Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Ninety-fifth meeting (Safety evaluation of certain food additives)
Virtual meeting, 6–17 and 22 June 2022

SUMMARY AND CONCLUSIONS

Issued on 1 July 2022

A virtual meeting of the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) was held on an online platform on 6–17 and 22 June 2022. The purpose of the meeting was to evaluate the safety of certain food additives and flavourings. The present meeting was the Ninety-fifth 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.

Because of the travel restrictions resulting from the COVID-19 pandemic in many countries, it was not possible to convene a physical meeting; instead, it was decided to hold the meeting online by video-conferencing. In view of the time differences in the countries of origin of the invited experts, the video-conference was restricted to a 4-hour time slot (12:00–16:00 Central European Summer Time) each day. This allowed only 40% of the usual daily length (8–10 h) of a typical JECFA meeting.

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

Ms N.Y. Ho (WHO), Dr M. Lipp (FAO), Mr K. Petersen (WHO) and Ms A. Vlachou (FAO) served as joint secretaries.

The Committee evaluated the safety of nine food enzymes, revised the specifications for one food additive and evaluated the safety of two flavouring agents.

The report of the meeting will be published in the WHO Technical Report Series. The report, dedicated to Dr J. Smith, 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. Information of a general nature that the Committee wishes to disseminate quickly is provided in Annex 2. Future work and recommendations arising from the summary report of the Ninety-fifth JECFA meeting are summarized in Annex 3. Annex 4 discusses the effects of holding the expert meetings online rather than in person. Finally, Annex 5 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. 82. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs No. 30.

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/.

Toxicological and dietary exposure information and information on specifications

Food additives evaluated toxicologically and assessed for dietary exposure

Food additive	JECFA enzyme identifier	Specifications	ADIs and other conclusions on toxicology and dietary exposure
α-Amylase from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*	JECFA95-1	N, T	The Committee concluded that dietary exposure to this α-amylase is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 67 mg TOS/kg bw per day, the highest dose tested in a 13-week oral toxicity study in rats. When this NOAEL is compared with the dietary exposure estimate of 0.2 mg TOS/kg bw per day, a MOE of more than 330 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established a temporary ADI "not specified"[a] for α-amylase (JECFA95-1) from *G. stearothermophilus* expressed in *B. licheniformis*, when used in the applications specified, at the levels of use specified and in accordance with current GMP. This ADI "not specified" was made temporary because of the tentative nature of the specifications.
α-Amylase from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*	JECFA95-2	N, T	The Committee concluded that dietary exposure to this α-amylase is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 660 mg TOS/kg bw per day, the highest dose tested in a 13-week oral toxicity study in rats. When this NOAEL is compared with the dietary exposure estimate of 0.08 mg TOS/kg bw per day, a MOE of more than 8000 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established a temporary ADI "not specified" for α-amylase (JECFA95-2) from *G. stearothermophilus* expressed in *B. licheniformis*, when used in the applications specified, at the levels of use specified and in accordance with current GMP. The ADI "not specified" was made temporary because of the tentative nature of the specifications.
α-Amylase from *Rhizomucor pusillus* expressed in *Aspergillus niger*	JECFA95-3	N, T	The Committee concluded that dietary exposure to this α-amylase is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 1400 mg TOS/kg bw per day, the highest dose tested in a 13-week oral toxicity study in rats. When this NOAEL is compared with the dietary exposure estimate of 4 mg TOS/kg bw per day, a MOE of more than 350 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established a temporary ADI "not specified" for α-amylase (JECFA95-3) from *R. pusillus* expressed in *A. niger*, when used in the applications specified, at the levels of use specified and in accordance with current GMP. The ADI "not specified" was made temporary because of the tentative nature of the specifications.
Amyloglucosidase from *Rasamsonia emersonii* expressed in *Aspergillus niger*	JECFA95-4	N, T	The Committee noted that amyloglucosidase may pose a risk as a respiratory allergen. In the absence of any information regarding its stability within the gastrointestinal tract, the Committee could not complete the assessment of the risk for allergenicity from dietary exposure to this enzyme. The Committee identified a NOAEL of 1500 mg TOS/kg bw per day in a 13-week study of oral toxicity in rats. When this NOAEL, the highest dose tested, is compared with the conservative dietary exposure estimate of 9 mg TOS/kg bw per day, a MOE of more than 160 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established a temporary ADI "not specified" for amyloglucosidase (JECFA95-4) from *R. emersonii* expressed in *A. niger* when used in the applications specified, at the levels of use specified and in accordance with current GMP. The ADI "not specified" was made temporary because of the tentative nature of the specifications and the inability to complete the allergenicity assessment.

Asparaginase from *Pyrococcus furiosus* expressed in *Bacillus subtilis*	JECFA95-5	N, T	The Committee concluded that dietary exposure to the enzyme preparation is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 1207 mg TOS/kg bw per day, the highest dose tested, in a 13-week study of oral toxicity in rats. When this NOAEL is compared with dietary exposure estimate of 0.4 mg TOS/kg bw per day, a MOE of more than 3000 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established a temporary ADI "not specified" for asparaginase (JECFA95-5) from *Pyrococcus furiosus* expressed in *Bacillus subtilis* when used in the applications specified, at the levels of use specified and in accordance with current GMP. The ADI "not specified" was made temporary because of the tentative nature of the specifications.
β-Amylase from *Bacillus flexus* expressed in *Bacillus licheniformis*	JECFA95-6	N, T	The Committee concluded that dietary exposure to the enzyme preparation is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 1199 mg TOS/kg bw per day, the highest dose tested, in a 13-week study of oral toxicity in rats. When this NOAEL is compared with the dietary exposure estimate of 1 mg TOS/kg bw per day, a MOE of around 1200 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established a temporary ADI "not specified" for β-amylase (JECFA95-6) from *Bacillus flexus* expressed in *B. licheniformis* when used in the applications specified, at the levels of use specified and in accordance with current GMP. The ADI "not specified" was made temporary because of the tentative nature of the specifications.
Lipase from *Thermomyces lanuginosus* and *Fusarium oxysporum* expressed in *Aspergillus oryzae*	JECFA95-7	N	The Committee concluded that dietary exposure to this lipase is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 1080 mg TOS/kg bw per day, the highest dose tested in the 13-week study of oral toxicity in rats. When this NOAEL is compared with the dietary exposure estimate of 0.2 mg TOS/kg bw per day, a MOE of more than 5000 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee established an ADI "not specified" for lipase (JECFA95-7) from *T. lanuginosus* and *F. oxysporum* expressed in *A. oryzae* when used in the applications specified, at the levels of use specified and in accordance with current GMP.
Phospholipase A2 (PLA2) from porcine pancreas expressed in *Aspergillus niger*	JECFA95-8	No[b]	Because of the late submission of highly relevant toxicological data, other missing information and time constraints, the Committee was unable to complete this evaluation. The Committee recommended that the evaluation of this enzyme preparation is completed at a future meeting.
Xylanase from *Bacillus licheniformis* expressed in *Bacillus licheniformis*	JECFA95-9	N, T	The Committee concluded that dietary exposure to this xylanase is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 1020 mg TOS/kg bw per day, the highest dose tested, in the 13-week study of oral toxicity in rats. When this NOAEL is compared with the dietary exposure estimate of 0.01 mg TOS/kg bw per day, a MOE of more than 100 000 can be calculated. Based on this MOE and the lack of concern for genotoxicity, the Committee allocated a temporary ADI "not specified" for xylanase (JECFA95-9) from *B. licheniformis* expressed in *B. licheniformis* when used in the applications specified, at the levels of use specified and in accordance with current GMP. The ADI "not specified" was made temporary because of the tentative nature of the specifications.

ADI: acceptable daily intake; GMP: Good Manufacturing Practices; MOE: margin of exposure; N: new specification; NOAEL: no-observed-adverse-effect limit; T: tentative specification; TOS: total organic solids.

[a] The reader is referred to the Technical Report of the Eighty-seventh JECFA meeting for clarification of the term ADI "not specified".

[b] No specifications were prepared. Information is required to prepare specifications (see Annex 3).

Food additives considered for specifications only

Food additive	Specification
Spirulina extract (INS 134)	R

R: revised specification.

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

Alicyclic ketones, secondary alcohols and related esters

Flavouring agent[a]	No.	Specifications	Conclusion based on current estimated dietary exposure
Trans-4-*tert*-butylcyclohexanol	2263	N	No safety concern
Caryophylla-3(4),8-dien-5-ol	2264	N	No safety concern

N: new specification.

[a] Both flavouring agents are in structural class I.

Annex 1. List of participants

Members

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Dr J.N. Barrows, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park (MD), United States of America

Dr D. Benford, Cheddington, United Kingdom (Vice-chairperson)

Dr R. Cantrill, Bedford, Nova Scotia, Canada (Chairperson)

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Experts

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Secretariat

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Dr E. Rowan, Contin, United Kingdom (WHO technical editor)

Ms A. Vlachou, Food Systems and Food Safety Division, Food and Agriculture Organization of the United Nations, Rome, Italy (FAO joint secretary)

Annex 2. General considerations

Naming and identification of JECFA enzyme preparations

The Committee reviewed the list of enzyme preparations for evaluation and noted that there were two different formats for the title. Reflecting on past evaluations and considering ease of use, the Committee decided that the name given to the enzyme preparation should correspond to the name of the enzyme activity or activities that most accurately characterize the preparation, the donor(s) of the genetic material and the production microorganism. However, the Committee noted that by following this naming convention, two of the enzyme preparations would have the same name; the Committee therefore decided that an identification system would also be used for all enzyme preparations, consisting of the JECFA meeting number followed by the agenda item number of the substance (e.g. JECFA95-1).

Data submission on Class 1, Type iii enzyme preparations

Under the current JECFA enzymes guidelines described in Environmental Health Criteria 240, toxicological data and dietary exposure information are not required for Class 1, Type iii preparations. However, for many of the enzyme preparations that the Committee considers, toxicological data and dietary exposure assessment data are available. The Committee therefore wishes to emphasize that, when such data exist, they should be submitted to the Committee for evaluation.

Consideration of information labelled confidential

The Committee discussed the requests for confidentiality made by sponsors for some information, and determined that any information that can be found in the public domain will be included in JECFA publications as necessary.

Data required to support the evaluation of enzyme preparations

The Committee expressed its frustration that many of the current data submissions were inconsistent with key aspects of the guidelines published by the Committee. The Committee noted when preparing the specifications monographs for individual enzyme preparations that a considerable amount of supporting information was not made available, even when requested on more than one occasion. In addition, the details of the assays supplied included the use of an enzyme reference or calibrant, rather than a direct link to an original enzyme assay from which a meaningful unit definition could be derived. The consequence of the absence of such data has resulted in the Committee designating many of the enzyme specifications “tentative” and toxicological evaluations “temporary” at the present meeting. It should also be noted that, for one enzyme preparation, the Committee became aware that highly relevant toxicological studies, now known to have been submitted to at least one regulatory body in 2005, were not submitted to JECFA. The Committee asks the JECFA Secretariat to urge sponsors and Codex Members to ensure that all required information is available for evaluation prior to requesting inclusion in the Codex Committee on Food Additives JECFA Priority List.

Annex 3. Recommendations and future work

As reported elsewhere (see Annex 2), the Committee expressed its frustration that many of the current data submissions were either inconsistent with key aspects of the guidelines published by the Committee, or else inadequate or incomplete. To be able to complete the safety evaluations of the food enzymes assessed at this meeting, the Committee recommends that the information listed in the following table be provided.

Report item	Recommendation
3.1.1. α-Amylase (JECFA95-1) from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • validated method of analysis to determine α-amylase activity, including the validation report; • unit definition for α-amylase activity based on the method of assay; and • analytical data using the validated method for at least five different batches of commercially available products.
3.1.2. α-Amylase (JECFA95-2) from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • validated method of analysis to determine α-amylase activity, including the validation report; • unit definition for α-amylase activity based on the method of assay; and • analytical data using the validated method for at least five different batches of commercially available products.
3.1.3. α-Amylase (JECFA95-3) from *Rhizomucor pusillus* expressed in *Aspergillus niger*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • validated method of analysis to determine α-amylase activity, including the validation report; • unit definition for α-amylase activity based on the method of assay; and • analytical data using the validated method for at least five different batches of commercially available products.
3.1.4. Amyloglucosidase (JECFA95-4) from *Rasamsonia emersonii* expressed in *Aspergillus niger*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • digestibility data in order to complete the allergenicity assessment; • validated method of analysis to determine amyloglucosidase activity, including the validation report; • unit definition for amyloglucosidase activity based on the method of assay; and • analytical data using the validated method for at least five different batches of commercially available products.
3.1.5. Asparaginase (JECFA95-5) from *Pyrococcus furiosus* expressed in *Bacillus subtilis*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • validated method of analysis to determine asparaginase activity, including the validation report; • unit definition for asparaginase activity based on the method of assay; and • analytical data using the validated method for at least five different batches of commercially available products.
3.1.6. β-Amylase (JECFA95-6) from *Bacillus flexus* expressed in *Bacillus licheniformis*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • validated method of analysis to determine β-amylase activity, including the validation report; and • analytical data using the validated method for at least five different batches of commercially available products.
3.1.8. Phospholipase A2 (PLA2; JECFA95-8) from porcine pancreas expressed in *Aspergillus niger*	The Committee recommends that the evaluation of this enzyme preparation is completed at a future meeting. The Committee requested the JECFA Secretariat to urge the sponsor and Codex Members to ensure that the following additional information is available for evaluation prior to requesting inclusion of this enzyme preparation in the CCFA JECFA Priority List: • additional data to clarify the genotoxic potential of the PLA2 enzyme concentrate; • digestibility data for enzyme preparations containing both glucoamylase and PLA2;

	• results from five different batches of all types of PLA2 enzyme preparations using the assay to determine PLA2 activity provided in the dossier; • validation information of the alternative method of analysis used to determine PLA2 activity (this should include the method description in English); • unit definition for the PLA2 activity based on the alternative method of assay; and • analytical data using the alternative validated method for at least five different batches of all commercially available products.
3.1.9. Xylanase (JECFA95-9) from *Bacillus licheniformis* expressed in *Bacillus licheniformis*	The Committee requested the following information, by the end of 2023, to complete the safety assessment: • validated method of analysis to determine xylanase activity, including the full validation report; • unit definition for xylanase activity based on the method of assay; and • analytical data using the validated method for at least five different batches of commercially available products.

Annex 4. Procedural matters

Because of the travel restrictions as a result of the COVID-19 pandemic in many countries, it was not possible to convene a physical meeting; instead, it was decided to hold the meeting online by video-conferencing. In view of the time differences in the countries of origin of the invited experts, the video-conference was restricted to a 4-hour time slot (12:00–16:00 Central European Summer Time) each day.

All participating experts reaffirmed that online meetings did not permit the necessary in-depth, robust scientific discussions that have been a characteristic of past JECFA physical meetings, and were therefore not a suitable substitute. In particular, the experts felt that the online format did not foster the atmosphere of trust, inclusiveness and openness that has marked all JECFA physical meetings, making participation for new experts especially challenging. The experts considered that the success of the Ninety-fifth meeting was mainly a result of the cohesion between them, which stemmed from the trust built on the relationships they had formed during previous face-to-face meetings. The experts also decried the significant difficulty of holding any informal meetings outside the scheduled meeting times because of the widely differing time zones. They noted that such informal interactions during the physical meetings were instrumental in solving problems and discussing issues in depth, bilaterally or in small groups, and added that such informal settings often gave rise to equitable solutions to difficult problems.

The experts also emphasized that an invitation to a physical JECFA meeting at the FAO or WHO headquarters gives rise to a more significant recognition by the expert's employer of the weight, reach, responsibility and workload required for full participation in a JECFA meeting. The same degree of acknowledgement was not granted by employers for this online meeting, as the experts remained available locally. This lack of recognition of the workload and significance of participation in a JECFA meeting led to an increase in other demands on the experts, resulting in greater distractions and more frequent scheduling conflicts.

Cumulatively, the experts concluded that maintaining the online-only format would be counterproductive for participation in future JECFA meetings.

In recognition of the difficulties experienced and the tremendous efforts made, the Joint FAO/WHO Secretariat expressed its deep gratitude to all the experts for their commitment and flexibility, especially as the scheduled meeting times were exceedingly inconvenient for many.

The meeting report was adopted on 22nd June 2022.

Annex 5. Corrigenda

The Committee discussed the tentative errata. One request was for the amendment of the name of the microorganism *Geobacillus stearothermophilus* used for the Glucosyl Steviol Glycosides (GSG) production (Annex 4 of Steviol glycosides Framework) by replacing the existing name of the microorganism with *Anoxybacillus caldiproteoliticus* (or adding it as alternative name). The Committee decided to refer this request to a later meeting to allow for a more careful evaluation of the possible implications of this requested name change. The following requests for corrections, reported to the Joint JECFA Secretariat, were evaluated by the Committee and found to be necessary. However, these corrections will only be made in the electronic versions available in the online database.

Substance	Original text	Revised text	Additional information
Saccharin	An ADI of 0–5 mg/kg bw for saccharin and its Ca, K, Na salts was established at 41st JECFA.	A group ADI of 0–5 mg/kg bw for saccharin and its Ca, K, Na salts, expressed as Na saccharin, was established at 41st JECFA.	The reporting basis for saccharins should be revised as "For saccharin and its Ca, K, Na salts, expressed as Na saccharin"
Paprika oleoresin Monograph	Functional uses: colour, flavouring agent	Functional uses: flavouring agent	Correct functional class
Lysozyme Monograph	Functional uses: preservative (mainly to prevent the late blowing of cheese caused by *Clostridium tyrobutyricum*)	Functional uses: processing aid for cheese production	Correct functional class
β-carotene, synthetic INS 160a(i) Monograph	In the "purity test", "procedure" section, the impurity at relative retention time of 0.85 currently reads all-*trans*-□-carotene (0.85), In the "purity test", "calculation" section, the formula is wrong; the multiplication sign should be replaced by a subtraction sign	It should read "all-trans-γ-carotene". $\frac{A_{\text{total}} - A_{\beta\text{-carotenes}}}{A_{\text{total}}} \times 100$	Transcription errors
Jagua blue Monograph	Synonyms: Jagua blue Name: "Jagua (genipin-glycine) blue (Jagua blue)"	Add synonyms. Synonyms: Jagua blue, Genipapo, huito blue, huito, jagua. Name: jagua (genipin-glycine) blue	Improves understanding Transcription error
Steviol glycosides Framework	"Reagents" section (page 11) - Mobile phase A: Deionized water, HPLC or LC-MS grade, filtered using a 0.2-µm filter, with 0.1% formic acid or acetic acid. (Note: If only UV detection will be used, 20 mM sodium phosphate buffer at pH 2.6 or 0.01% trifluoroacetic acid may be used.)	"Reagents" section (page 11) to be amended to read: "0.01% formic acid or acetic acid."	Transcription error
Steviol glycosides Framework	The Molecular Weight RRF values in Table 2: Rebaudioside B: 0.82 Steviolbioside: 0.83	The Molecular Weight RRF values located in Table 2 (pages 13, 14) to be amended: Rebaudioside B: 0.83 Steviolbioside: 0.66	Transcription error
Steviol glycosides Framework	Calculate the concentration of minor steviol glycosides: Conc. (% w/w) = CX x MX x 100 / MA x Csample	Conc. (% w/w) = CX x MX x 100 / (MA x Csample)	Transcription error
Steviol glycosides	"Equilibration"	"Equilibration"	Item for discussion: request for

Framework	Powdered samples should be equilibrated in the lab not less than 12 hours before assaying.	"Powdered samples and powdered standards should be equilibrated in the lab not less than 12 hours before assaying." Addition of Note: "An unopened reference standard with moisture listed on a Certificate of Analysis may be used without equilibrating."	amendment to and addition of a note to the "Equilibration" section
Steviol glycosides Framework	"Equilibration" The loss on drying of the equilibrated sample should be determined concurrently with performing the assay using the conditions in Annexes 1–4 (Vol. 4).	"Equilibration" "The loss on drying of the equilibrated sample should be determined concurrently with performing the assay using the conditions in Annexes 1–4 (Vol. 4). Karl Fischer titration may be used as an alternative to loss on drying for determining moisture of equilibrated samples and standards when performing the assay."	Item for discussion: request for addition of Karl Fischer titration as alternative