410.31 (dihydrate)	
Pentasodium triphosphate INS 451(i)	Dowex F x 8	Dowex 1 x 8	Correction to the resin in the procedure of method of assay
Talc INS 553(iii)	A range of length:width ratios of 20:1 to 100:1 or higher for fibres longer than 5 m	A range of length:width ratios of 20:1 to 100:1 or higher for fibres longer than 5 µm	Length of fibre corrected
Annatto extracts (norbixin-based) INS 160b(ii) 1. Alkali processed norbixin, acid precipitated 2. Alkali processed norbixin, not acid precipitated 3. Solvent extracted norbixin	CAS Nos <i>cis</i> -Norbixin: 542-40-5 <i>cis</i> -Norbixin dipotassium salt: 33261-80-2 <i>cis</i> -Norbixin disodium salt: 33261-81-3	CAS Nos <i>cis</i> -Norbixin: 626-76-6 <i>cis</i> -Norbixin dipotassium salt <i>cis</i> -Norbixin disodium salt:	Correction to the CAS No. of <i>cis</i> -norbixin and deletion of the incorrect CAS Nos for the dipotassium and disodium salts

Annex 3

Future work and recommendations

Carbohydrate-derived fulvic acid

The Committee requires data to characterize the products of commerce in order to evaluate the product for use as a preservative. The required information includes a detailed description of the manufacturing processes and thorough chemical characterization of the commercial products.

The following information is required:

- the full composition of the products;
- a detailed description of the manufacturing process;
- analytical methods and data on method validation; and
- analytical data for five non-consecutive batches of commercial products, including information on impurities.

The sponsor is encouraged to offer a rationale for whether a single monograph covering all products or individual monographs should be prepared.

Given the deficiencies of the toxicological database, the Committee recommends that the following studies be conducted. The test protocols should be in accordance with the relevant current guidelines, and the test materials should be well characterized in relation to the article(s) of commerce:

- absorption, distribution, metabolism and excretion;
- repeated-dose 90-day oral toxicity in rodents;
- two-generation reproductive toxicity **or** extended one-generation reproductive toxicity;
- prenatal developmental toxicity;
- additional studies, including an *in vitro* micronucleus test in mammalian cells, might be required, depending on elucidation of the article(s) of commerce and the provision of full information on their composition; and
- information on the potential of the material to induce antimicrobial resistance.

In addition, use levels should be provided for estimating dietary exposure.

Withdrawal of the ADI for lipase from *Aspergillus oryzae*, var.

The Committee noted that specifications for other food additives had been withdrawn at the 55th meeting without addressing the consequences for the respective ADIs. The Committee recommends reconsideration of the ADIs concerned at a future meeting.

Riboflavin from *A. gossypii*

The Committee drafted a chemical and technical assessment and new specifications for riboflavin from *A. gossypii* from the data submitted by the sponsor, but did not finalize them for publication. The Committee recognized the benefits of simultaneous review and harmonization of new specifications with existing specifications for riboflavin as a synthetic product and as a product of *B. subtilis* and recommended that this work be undertaken at a future meeting.

Sucrose esters of fatty acids (INS 473) and sucrose oligoesters types I and II (INS 473a)

To refine the dietary exposure estimates of SEFs and SOEs, either alone or summed, the Committee recommends that sponsors submit information on:

- typical or mean and high use levels for foods in which the food additives are used; and
- foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used.

In both cases, the information should be as specific as possible, and the foods should be classified according to the FoodEx2 classification system, which is that used for the CIFOCCOs and GIFT food consumption databases, or another appropriate system.

The Committee did not use the CIFOcOss and GIFT databases to assess dietary exposure to SEFs and SOEs, partly because calculations of exposure would have been laborious in view of the number of broad food categories for which use levels were provided. In order to use these data for dietary exposure assessment of food additives that are present in large numbers of food categories, a table should be developed to map the foods recorded in both databases according to the FoodEx2 classification to the food categories of the GSFA. That will also ensure that mapping is consistent for all meetings.

The Committee recommends that more detailed information on the use of SEFs and SOEs in foods and a mapping table be made available within 2 years.

Polyvinyl alcohol

The Committee recommended that the CCFA determine whether the food-grade PVOH products currently available in commerce comply with the narrow range of viscosity (4.8–5.8 mPa × s) and degree of hydrolysis (86.5–89%) in the specifications. Any deviations would necessitate a review of its safety evaluation.

The Committee also noted that the gas chromatographic method for determining methanol and methyl acetate in PVOH is a packed-column method and recommended that it be replaced by a suitable capillary or wide-bore column gas chromatographic method.

Sorbitan esters of fatty acids (INS 491, INS 492 and INS 495)

The Committee recommends that a new call for data be issued in order to proceed with an updated safety evaluation and specifications for the five sorbitan esters of fatty acids at the same time.

The Committee also noted that five polyoxyethylene sorbitan esters (polysorbates) were evaluated by JECFA at its 17th meeting Annex 1, reference 32), and specifications were established. The Committee recommends that a new call for data be issued for their full evaluation.

Annex 4

Procedural matters

The 89th meeting of JECFA was originally scheduled for 2–11 June 2020 at WHO headquarters in Geneva, Switzerland. Because of the travel restrictions and lock-downs due to the COVID-19 pandemic in many countries, however, the joint FAO/WHO JECFA secretariat was unable to convene the meeting as scheduled. The secretariat evaluated possible alternatives, including cancelling the meeting, but, to avoid a delay in delivering the requested scientific advice to the Codex Alimentarius Commission, the secretariat decided to hold the meeting online by video-conferencing. In view of the countries of origin of the invited experts, the only possible time for a video-conference was restricted to a 4-h time slot (12:00–16:00 CEST) a day. This allowed approximately 40% of the usual daily time (8–10 h) of a JECFA 8-day face-to-face meeting.

The FAO/WHO JECFA secretariat contacted all the invited experts and the Codex secretariat to discuss changes to the meeting format. The experts expressed their willingness and availability to participate remotely in the meeting as a one-time measure because of the exceptional circumstances of the COVID-19 pandemic. They agreed to extend the duration of the meeting by 2 days, adding Monday 1 June and Friday 12 June 2020; however, their commitments did not allow extension of the meeting into the week before or after those scheduled.

After discussion, the experts and the FAO/WHO JECFA secretariat decided that the 89th JECFA could evaluate only the compounds that are listed in the final table of contents because of the shortage of time. Natamycin (INS 234), natamycin (INS 235), α -glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*, collagenase from *S. violaceoruber* expressed in *S. violaceoruber*, phosphodiesterase from *Penicillium citrinum* and phospholipase A2 from *S. violaceoruber* expressed in *S. violaceoruber*, which had been scheduled for discussion, were therefore not considered. During the meeting, it became apparent that two further evaluations could not be completed, that for alicyclic ketones, secondary alcohols and related esters and a toxicological evaluation of riboflavin from *Ashbya gossypii*. All these compounds will be re-scheduled for evaluation at future JECFA meetings.

The 89th JECFA meeting was held on an online platform on 1–12 June 2020. While the experts participated fully, they noted that an online meeting does not facilitate the usual interaction between experts, within and across the WHO and FAO sub-groups. The experts considered that the success of the 89th meeting was due to a large extent to the cohesion among the experts that resulted from the trust generated during previous face-to-face meetings.

The experts decried the significant difficulty of meeting informally outside the scheduled meeting times because of the large differences in time zones. They noted that such informal interactions during physical meetings are instrumental to solving problems and to discussing issues in depth, bilaterally or in small groups, and added that informal meetings often gave rise to solutions to challenging problems. The inability to have such meetings was considered to have hindered progress at the current meeting and led to less efficient use of experts' time.

The experts emphasized further that an invitation to a physical JECFA meeting at FAO or WHO headquarters gives rise to significant recognition by the expert's employer of the weight and reach of the outcomes and the responsibility and workload required for full participation in a JECFA meeting. The lack of recognition of the workload and of the significance of participation in a JECFA meeting has led to an increase in other demands on experts, resulting in notable distraction, with more frequent scheduling conflicts. The experts concluded that, cumulatively, such factors would be significantly counterproductive for participation in future virtual JECFA meetings and for the efficiency of such meetings.

While the collaborative software solutions provided by FAO and WHO made the meeting possible, the experts urged FAO and WHO to explore means to improve the stability of the platforms used; significant meeting time was lost due to slow responses of both systems. Furthermore, the stability, reliability and consistency of the experts' Internet services did not at times fulfil the minimum requirements necessary for effective participation in the meeting, as frequent disconnections and slow transmission of shared content were frequent issues for some experts.

In recognition of the difficulties and the tremendous effort made, the joint FAO/WHO secretariat expresses its deep gratitude to all the experts for their commitment and flexibility, not least as the

scheduled meeting times were inconvenient for many.