Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

Ninety-ninth meeting (Safety evaluation of certain food additives)

11–20 June 2024

SUMMARY AND CONCLUSIONS

Issued on 5 July 2024

The Ninety-ninth meeting of the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Executive Committee on Food Additives (JECFA) was held in Geneva from 11 to 20 June 2024. The purpose of the meeting was to evaluate the safety of certain food additives. The present meeting was the Ninety-ninth in a series of similar meetings. The tasks before the Committee were to (a) further elaborate principles governing the evaluation of food additives and enzymes; (b) undertake safety evaluations of certain food additives and enzymes; (c) review and prepare specifications for certain food additives and enzymes; and (d) review specifications for certain flavouring agents.

Dr D. Benford served as Chairperson and Dr R. Cantrill served as Vice-chairperson. Mr K. Petersen and Ms A. Vlachou served as joint secretaries.

The Committee evaluated the safety of four food additives and four processing aids, and revised the specifications for 10 flavouring agents.

The report of the meeting will be published in the WHO Technical Report Series (No. 1056). 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, enzymes examined by the Committee and 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. A related checklist to assist sponsors in the provision of information required for the safety assessment of enzyme preparations for use in foods is provided in Annex 3. Recommendations made by the Committee at the Ninety-ninth JECFA meeting are summarized in Annex 4.

Toxicological monographs summarizing the data that were considered by the Committee in establishing ADIs will be published in WHO Food Additives Series No. 90. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs No. 34.

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 conclusions

Food additives evaluated toxicologically, assessed for dietary exposure and specifications

Food additive	JECFA enzyme identifier	Specifications	ADIs and other conclusions on toxicology and dietary exposure
Adenosine-5′-monophosphate deaminase from *Aspergillus sp.*	JECFA99-1	No[a]	Because of a lack of information to confirm the identity of the production organism and whether the test material used in the toxicity studies is representative of the current article of commerce, the Committee could not complete the safety evaluation of this enzyme preparation.
Butterfly pea flower extract	–	No[a]	Because of the limited nature of the toxicological data and the uncertainties concerning the specifications for the commercial product and the characterization of the test materials in the submitted toxicity studies, the Committee was unable to complete the safety assessment of butterfly pea flower extract.
Endo-1,4-β-xylanase from *Bacillus subtilis* expressed in *Bacillus subtilis*	JECFA99-2	N	The Committee concluded that dietary exposure to this endo-1,4-β-xylanase enzyme preparation is not anticipated to pose a risk for allergenicity. The Committee identified a NOAEL of 147.3 mg TOS/kg bw per day, the highest dose tested, in a 13-week study in rats. Comparison of this NOAEL with the estimated dietary exposure of 0.008 mg TOS/kg bw per day gives an MOE of more than 18 000. Based on this MOE and the lack of concern for genotoxicity, the Committee established an ADI "not specified"[b] for endo-1,4-β-xylanase (JECFA99-2) from *Bacillus subtilis* expressed in *Bacillus subtilis* when used in the applications specified, at the levels of use specified and in accordance with current GMP.
Endo-1,4-β-xylanase from *Rasamsonia emersonii* expressed in *Aspergillus niger*	JECFA99-3	N	The Committee concluded that the risk of allergenicity upon dietary exposure to this endo-1,4-β-xylanase is low. The Committee identified a NOAEL of 1850 mg TOS/kg bw per day, the highest dose tested in the 13-week study in rats. Comparison of this NOAEL with the highest estimated dietary exposure of 0.380 mg TOS/kg bw per day in toddlers gave a margin of exposure (MOE) of more than 4800. On the basis of this MOE and lack of concern about genotoxicity, the Committee established an ADI "not specified" for this endo-1,4-β-xylanase (JECFA99-3) from *R. emersonii* expressed in *A. niger* when used in the applications specified, at the levels of use specified and in accordance with GMP.
Glucosidase from *Aspergillus niger* expressed in *Trichoderma reesei* exhibiting α-glucosidase and transglucosidase activity	JECFA99-4a, JECFA99-4b	N	The Committee concluded that dietary exposure to this glucosidase is not anticipated to pose a risk for allergenicity. The Committee also had no concerns about potential genotoxicity of the enzyme concentrate. The Committee identified a NOAEL of 74.8 mg TOS/kg bw per day, the highest dose tested, for the enzyme concentrate in the 18-week study in rats. Comparison of this NOAEL with the estimated dietary exposure of 0.443 mg TOS/kg bw per day gave an MOE of 169. The Committee therefore established an ADI "not specified" for glucosidase from *A. niger* expressed in *T. reesei* exhibiting α-glucosidase (JECFA99-4a) and transglucosidase (JECFA99-4b) activity when used in the applications specified, at the levels of use specified and in accordance with GMP.
Natamycin	–	R	Based on the available data, the Committee concluded that there is no concern for the induction of antimicrobial resistance and that the risk of natamycin having a disrupting effect on the microbiome of the human gastrointestinal tract is low. The Committee re-affirmed the ADI of 0–0.3 mg/kg bw for natamycin established by the previous Committee at its Twentieth meeting. The Committee further noted that the NOAELs in the new 13-week and 1-year studies in rats (42 and 26 mg/kg bw per day, respectively), with the application of a 100-fold uncertainty factor, support the current ADI of 0–0.3 mg/kg bw.
Nisin A	–	R	Based on the available data, the Committee concluded that there is no concern for the induction of antimicrobial resistance, and that the risk of nisin having a disrupting effect on the microbiome of the human gastrointestinal tract is low. The new toxicological information available for this evaluation did not provide any reason to revise the ADI for nisin. The Committee re-affirmed the ADI of 0–2 mg/kg bw for nisin established by the previous Committee at the Seventy-seventh meeting, but noted that the critical toxicological studies were conducted

			with nisin A; the Committee therefore concluded that the ADI applies only to nisin A.
Polyglycerol esters of fatty acids	–	R	At its Seventeenth meeting, the Committee established an ADI of 0–25 mg/kg bw for Polyglycerol esters of fatty acids, based on a long-term study in rats in which there were no effects at 2500 mg/kg bw, the highest dose tested. In the absence of any new toxicological information, the present Committee re-affirmed the ADI of 0–25 mg/kg bw.

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

[a] Specifications were drafted but could not be finalized for publication because of a lack of critical information. Information is required to complete the specifications.

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

Favouring agents considered for specifications only

Food additive	No.	Specification
S-methyl thioacetate	482	R
S-methyl 3-methylbutanethioate	487	R
4,5-dihydro-3(2*H*) thiophenone	498	R
2-methyltetrahydrothiophen-3-one	499	R
1-Butanethiol	511	R
o-Toluenethiol	528	R
bis(Methylthio)methane	533	R
3-Mercaptohexyl acetate	554	R
3-Mercaptohexyl butyrate	555	R
3-Mercapto-2-pentanone	560	R

R: revised specification.

Annex 1. List of participants

Members

Dr S. Barlow, Brighton, East Sussex, United Kingdom of Great Britain and Northern Ireland

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Secretariat

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Dr H.-J. Yoon, Department of Food Safety and Regulatory Science, Chung-Ang University, Republic of Korea *(WHO Expert)*

Annex 2. General considerations

Lack of data for food additives prioritized by the Codex Committee on Food Additives (CCFA) for re-evaluation by JECFA

During the meeting, the Committee noted that CCFA prioritized certain food additives for JECFA re-evaluation. The Committee was extremely disappointed to find that no new data on the microbiological effects were submitted for natamycin and nisin of relevance to the request from CCFA. In addition, no new toxicological data were submitted for nisin. For polyglycerol esters of fatty acids, no new toxicological data were submitted or found in a literature search.

The Committee would like to remind CCFA of the limited resources of JECFA, and recommends that CCFA place greater emphasis on ensuring the availability of new data before a food additive is prioritized for JECFA re-evaluation.

Mapping food categories of the General Standard for Food Additives (GSFA) to the FoodEx2 classifications

At its Eighty-ninth meeting, the Committee concluded that an appropriately refined dietary exposure assessment for Sucrose esters of fatty acids (INS No. 473) and Sucrose oligoesters, type I and type II (INS No. 473a) could not be undertaken using the FAO/WHO Chronic individual food consumption database (CIFOCOss) because of the inability to map it to the large number of food categories with use levels provided. It was concluded that food category mapping between the FoodEx2 categories *(1)* used for the food consumption data and GSFA food categories was needed. This issue with calculations of exposure also arose at the current meeting for the dietary exposure assessment of Polyglycerol esters of fatty acids (INS No. 475).

The Committee is aware of the work currently being undertaken by a group of CCFA members to map the GSFA food categories to the FoodEx2 food classification system, and requests that the mapping be finalized as soon as practicable.

The mapping, together with submissions of food industry data on uses and use levels for food additives under evaluation by the Committee, will enable more refined estimates of dietary exposure to be undertaken for a greater number of countries. This will inevitably better support the CCFA by providing clear conclusions on the safety assessments of food additives and will assist in the establishment of its priority list of food additives for re-evaluation by JECFA.

Enzyme submissions

The Committee reiterated the conclusions from the Ninety-fifth meeting *(2)* that, when considering enzymes as processing aids, the submissions from the sponsor did not always conform to the requirements set out in the appendix of section 9.1.4.2 of the second edition of *Principles related to specific groups of substances*, chapter 9 of Environmental Health Criteria 240 *(3)*. The Committee recommends that sponsors use the checklist (Annex 3) and supply the requested information, at a minimum as a link to the required information, among their submission documents. The Committee asked the JECFA Secretariat to include a reference to the checklist in future calls for data for enzymes.

Sponsors are reminded of the requirement to provide a statement detailing the enzyme activity as per the checklist. To clarify, this statement should take the following format: “One unit of XX enzyme activity is defined as the amount of enzyme required to convert one (1) μmole of substrate to product per minute under the conditions of the test”. The method that is submitted should be sufficiently detailed to be easy to apply in any laboratory; it should not require unique or expensive equipment (such as an autoanalyser), a calibrant with unique assigned activity or other restricted substances.

References

1. The food classification and description system FoodEx2 (revision 2). Parma: European Food Safety Authority; 2015.
2. Evaluation of certain food additives and contaminants: ninety-fifth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1042, https://iris.who.int/handle/10665/370106, accessed 1 July 2024).
3. Section 9.1.4.2. Enzymes. Chapter 9. Principles related to specific groups of substances, second edition. In: Environmental health criteria 240. Rome: Food and Agriculture Organization of the United Nations; Geneva: World Health Organization; International Programme on Chemical Safety (IPCS); 2020 (https://www.who.int/docs/default-source/food-safety/publications/section9-1-4-2-enzymes.pdf?sfvrsn=e238e86e_2, accessed 3 July 2024).

Annex 3. JECFA enzyme submission checklist

Information to be provided by the sponsor for the safety assessment of enzyme preparations for use in foods

No.	Class(es)[a]	Information required	Details/rationale	Information to be provided by sponsor (document title, section, page number)
Enzyme classification and description of active components of enzyme preparation				
1.	All	Name of enzyme(s)	e.g. Triacylglycerol phosphodiesterase	
2.	All	Systematic name(s) and number(s)	EC/IUBMB no.; CAS no. (where appropriate)	
3.	All	Molecular weight(s)	As determined by SDS PAGE, gel filtration chromatography etc.	
4.	All	Amino acid sequence(s)	Predicted and determined primary amino acid sequence	
5.	All	Catalytic activity	All reactions catalysed including any secondary activities, conditions under which catalysis occurs (e.g. pH, temperature)	
6.	All	Historical use(s) in food-based applications	Evidence of commercial food use, including from the parent strain or the lineage (e.g. as a processing aid in the manufacture of bakery products, pasta and noodles, in egg yolk and in oil degumming)	
7.	All	Use levels in food(s)	Express each use as total organic solids (TOS) in mg/kg food	
8.	All	Fate in final food(s)	Is the enzyme active, inactive or removed? How is the enzyme inactivated/removed?	
9.	All	Existing safety evaluations	Include any existing health-based guidance values (e.g. ADI)	
Details about the production organism				
10.	All	Identity of the production organism	Identify genus, species, strain	
11.	I (iii), II	Host/recipient organism	Identify genus, species	
12.	I (iii), II	Donor/source of genetic material	e.g. Identify source of genetic material by genus, species (native, modified or synthetic)	
13.	I (iii), ii	Details of genetic modification:		
		(i) to host genome;	History of development of host strain (e.g. deletion of gene clusters that encode for aflatoxins, modifications that make host extracellular protease deficient or make it non-sporulating, etc.), identification of genes removed/added	
		(ii) addition of rDNA (gene of interest from another microorganism) to host microorganism through mobile genetic elements	Donor/source of genetic material, details on how the genetic element was designed and the identity of genes on the element, stability information, copy numbers, whether it integrates or does not integrate into host genome, etc. Evidence that genetic material does not contain genes coding for virulence factors, protein toxins, or any enzymes that may be involved in the synthesis of mycotoxins.	
14.	I (iii), II	Genetic modification techniques	Site-directed mutagenesis, chemical mutagenesis, recombinant DNA technology, etc.	
15.	I (iii), II	Description of intended and non-specific effects resulting from genetic modification and any changes carried out to prevent unwanted side reactions/products	e.g. An intended effect may be increased yield; a non-specific effect may be activation of toxin production. Rectification measures may include genetic modifications, specific fermentation conditions etc.	
16.	All	Deposit information (if applicable)	e.g. ATCC no.	
Production of enzyme concentrate and preparation				
17.	All	Detailed manufacturing process	For enzymes in Class I(i) and Class I(ii), and Class II enzymes	

			derived from plants and animals, manufacturing details are required. For enzymes in Class I(iii) and Class II produced by microorganisms, include details describing controlled fermentation inputs and conditions; the steps taken to retain genetic modifications; and further processing, purification and concentration steps. Indicate how production strains are maintained under conditions that ensure the absence of genetic drift and, when used in the production of enzyme preparations, indicate the methods and conditions that are applied to ensure consistency and reproducibility from batch to batch. Such conditions must ensure the absence of toxin production by the source organism and prevent the introduction of microorganisms that could be the source of toxic or other undesirable substances.
18.	All	Formulation ingredients	Identify the carriers, diluents, excipients, supports and other additives and ingredients (including processing aids) used in the production, stabilization and application of enzyme preparations, which must be acceptable for food use. In order to distinguish the proportion of the enzyme preparation derived from the source material as opposed to that contributed by diluents and other additives and ingredients, individual specifications require a statement of percentage TOS defined: $\% \text{ TOS} = 100 - (A + W + D)$ where A = % ash, W = % water and D = % diluents and/or other additives and ingredients. TOS content is usually expressed in milligrams or micrograms TOS per kilogram body weight per day.
Specifications and data required for enzyme concentrates and preparations			
19.	All	Description	Physical form of the enzyme preparation (liquid, semiliquid or dried product)
20.	All	Purity	Impurities including elemental and microbiological impurities. Analytical test methods, validation data, representative batch data (minimum of 5 batches) are required.
21.	All	Enzyme characterization	Enzyme activity (including method of assay, activity unit definition), molecular weight determination for the enzyme and other specific identification techniques. A universally usable test method to define enzyme activity present in the preparation should be submitted. Analytical test methods, validation data, representative batch data (minimum of 5 batches) are required.
22.	All	Analysis of at least five non-consecutive batches of the enzyme concentrate (for enzymes in Class II, at least one of which should have been used for toxicological testing)	e.g. TOS, enzyme activity, protein concentration, impurities, absence of antibiotic inactivating proteins, etc.
23.	All	Composition of at least five non-consecutive batches of the product(s) of commerce (enzyme preparation)	e.g. Stabilizers, pH adjustment agent, carriers, diluents, preservatives, etc.
24.	I (iii), II	Information on carryover of allergens from the fermentation media to the enzyme concentrate	Identification of major food allergens in media components
25.	I (iii), II	Evidence for absence of recombinant DNA and production	

	organisms in the enzyme concentrate	
Assessment of potential allergenicity of the enzyme		
26. I (iii), II	Comparison of the amino acid sequence of the enzyme to known allergens	In silico comparison of primary amino acid structure with allergen databases to confirm the absence of sequence homology with known allergenic proteins. (i) Sequence homology (35% of a sliding window of 80 amino acids) (ii) Sequence identity in contiguous stretches of 8 amino acids within the enzyme sequence. All the information resulting from the sequence homology comparison between an expressed enzyme and known allergens should be reported. If any of the identity scores equal or exceed 35%, this is considered to indicate significant homology and needs to be scientifically considered in the context of a safety assessment for enzymes in food.
27. I (iii), II	Proteolysis resistance/digestibility of the enzyme	e.g. Simulated gastric fluid studies, etc.
Toxicology		
28. II	Results of toxicological testing of the enzyme concentrate	It is necessary to conduct toxicological studies in order to establish an ADI: (i) 90-day oral toxicity test in a rodent species; and (ii) two short-term genotoxicity tests (mutagenicity and clastogenicity): (a) for gene-mutation in bacteria and (b) for chromosomal aberrations (preferably in vitro)
29. I (iii), II	Bioinformatic analysis of the amino acid sequence for potential matches with known toxins	Explanation of the analysis and interpretation should be provided
Dietary exposure assessment		
30. II	Estimate of dietary exposure to the enzyme preparation calculated on the basis of TOS. Separate dietary exposure situations may need to be considered with respect to the enzymes described in Classes I (iii) and II, depending on whether they are (i) enzyme preparations added directly to food and not removed; (ii) enzyme preparations added to food but removed from the final product according to GMP; or (iii) immobilized enzyme preparations that are in contact with food only during processing.	Express the dietary exposure as mg TOS/kg bw per day; provide an explanation of the methodology used to derive the estimated dietary exposure
31.	Additional information and comments	Additional items considered helpful in the safety assessment

ADI: acceptable daily intake; ATCC: American Type Culture Collection; CAS: Chemical Abstracts Service; EC: Enzyme Commission; GMP: Good Manufacturing Practices; IUBMB: International Union of Biochemistry and Molecular Biology; TOS: total organic solids.

[a] Class I: enzymes derived from sources that are considered safe for consumption and for which toxicological evaluations are not normally required. Type i: enzymes obtained from edible tissues of plants or animals commonly used as foods. Type ii: enzymes derived from microorganisms that are traditionally accepted as constituents of foods or are normally used in the preparation of foods. Type iii: enzymes derived from a Safe Food Enzyme Production Strain or a Presumed Safe Progeny Strain. Class II: enzymes derived from sources which are NOT considered safe for consumption and are not in any of the sub-categories listed above.

Annex 4. Recommendations and future work

Information required to be submitted for review

Food additive	JECFA enzyme identifier	Recommendations
Adenosine-5′-monophosphate deaminase from *Aspergillus sp.*	JECFA99-1	The Committee requires the following information to be submitted before the enzyme preparation can be considered for review at a future meeting: results from whole genome sequencing, using appropriate technologies, to confirm the identity of the current production organism (genus, species and strain); data demonstrating that the current large-scale production conditions do not lead to the synthesis of toxic secondary metabolites; data demonstrating multigenerational stability of the current production organism; results from five batches of the article of commerce produced by the current production organism showing the absence of mycotoxins; a robust method of enzyme activity assay using commercially available standards that does not use a proprietary enzyme as a calibrant; and data to determine whether the batches of test materials used in the already submitted toxicological studies are representative of the current article of commerce.
Butterfly pea flower extract	–	The following information is required to complete the specifications for butterfly pea flower extract: quantitative composition of non-colouring components (carbohydrates, proteins and plant lipids) of butterfly pea flower extract from at least five batches of the article of commerce; detailed methods for determination of water content, Brix and colour strength; and analysis of the article of commerce using both alkali saponification and acid hydrolysis. In addition, the following information is required to complete the safety assessment for butterfly pea flower extract: studies on reproductive and developmental toxicity with a test material that is representative of the article of commerce, given the indications of systemic exposure and possible estrogenic activity of the polyphenol constituents (i.e. delphinidin, quercetin and kaempferol); quantitative characterization of the test articles used in the already submitted toxicity studies to assess whether they are representative of the article of commerce; and, if the article of commerce differs substantially from the test material used in the already submitted toxicity studies (90-day and genotoxicity studies), new studies on the same end-points.
Polyglycerol esters of fatty acids	–	The Committee makes the following recommendations. Considering the potential high exceedance of the ADI based on the estimated dietary exposures, the CCFA should review and revise current uses of Polyglycerol esters of fatty acids in the GSFA, including the maximum permitted levels and the food categories in which this food additive is permitted to be used. The food industry should provide use levels of Polyglycerol esters of fatty acids by the end of 2026 to enable more refined estimates of dietary exposure to be calculated by the Committee. When these data are provided, the Committee will reconsider the safe use of Polyglycerol esters of fatty acids. Dietary exposure estimates are required from a larger number of countries before the Committee can draw robust conclusions about the safety of use of Polyglycerol esters of fatty acids. These should be based on industry use levels where possible. The Committee encourages Member States to provide dietary exposure estimates by the end of 2026.

ADI: acceptable daily intake; CCFA: Codex Committee on Food Additives; GSFA: General Standard for Food Additives.