

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 3(b)

CX/FA 26/56/4 Add.1

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Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-sixth Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 100TH JECFA MEETING

COMMENTS AT STEP 3 IN REPLY TO CL 2026/20-FA

(Comments by Australia, Chile, Ecuador, Egypt, Iraq, Paraguay, Philippines, Qatar, Senegal, and Calorie Control Council (CCC), International Food Additives Council (IFAC))

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2026/20-FA¹ issued in January 2026. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

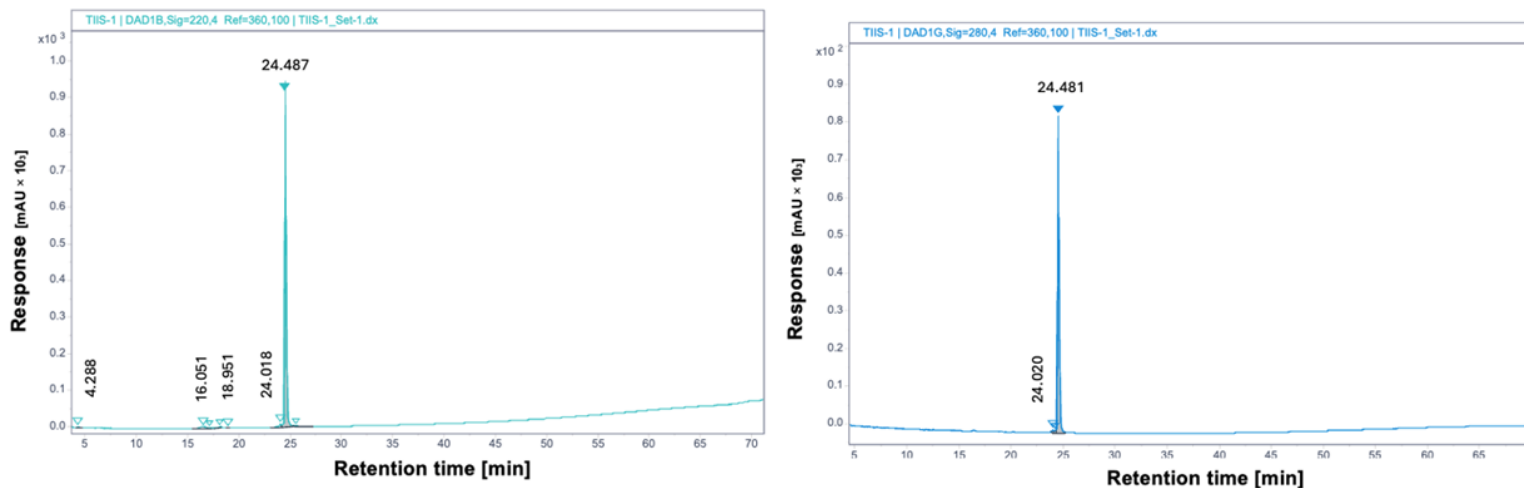
¹ <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCFA>

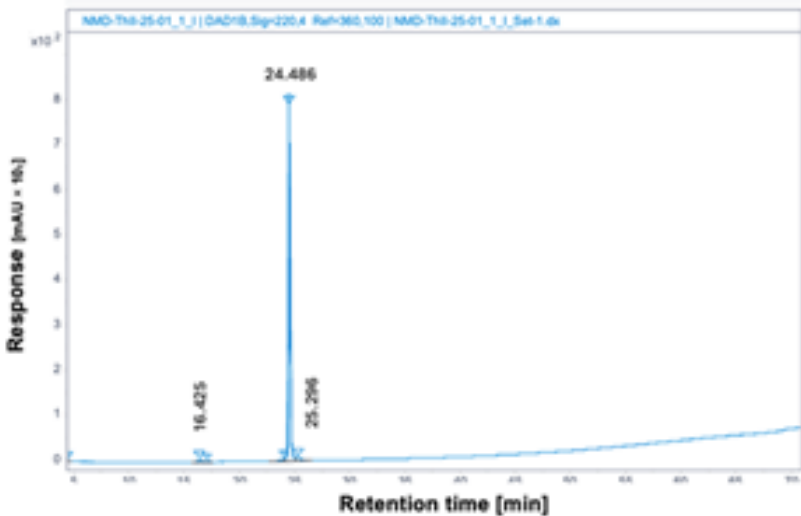
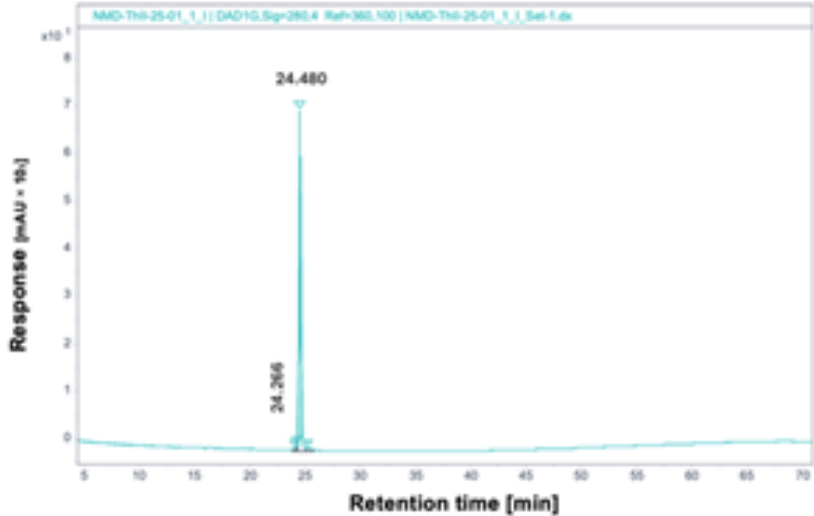
ANNEX

COMMENT	MEMBER / OBSERVER
Australia supports the adoption of all the listed food additives and Processing aids.	Australia
Chile agradece el trabajo realizado por JECFA y esta de acuerdo con las especificaciones de aditivos y de coadyuvantes de elaboración designadas como completas	Chile
Ecuador expresa su apoyo general al avance de los anteproyectos de especificaciones de identidad y pureza de los aditivos alimentarios evaluados por el JECFA, reconociendo el rigor científico y la relevancia de dichas especificaciones para la protección de la salud del consumidor y la armonización internacional. No obstante, el país considera importante que, durante el proceso de adopción final, se tengan en cuenta las capacidades técnicas y regulatorias de los países en desarrollo, en particular en lo referente a: • La disponibilidad y aplicabilidad de métodos analíticos, recomendando la inclusión de métodos alternativos o equivalentes validados, cuando sea técnicamente viable. • La adecuada justificación de los criterios de pureza y de los límites de impurezas, basados en evaluaciones de riesgo, a fin de evitar barreras técnicas innecesarias al comercio. • La necesidad de prever periodos de transición razonables y promover acciones de cooperación técnica y fortalecimiento de capacidades para facilitar la implementación efectiva de las especificaciones.	Ecuador
Egypt appreciates the work undertaken in the 100th meeting of the Joint FAO/WHO Expert Committee on Food Additives and expresses its support for the proposed draft specifications resulting from this meeting.	Egypt
Agree.	Iraq
Paraguay reconoce la importancia del trabajo científico realizado por el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA) en su 100.ª reunión, en la revisión y elaboración de especificaciones de identidad y pureza aplicables a aditivos alimentarios y coadyuvantes de elaboración. Estas especificaciones constituyen una referencia técnica fundamental para la armonización normativa internacional y regional, particularmente en el contexto de la incorporación de coadyuvantes de elaboración en los marcos regulatorios regionales. Paraguay destaca la relevancia de estos trabajos para el fortalecimiento y consolidación de su marco regulatorio nacional en materia de aditivos alimentarios y coadyuvantes de elaboración, en coherencia con el uso de evaluaciones científicas internacionales como base para la toma de decisiones regulatorias. En virtud de lo expuesto, Paraguay acompaña que las especificaciones designadas como completas sean adoptadas como especificaciones del Codex de identidad y pureza de los aditivos alimentarios.	Paraguay
The Philippines supports the recommendation to adopt the specifications of food additives, whether new or revised, including the new specifications for the processing aids designated as “FULL” arising from the 100th JECFA Meeting. JECFA evaluated the food additives toxicologically and assessed their dietary exposure based on available data, leading to the reaffirmation of previously established ADIs and revision of others, including the withdrawal of numerical limits and the establishment of group ADIs of “not	Philippines

COMMENT	MEMBER / OBSERVER
specified,” and concluded that the dietary exposure, including the additives’ relevant impurities, does not pose a safety concern under the intended conditions of use. Furthermore, the specifications of processing aids under consideration were revised accordingly based on existing data, removing the tentative status of previous specifications and reaffirming the ADI as “not specified”.	
Qatar offers no objections to the progression of the proposed draft specifications at this stage and looks forward to continued constructive engagement during discussions at CCFA56.	Qatar
Le Sénégal appuie les recommandations du JECFA concernant l'adoption des 06 additifs alimentaires et des sept auxiliaires technologiques dont les spécifications sont désignées « complètes », tels qu'énumérés dans l'Annexe du CX/FA 26/56/4 (reprise ci-dessus).	Senegal
All page numbers below refer to FAO JECFA Monographs 35 (2026), which is available at: https://openknowledge.fao.org/items/c69eaacfd6b-478e-ad98-3e7d90df6275 Page: 50 (title page) Section: DEFINITION “Thaumatococcus protein is produced by expressing the thaumatococcus II gene in the seeds of the host plant, <i>Nicotiana glauca</i> (L.), via stable expression in lines generated by <i>Agrobacterium tumefaciens</i>-mediated methods.” Justification/Explanation for Revisions The Latin binomials should remain italicized, as they currently appear in the Monograph. The first sentence in the DEFINITION paragraph incorrectly refers to the method used for genetic expression of the thaumatococcus II gene as “induction.” While prior methods have used induction techniques (e.g., viral vector; chemical), the current process relies on stable expression of the thaumatococcus II gene in the seeds of the host plant. Page: 50 (title page) Section: IDENTIFICATION > HPLC “The retention time corresponding to Thaumatococcus II is approximately 24.5±0.1 min” Justification/Explanation for Revisions The retention time is expressed as a deviation range, so the symbol should be “±” (plus/minus) and not + Page: 51 Section: TESTS > Purity > Reagents “ – Aliquots of lyophilized TIIS can be stored at room temperature, but preferably at 4 °C, and dissolved in deionized water before use.” Justification/Explanation for Revisions The words “are” and “as needed” as they appear in that sentence were deleted and replaced with the revised sentence shown above for better accuracy Page: 52 Section: TESTS > Purity > Equipment “Vortex mixer: Minishaker (IKA-Werke or equivalent)”	CCC

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Justification/Explanation for Revisions The word “Vortexer” in the current document was replaced with the word “Vortex mixer” as the more conventional term Section: TESTS > Purity > HPLC Conditions “— Retention time: Approximately 24.5+0.1 min (Thaumatococcus II)” “— Retention time of Working Standard (TIIS): Approximately 24.5+0.1 min (Thaumatococcus II)” Justification/Explanation for Revisions The retention time is expressed as a deviation range, so the symbol should be “+” (plus/minus) and not + Page: 53 Section: TESTS > Purity > System Suitability “System Suitability Standard Solution Preparation for Analysis MassPREP Protein Standard Mix (Waters Inc.) is dissolved in 0.1% TFA, aliquoted to 50 µl in HPLC vials and stored at -20 °C. For analysis, the HPLC vials are removed from the freezer and transferred into the LC autosampler. 5 µl of System Suitability Standard Solution is used for injection in triplicates.” Justification/Explanation for Revisions The title should be revised as shown for uniformity to other sections. System Suitability Standard Solution should be capitalized as it is a referenced substance, just like Protein Standard Mix. Page 53 Section: TESTS > Purity > Thaumatococcus II Standard “Thaumatococcus II Standard (TIIS) Solution Preparation for Analysis The content of one tube of TIIS is dissolved in deionized water to prepare a primary TIIS stock solution of 5 mg/ml protein concentration....” Justification/Explanation for Revisions The title was revised for clarity. The first sentence was revised because freeze-dried Thaumatococcus II Standard (TIIS) is stored at RT or 4°C; therefore, thawing is not required and the phrase referencing thawing (“Freeze-dried TIIS are thawed to room temperature”) was removed. Page 53 Section: TESTS > Purity > Sample Preparation for Analysis “Sample Preparation for Analysis. Thaumatococcus II-containing samples of freeze-dried powders...” Justification/Explanation for Revisions The first sentence should read “Thaumatococcus II-containing samples”, rather than “Thaumatococcus II samples”. Section: TESTS > Purity > Results “4. The retention time for Thaumatococcus II is 24.5+0.1 min ...” Justification/Explanation for Revisions The retention time is expressed as a deviation range, so the symbol should be “+” (plus/minus) and not + Page: 54 Section: TESTS > Purity > Data Processing The equation should be changed to: “%Thaumatococcus II Purity = [Wt/W] x [A/At] x P x 100”	

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And the legend below the new equation should include, as the last entry line: “P: purity of the Working Standard (expressed as a decimal, e.g., 0.98 for 98%)” Justification/Explanation for Revisions The current formula in the monograph for Thaumatin II purity (%Thaumatin II = $[Wt/W] \times [At/A] \times 100$) ignores the purity of the Standard, treating it as if it were 100% pure, which is usually not the case. We would prefer to use the formula shown above that takes into account the purity (P) of the Standard, which may vary from lab to lab conducting the assay. In addition, a new line entry should be added to the legend below the new equation, with the definition of Purity (P). Pages: 54 and 55 Section: TESTS > Purity > Results The titles for Figure 5 and Figure 6 should be revised to read: “Figure 5. Representative chromatograms for Thaumatin II in the Working Standard at 220 nm (top image) and 280 nm (bottom image) are shown”  “Figure 6. Representative chromatograms for Thaumatin II in Sample at 220 nm (top image) and 280 nm (bottom image) are shown”	

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  Justification/Explanation for Revisions The titles were inconsistent and have been corrected. Figure 6 should specifically state that the chromatograms are for Thaumatin II in the product Sample. Page: 55 Section: TESTS > Total Protein > Bradford assay definition “Bradford protein analysis with a bovine serum albumin (BSA) standard curve is used to determine the total protein in the dry bulk product.” Justification/Explanation for Revisions The text “...in the dry bulk product” was added for clarity Page: 56 Section: TESTS > Total Protein > Bradford assay > Consumables The names of consumables need not be capitalized (i.e., use serological instead of Serological; disposable instead of Disposable; plastic instead of Plastic; etc.) Justification/Explanation for Revisions The words for supplies were de-capitalized following convention Page 56 Section: TESTS > Total Protein > Bradford assay > Protein assay dye reagent The following revised paragraph should be used: “Protein assay dye reagent	

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Gently mix the Bradford Reagent in the bottle and bring to room temperature. Prepare dye reagent by diluting 1 part Dye Reagent Concentrate with 4 parts deionized water. Filter through Whatman #1 filter (or equivalent) to remove particulates. This diluted reagent should be stored in the dark and preferably used shortly after preparation, but may be stored for up to 2 weeks if kept at room temperature.” Justification/Explanation for Revisions There were several incorrect statements in the original text. Terms including “approximately”, “stored in the dark”, and “diluted dye reagent is freshly prepared” were deleted and the narrative detail was expanded, for accuracy, as shown above. Page 56 Section: TESTS > Total Protein > Bradford assay > Sample solutions The referenced solutions should be capitalized as shown below. Note: the terms that were correctly italicized in the original document should remain italicized in the updated document. Sample solutions “1. Sample Stock Solution (2 mg/ml): Dissolve and dilute the dry Thaumatin II-containing product samples to 2 mg/ml (w/w) with deionized water. Prepare in triplicate. 2. Diluted Sample Solutions (0.2 mg/ml): Prepare independent 1:10 dilutions of each Sample Stock Solution from step 1 by combining 100 µl of each 2 mg/ml Sample Stock Solution and 900 µl deionized water. Prepare in duplicate and label accordingly. 3. Working Sample Solutions: Prepare Working Sample Solutions from the Diluted Sample Solutions (0.2 mg/ml) from step 2 as shown below. Prepare in duplicate. Transfer 100 µl aliquots of each of the Working Sample Solutions into clean 1.5 ml reaction tubes.” Justification/Explanation for Revisions The terms are referenced substances and should be capitalized for uniformity with other sections. Also, in the first entry (number 1), the description of the Sample Stock Solution preparation was expanded to clarify that the sample being prepared for analysis is the dry Thaumatin II-containing product, and not purified Thaumatin II. Page 57 Section: TESTS > Total Protein > Bradford assay > Procedure In item No. 6 on the same list, please revise the first sentence to read: “Calculate the total protein content of the sample...” (instead of the current: “Calculate Thaumatin II protein content...”, and revise the equation below item No. 6 to read: “%[Total Protein] = ...” (instead of the current: “%[Thaumatin II] =.” Justification/Explanation for Revisions The Bradford method is used to determine the total protein content in a product sample, not only the content of Thaumatin II. The Thaumatin II content is determined as shown in the section below, using a simpler calculation. Page: 57 Section: TESTS > Total Protein > Bradford assay > Procedure In item No. 1 on the list, please capitalize the term: “Working Sample Solutions” In item No. 5 on the list, please revise the first sentence to read: “Calculate the protein concentration in the Thaumatin II-containing samples as shown below. Only Blank-subtracted values...”	

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Justification/Explanation for Revisions The change in the text for item No. 5 was made to emphasize that the analyte is a Thaumatin II-containing sample and that total protein is being analyzed, not only Thaumatin II protein, which was implied by the current language. Page: 57 Section: METHOD OF ASSAY We suggest that the title of this section be changed to “METHOD OF CALCULATION” from the current METHOD OF ASSAY, as the equation that follows describes the calculation used to determine Thaumatin II concentration in the dry bulk product sample. In addition, we request that the current equation in this Section be replaced by the simpler equation shown below, including the subsequent explanation/example to appear following the equation: “%[Thaumatin II] = %Total protein in bulk product (w/w) x (decimal %Thaumatin II Purity) For example, in a bulk product containing 80% total protein (w/w; Bradford) and a Thaumatin II purity relative to total protein of 95% (w/w; HPLC, as 0.95), the Thaumatin II content of the product would be 76% (w/w); i.e., $80\% \times 0.95 = 76\%$ (w/w).”	
IFAC is providing comments specifically on the specifications for glycolipids (INS 246). Our comments are mainly editorial notes, such as duplications and the avoidance of brand names, in order to make the specification timeless. IFAC would like the heavy metal values to be included and adapted to the European Union (EU) and U.S. Food and Drug Administration (FDA) specifications. IFAC will be sending specific comments by email on the FAO JECFA Monographs Compendium of Food Additive Specifications 100th Meeting, specifically on glycolipids pages 38-43 of that document. Specific comments are available here.	IFAC