48th Meeting of the Codex Contact Points in the Arab Region

PREPARATION FOR THE 56TH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES

(CCFA56)

April 7th , 2026

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Agenda Item 3(b)

Proposed draft specifications for the identity and purity of food additives arising from the 100th JECFA meeting

- **Documents :CX/FA 26/56/4 ; CX/FA 26/56/4 Add.1**

Presented by : Noha Mohamed, Egypt- Najla, Jordan

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Background : Agenda Item 3 (b)

At the 100th meeting held in Rome, from 10 to 19 June 2025, Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the safety of five (5) food additives and seven (7) processing aids

A. Draft Specifications (For Adoption Consideration)
Newly Established ("Full") Specifications for Food Additives

Full specifications were prepared for four (4) food additives:

i. Gardenia (Genipin) Blue (INS 165) –colorant

ii. Low-acyl clarified Gella gum (INS 418(iii)) – gelling/thickening agent

iii. Glycolipids (INS 246) – emulsifier

iv. Thaumatin II – natural sweet protein

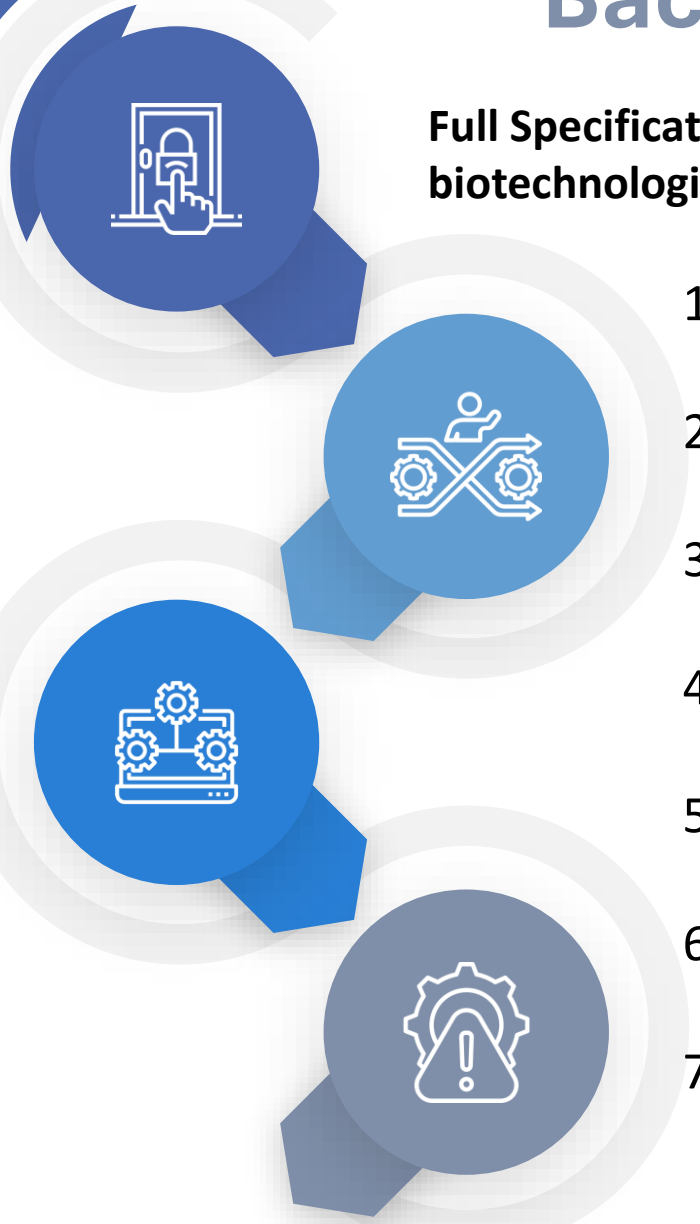
B. Revised Specifications for Existing Additives

Revised specifications were prepared for two (2) food additives:

i. Ascorbyl palmitate (INS 304) – antioxidant

ii. Gellan gum (INS 418(i)) – thickener/stabilizer

Background : Agenda Item 3 (b)



Full Specifications for seven (7) enzyme-based processing aids derived from microbial and biotechnological sources, namely:

1) α-Amylase (JECFA95-1) from Geobacillus stearothermophilus expressed in Bacillus licheniformis (N)
2) α-Amylase (JECFA95-2) from Geobacillus stearothermophilus expressed in Bacillus licheniformis (N)
3) α-Amylase (JECFA95-3) from Rhizomucor pusillus expressed in Aspergillus niger (N)
4) Amyloglucosidase (JECFA95-4) from Rasamsonia emersonii expressed in Aspergillus niger (N)
5) Asparaginase (JECFA95-5) from Pyrococcus furiosus expressed in Bacillus subtilis (N)
6) β-Amylase (JECFA95-6) from Bacillus flexus expressed in Bacillus licheniformis (N)
7) Xylanase (JECFA95-9) from Bacillus licheniformis expressed in Bacillus licheniformis (N)

Analysis

Stricter Lead Limit for Infant Products

A safety revision was highlighted:

For carob bean gum (INS 410):

- Maximum lead level reduced from 2 mg/kg → 0.5 mg/kg

Applies to:

Infant formula

Special medical formulas for infants

This reflects increased safety standards for vulnerable populations.

Key discussions and comments

- Nine delegations expressed strong support for adopting the proposed JECFA specifications, recognizing their scientific credibility and global relevance.
- No significant objections were raised; issues identified are mainly implementation-related, not scientific.
- No major scientific objections were raised against individual specifications; the issues identified are primarily implementation-related.
- Australia, Egypt, Iraq, Qatar, Chile, and Paraguay explicitly support adoption of all proposed specifications for both food additives and processing aids.
- Ecuador supports the proposals in principle but highlights key challenges for developing countries, including:
  - limited availability and applicability of analytical methods,
  - the need for clearer risk-based justification of purity criteria and impurity limits, and
  - the importance of reasonable transition periods and technical assistance.
- Several delegations emphasized the importance of continuous updating of specifications to reflect evolving manufacturing practices and advances in analytical methods.
- For Gardenia Blue, glycolipids, and Thaumatin II, comments mainly concern technical refinements to the specifications, rather than substantive concerns

Recommendations

The following recommendations may guide the regional coordination/ engagement at CCFA56:

- Support the adoption of the proposed draft specifications designated as “Full” arising from the 100th JECFA meeting, recognizing their scientific basis and level of technical maturity.
- highlight the importance of addressing implementation challenges, particularly in developing countries, including access to validated analytical methods, technical cooperation, and appropriate transition periods.
- emphasize that the specifications should adequately reflect stricter safety requirements for infant foods, ensuring that impurity limits are consistent with Codex standards for finished products.
- Seek clarification on whether the specifications clearly distinguish between general food uses and infant-formula uses, and whether impurity limits are sufficiently explicit to avoid ambiguity in national implementation.

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Agenda Item 4(a)

Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards

Presented by : Ahmed ELTOUKHY, Arab Republic of Egypt (EG)

Agenda Item 4(a)

4.1 Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards

(Document Number: CX/FA 26/56/5)

4.1.1 Endorsement and/or revision of maximum levels for food additives and processing aids in Codex standards (CCFO)

(Document Number: CX/FA 26/56/5 Add.1)

4.1.2 Endorsement of the food additives provisions of commodity standards,

(Document Number: CX/FA 26/56/5 Add.2)

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Agenda Item 4(a)

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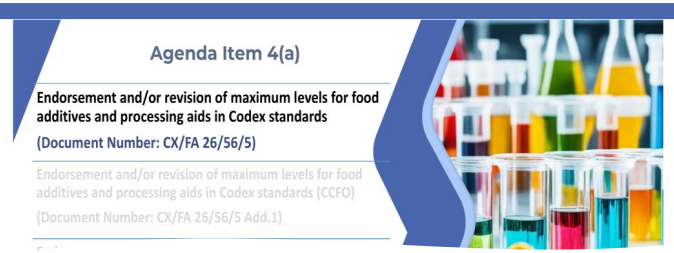
What is Requested from CCFA56?

CCFA56 is invited to consider for endorsement of the food additive provisions (refer to the document Annex) forwarded by:

- **The 23rd Session of the FAO/WHO Coordinating Committee for Asia (CCASIA23) (REP25/ASIA)**
  - Regional standard for quick-frozen dumplings (Asia) (for adoption by CAC at Step 8)
- **The 12th Session of the FAO/WHO Coordinating Committee for Near East (CCNE12) (REP25/NE)**
  - Regional standard for doogh (Near East) (CXS 332R-2018) (food additive provisions for adoption by CAC at Step 8)
  - Regional standard for maamoul (Near East) (for adoption by CAC at Step 8)
- **The 8th Session of the Codex Committee on Spices and Culinary Herbs (CCSCH8) (REP26/SCH)**
  - Standard for spices derived from dried or dehydrated fruits and berries - Requirements for vanilla (for adoption by CAC at Step 8)
  - Standard for spices in the form of dried fruits and berries - Requirements for large cardamom (for adoption by CAC at Step 5/8)
  - Standard for spices in the form of dried seeds - Requirements for coriander (for adoption by CAC at Step 5/8)
  - Standard for herbs - Requirements for sweet marjoram (for adoption by CAC at Step 5)

Analysis:



❖ The document primarily focuses on :

Alignment of additive provisions with GSFA	**Safety evaluation through ADI concepts**	**Technological justification of additive use**	**Endorsement of regional standards (Asia, Near East, Spices Committee)**

❖ The review is conducted in line with Codex principles, including:

Verification of compliance with GSFA provisions	**Assessment of technological justification**	**Evaluation of safety based on internationally recognized references (e.g., JECFA)**

❖ Key issues identified during the preliminary review include:

Alignment of certain additives with Codex maximum permitted levels	**Justification of functional use in the product matrix**	**Consistency between labeling and actual formulation**

1) Overall direction of the revisions

The document generally **aims** to incorporate food additives that support :

- Product stability and shelf-life.
- Sensory attributes (taste, texture, appearance).
- Processing efficiency.
- However, the level of alignment with Codex varies across additives.

2) Assessment of Food Additives

The evaluation of additives indicates three main categories:

Additives aligned with Codex	**Additives requiring clarification**	**Additives requiring reconsideration**

Recommendations:

Considering the above analysis for Agenda Item 4a, the following recommendations may guide the regional coordination/ engagement at CCFA56:

- Support the existing additive provisions in the Regional Standards for Doogh, Maamoul, and the CCSCH spices and herbs, noting their alignment with GSFA and their technical justification.
- Support the continuation of differentiated additive frameworks where justified by product characteristics, as in Doogh, while maintaining simplified, harmonized approaches for products with less complexity, such as Maamoul and spices.
- Encourage CCFA56 to consider aligning additive provisions across similar traditional products to promote consistency and avoid trade barriers, while respecting product-specific technological needs.

Agenda Item 4(a)

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Background

CCFO29(2026) agreed to forward the proposed draft standard for microbial omega-3 oils to CAC49 for adoption at Step 5 and the food additive provisions to CCFA for endorsement and requested CCFA to advise on the appropriate categorisation of microbial omega-3 oils.

Part A: Determination of appropriate food category

Part B: Endorsement of food additive provisions in proposed draft standard for microbial omega-3 oils

What is Requested from CCFA56?

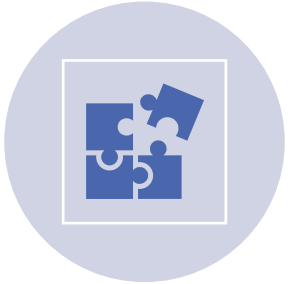
CCFA56 is invited to:

- advise on the appropriate categorisation of microbial omega-3 oils in the GSFA, as well as the recommendations submitted (refer to Part A); and
- consider for endorsement of the food additive provisions in the proposed draft standard for microbial omega-3 oils (refer to Part B and the Annex to this document).

Analysis :Standards for Microbial Omega-3 Oils

CCFO29 forwarded the draft standard for microbial omega-3 oils for adoption, including additive provisions.

A new category, FC 02.1.4 – microbial oils and fats, is proposed to cover products not in current GSFA categories.



Additives endorsed include antioxidants, emulsifiers, and sequestrants (Tables 1 & 2), with no Table 3 provisions required.

The Chair proposes referring the creation of FC 02.1.4 to the GSFA EWG and endorsing additive provisions for incorporation into the GSFA while awaiting formal category endorsement.

Recommendations:

Considering the above analysis for Agenda Item 4a (add.1), the following recommendations may guide the regional coordination/ engagement at CCFA56:

- **Agree to establish** a new food category (FC 02.1.4) for microbial oils and fats within GSFA.
- **Support** the expansion of FC 02.0 and FC 02.1 definitions to explicitly include microbial sources, ensuring clarity and consistency.
- **Agree to endorse** the proposed food additive provisions, as they are aligned with GSFA Tables 1 and 2.
- **Ensure consistency** between the assigned food category and additive permissions to avoid regulatory gaps.
- **Encourage** careful monitoring of antioxidant levels, given the high susceptibility of omega-3 oils to oxidation.
- **Recommend future review**, particularly as additional microbial-derived products emerge in the market.

Agenda Item 4(a)

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List of Annexes

Annex 1: Explanatory document – questions, comments and chair's proposals for the PWG

Annex 2: Proposed amendments to the food additive provisions of the Regional standard for quick-frozen dumplings (Asia) (submitted by CCASIA) and to Tables 1, 2 and 3 of the GSFA relating to the alignment of that standard

Annex 3: Proposed amendments to the food additive provisions of the Regional standard for maamoul (Near East) (submitted by CCNE), and to Tables 1, 2 and 3 of the GSFA relating only to the alignment of that standard.

Background & Analysis :Regional Standard for quick-frozen dumplings (Asia)

- At CCASIA23 (2025), The standard for quick-frozen dumplings demonstrates a dynamic and evolving alignment with the GSFA.
- extensive discussions took place regarding the appropriate food category, with agreement to assign FC 06.4.3 (pre-cooked pastas and noodles and like products) as the most suitable reference.
- However, it was recognized that existing GSFA provisions in this category did not fully reflect actual additive uses in dumplings.
- Consequently, CCASIA23 agreed to propose specific revisions to the GSFA, including the introduction of **new notes** to extend the applicability of certain additives to dumplings and adjustments to functional classes (e.g., inclusion of raising agents and firming agents, and broader use of flavour enhancers).
- This indicates that endorsement of this standard is closely linked to parallel modifications of the GSFA, highlighting an interactive and adaptive approach between commodity standards and the GSFA framework.

Proposed revisions for GSFA Table 1 and 2

Food Category No. (2)	Food Category Name (2)	Maximum Use Level (3)	Comments (4)
06.4.3	Pre-cooked pastas and noodles and like products		**Add a new note AA:** For use in products conforming to the Regional standard for quick-frozen dumplings (CXS **R-202*) only.

Proposed revisions to References to Commodity Standards for GSFA Table 3 Additives

06.4.3	Pre-cooked pastas and noodles and like products
	Acidity regulators, colours, emulsifiers, firming agents, flavour enhancers, humectants, preservatives, raising agents, stabilizers and thickener listed in Table 3 are acceptable for use in foods conforming to this standard.
Codex Standard	Quick-frozen dumplings (CXS **R-202*)

Analysis :Regional Standard for quick-frozen dumplings (Asia)

- Quick-frozen dumplings are aligned with GSFA category FC 06.4.3 (pre-cooked pasta, noodles, and similar products).
- Functional classes justified include acidity regulators, colours, preservatives, stabilizers, humectants, thickeners, flavour enhancers, and emulsifiers (Tables 1 & 2), with additional classes in Table 3.
- **Chair's proposals:**
  - Permit additives in Tables 1 & 2 and Table 3 according to their functional classes.
  - Introduce a new note to allow specific "exclusive" additives (e.g., carmines INS 120, beta-carotenes INS 160a, phosphates, propylene glycol alginate INS 405, sucrose esters INS 473/474, sulfites INS 220–225/539) to be used in quick-frozen dumplings.
  - Revise Note 194 to clarify exclusive use in instant noodles and prevent conflict with the new note.

Analysis :Regional Standards for the Near East - *Doogh*

- **The Doogh standard (CXS 332R-2018)** demonstrates a highly structured and product-specific approach to regulation, particularly with respect to food additive use.
- Additive permissions are differentiated according to product type/plain or flavoured, heat-treated or non-heat-treated, and aligned with multiple GSFA dairy categories.
- This reflects a more complex and conditional framework, including technological justification and carry-over considerations

Analysis :Regional Standards for the Near East - *Maamoul*

- **The Maamoul standard** adopts a harmonized and simplified approach to food additive use. Permitted additives are those specified in Tables 1 and 2 of the General Standard for Food Additives (CXS 192-1995) for food category 07.2.1 (cakes, cookies, and pies, including fruit-filled or custard types), as well as those listed in Table 3 of the GSFA where appropriate.

- The Maamoul provisions do not impose additional conditional restrictions or product-specific limitations, reflecting a fully aligned and flexible framework suitable for bakery products with diverse ingredients.

Analysis :Regional Standards for the Near East

- ***Doogh دوغ***
  - Additive work has been on hold pending alignment with the fermented milk standard (CXS 243-2003).
  - Further technical justification is required, and endorsement is proposed to be held until CCNE completes its review.

- ***Maamoul***
  - Additives in Tables 1 & 2 of GSFA for FC 07.2.1 (cakes, cookies, pies) or listed in Table 3 are acceptable.
  - **The Chair proposes** permitting all additives from Tables 1 & 2 and referencing Table 3 without changes, ensuring full alignment with GSFA provisions.

Analysis :Standards for Culinary Herbs and Spices

Four standards were presented for **endorsement related to anticaking agents in Table 3.**

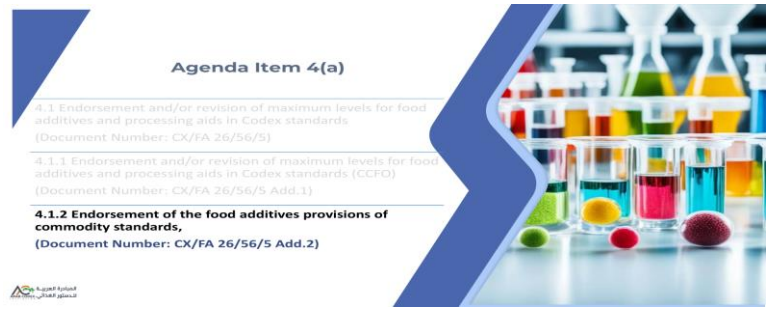
- Standard for spices derived from dried or dehydrated fruits and berries -Requirements for vanilla
- Standard for spices in the form of dried fruits and berries - Requirements for large cardamom
- Standard for spices in the form of dried seeds - Requirements for coriander
- Standard for spices derived from dried or dehydrated fruits and berries -Requirements for vanilla

Current issues include herbs being in the annex to table 3 and questions about including spices in table 3, pending CCSCH guidance.

The chair proposes delaying endorsement until CCSCH clarifies table 3 usage.

References should identify specific anticaking agents and link to tables 1 & 2 where appropriate.

Recommendations



Considering the above analysis for Agenda Item 4a (Add.2), the following recommendations may guide the regional coordination/ engagement at CCFA56:

- **Support the concurrent approach for endorsement and GSFA alignment**, while ensuring sufficient review time.
- **Agree to endorse** additive provisions for standards that are fully aligned with GSFA (e.g., dumplings, maamoul), with necessary notes.
- **Agree to hold endorsement where scientific justification is incomplete** (e.g., doogh).
- **Support the use of GSFA-based approaches rather than creating standalone additive lists.**
- **Encourage simplification** of GSFA notes system, to avoid excessive complexity.
- **Request further clarification** on the use of Table 3 for herbs and spices before endorsement.
- **Support** continued work through EWG for unresolved structural issues (e.g., microbial oils category).

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Agenda Item 4(b)

Alignment of the food additive provisions of commodity standards : Report of the Electronic Working Group on Alignment

Prepared by : YEMEN

Background & Context

- **Codex Alimentarius** International food standards body
- **CCFA** Responsible for food additives
- **GSFA** Global reference for additive permissions
- **EWG** Electronic Working Group (Established)
  - (chaired by Canada)
  - Tasked with alignment of commodity standards

- Need for **harmonization** across standards

Scope of Alignment Work- EWG

Covers multiple committees and standards:

- **CCAFRICA** : cassava, dried meat
- **CCNASWP** : kava, noni
- **CCLAC :** Culantro coyote, lucuma

- **CCCPC** : cocoa butter
- **CCFFP** : fish and seafood
- **CCPFV** : fruit juices and nectars

Regional Standards

- Fermented cooked cassava-based products (CXS 334R-2020)
- Africa

- Fresh leaves of Gnetum spp. (CXS 335R-2020)
- Africa

- Dried meat (CXS 350R-2022) القديد او اللحم المجفف
- Africa

- Lucuma (CXS 305R-2011)
- CCLAC

- Kava products (CXS 336R-2020)
- North America and SouthWest Pacific

- Fermented noni fruit juice (CXS 356R-2023
- CCNASWP

- Culantro coyote (CXS 304R-2011) كزبرة طويلة
- CCLAC

Commodity Standards

- Quick frozen raw squid (CXS 191-1996) كلمار او حبار مجمد
- CCFFP

- Fruit juices and nectars
- CCPFV

- Live and raw bivalve molluscs (CXS 292-1995) رخويات صدفية ذات مصراعين حية ونيئة
- CCFFP

- Cocoa butter (CXS 86-1981)
- CCCPC

- Live abalone (CXS 312-2013) أذن البحر الحي
- CCFFP

EWG Approach to Alignment

- GSFA as primary reference framework
- Alignment based on:

  Table 1: permitted additives

  Table 2: additives by food category

  Table 3: processing aids / exceptions
- Replace outdated provisions with GSFA references
- Harmonized drafting using(Codex Procedural Manual)

Key Achievements

- Consensus on **GSFA-based approach**
- Agreement on **harmonized structure and wording**
- **Progress** on technical **amendments**
- Improved **clarity and consistency** in additive provision
- Recognition of need to enhance **Table 3 usability**

Outstanding Conceptual Issues

- Misinterpretation of GSFA hierarchy
- Confusion between:
  - Parent categories
  - Subcategories
- Difficulty classifying:
  - Multi-character products
    - Processed vs fermented foods, frozen
- Need for clear conceptual guidance

Technical Challenges Identified

- **Incorrect** or inconsistent **category** references
- Use of broad categories instead of specific ones
- Legacy inconsistencies from past alignments
- Formatting and application issues in **Table 3**
- Practical implementation challenges

Key Updates to Food Additive Provisions and GSFA Alignment

Food Category Alignment

- Replacement of broad categories with more specific GSFA subcategories

Clarification of Product Classification

- Review of classification for products with multiple characteristics (e.g. cassava, kava)
- Reassessment of classification for certain raw materials (e.g. cocoa butter)

Correction of Legacy Issues

- Identification of inconsistencies in previously aligned standards (e.g. fish and seafood)

Harmonization of Drafting

- Standardization of wording in line with Codex Procedural Manual
- Clear references to GSFA Tables 1, 2, and 3

Table 3 Improvements

- Enhanced structure and usability of notes

Case Study : Cassava Products

- **Issue: classification uncertainty**
  - **Cooked vegetables vs fermented vegetables**
    - Product has **multiple processing characteristics**
    - **Requires clarification** from CCAFRICA
    - **Alignment pending** without clear categorization

- Fermented cooked cassava-based products (CXS 334R-2020)
- Africa

Case Study: Dried Meat

- Use of broad category (08.2)
- **The problem** : Risk of excluding permitted additives
- **Proposal**: use specific subcategories
- Clarification of product scope needed
- Requires clarification of product scope (e.g. **comminuted meat**)

- Dried meat (CXS 350R-2022) القديد او اللحم المجفف
- Africa

Case Study: Kava Products

- Exists in **Multiple forms**: fresh, dried, frozen
- **Challenge:**
  - **Single category may not be sufficient**
- **Consideration:**
  - **Use of multiple GSFA categories**
- **Input required from CCNASWP**

- Kava products (CXS 336R-2020)
- North America and SouthWest Pacific

Case Study: Cocoa Butter

- **Current classification**: **finished product category**
- **Issue**: **Cocoa butter is a raw material**
- **Options under discussion:**

  Fats and oils category

  New dedicated subcategory
- **Options**: fats & oils or new subcategory
- No consensus yet --- further consultation needed

- Cocoa butter (CXS 86-1981)
- CCCPC

Case Study: Fish Standards

- **Previously aligned standards** contain:
  - **Errors & Inconsistencies**
- **Issue**: Lack of coherence across standards
- **Recommendation:**
  - Conduct systematic review
- **Coordination** required with CCFF

- Quick frozen raw squid (CXS 191-1996) كلمار او حبار مجمد
- CCFFP

- Live and raw bivalve molluscs (CXS 292-1995) رخويات صدفية ذات مصراعين حية ونيئة
- CCFFP

- Live abalone (CXS 312-2013) أذن البحر الحي
- CCFFP

Key Amendments Across Annexes

- **Annexes include:**
  - Regional standards updates
  - Commodity-specific revisions
- **Key actions:**
  - Correct category assignments
  - Update additive provisions
  - Address technical inconsistencies
- Requires cross-committee collaboration

Table 3 Improvements

- Improved structure and readability
- Clarify notes and conditions of use
- Removal of redundant or unclear provisions
- Align with **GSFA database functionality**
- Enhance practical application for users

Cross-Cutting Alignment Issues

- Need for consistent use of subcategories
- Handling products with:
    - Multiple characteristics
    - Multiple forms
- Ensuring coherence across all standards
- Strengthening interpretation of GSFA framework

Key Issues for PWG Consideration

- Final classification of complex products
- Clarification of product definitions and scope
- Resolution of technical inconsistencies
- Input from relevant commodity committees
- Ensuring consistency in GSFA application

Recommendations

- Support agreed alignment proposals
- Address unresolved classification issues(challenges)
- Strengthen GSFA consistency
- Provide clear regional positions where needed
- Enhance inter-committee coordination

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Agenda Item 5(b)

GSFA: Proposals for new and/or revision of food additive provisions (replies to CL 2025/31-FA)

Documents :CX/FA 26/56/8

Presented by : HADI ELALEM, LIBYA

Background: Agenda item 5(b)

Proposals submitted by:

- Japan
- Republic of Korea
- EU & International organizations

Types of proposals:

- New additives
- Revision of existing provisions
- Extension of uses

Analysis : Agenda item 5(b)

Additives Analyzed:

- Gardenia Blue (INS 165) – Colour
- Steviol Glycosides (INS 960) – Sweetener
- Rosemary Extract (INS 392) – Antioxidant

👉 **Supported by:**

- JECFA safety evaluations
- Technological justifications

Analysis : Agenda item 5(b)

Gardenia Blue (INS 165)

✓ Wide application (dairy, beverages, snacks)
✓ ADI established by JECFA

⚠ **Key Concern:**

•Potential cumulative exposure

👉 **Position:**
Support with caution + request exposure assessment

Analysis : Agenda item 5(b)

Steviol Glycosides (INS 960)

✓ Widely used sweetener
✓ Supports sugar reduction
⚠ Key Concern:
Increased aggregate exposure
👉 **Position:**
Support with monitoring + ensure labelling

Analysis : Agenda item 5(b)

Rosemary Extract (INS 392)

✓ Used in fats and oils
✓ Improves shelf life

⚠ Key Concern:
Need for harmonization with other antioxidants

👉 **Position:**
Support with clarification of limits

Summary Table of Key Proposals

Additive	Type	Main Concern	Suggested Position
Gardenia Blue	New	Cumulative exposure	Support with caution
Steviol Glycosides	Revision	Aggregate intake	Support with monitoring
Rosemary Extract	Extension	Harmonization	Support with clarification
High-level colours	Multiple	Overexposure	Request justification
Notes-based additives	Multiple	Complexity	Simplify provisions

Recommendations

The following recommendations may guide the regional coordination at CCFA56:

- Support scientifically justified proposals, particularly where JECFA evaluations confirm safety.
- Encourage careful exposure assessment, especially for additives with expanded use.
- Ensure alignment with GSFA principles, including technological need and non-misleading use.
- Promote harmonization of use levels across food categories.
- Highlight the importance of clear labelling for consumer awareness.
- Support stepwise adoption, where necessary, pending further data.

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Agenda Item 8

Standard for baker's yeast _ At Step 4

Documents :CX/FA 26/56/11

Prepared by : Tunisia & Syria
Presented by : Dr. Balsam Jreikous - Syria

Analysis : Objectives

- Develop a Codex standard for baker’s yeast
- Ensure:
  - Product definition harmonization
  - Safety and quality
  - Alignment with GSFA
  - Facilitate international trade

Background: Agenda item 8

Standard for baker's yeast (STEP 4) *(Prepared by the Electronic Working Group (EWG) chaired by China and co-chaired by France and Türkiye)*

Document Number: CX/FA 26/56/11

Proposal submitted to CAC44 (2021) → Reviewed at CCFA53, CCFA54, CCFA55 → Approved as new work by CAC47 → EWG established (China – Chair; France & Türkiye – Co-chairs)

Analysis : Scope

Applies to:

- Baker’s yeast for direct sale
- Baker’s yeast used in food manufacturing

Yeast is:

- A food ingredient
- Not ready-to-eat

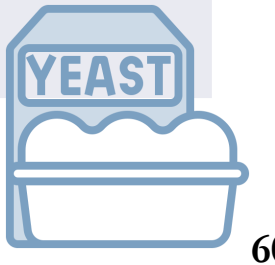
Analysis : Product Definition

Type	Definition
Baker's yeast	A type of unicellular fungus belonging to the species of Saccharomyces cerevisiae. It is produced by the multiplication of pure strains and is used as a biological leavening agent in bakery applications. Producing carbon dioxide and flavors. It is not a ready-to-eat product
Fresh yeast	A type of baker’s yeast with high moisture content, which is obtained by separation and other processes such as compression.
Dry yeast	A type of baker’s yeast, which is obtained by removing water from fresh yeast and then drying to a low water content to maintain a low metabolic activity.

Analysis : Yeast Types

According to product appearance and moisture content, baker's yeast shall be classified in two types:

Type	Forms
Fresh yeast	Fresh yeast is a milky white to yellowish brown solid or liquid with a smell typical for yeast and may be in three major forms: *Block yeast or compressed yeast, which shall be in the form of a block. The texture or consistency shall be characterized by being friable, breaking easily into small fragments and permitting kneading. *Granulated yeast or crumbled yeast, which shall be in the form of small granules. *Liquid yeast or cream yeast, which shall be a liquid suspension of yeast cells in water with a creamlike texture.
Dry yeast	Dry yeast is an ivory-coloured particle or granule, with a smell typical for yeast. Dry yeast may be classified into three types. *The active dry yeast is rehydrated to reactivate it in lukewarm water before use. The particles are rod-shaped or spherical in appearance, with a diameter of 0.2 mm - 3 mm *The instant dry yeast or instant active dry yeast is used in a way that can be added directly to the flour during mixing without a rehydration step in water. The product consists of porous cylindrical particles with a diameter of about 0.5 mm and length up to a few millimeters. *Semi-dry yeast is a form of baker's yeast that can be added directly to the flour during mixing without a rehydration step in water. The product consists of porous cylindrical particles with a diameter of about 0.5 mm and is stored in a frozen state prior to use.



Analysis : Quality Factors

Moisture Content:

*Fresh yeast: 60–86%

*Dry yeast: 2–10%

*Semi-dry: 15–26%

pH:

*Only for liquid yeast: 3 – 7.5

Analysis

Essential Composition

Product consists of:

- Yeast (as defined)

Optional ingredients:

- Under discussion / clarification

Food Additives

Allowed according to GSFA (CXS 192-1995) includes:

- Antioxidants
- Emulsifiers
- Preservatives
- Stabilizers

Approach:

- Functional classes (not individual listing)

Analysis

Processing Aids

*Must comply with: CXG 75-2010

*Aligned with Codex commodity standards

Contaminants

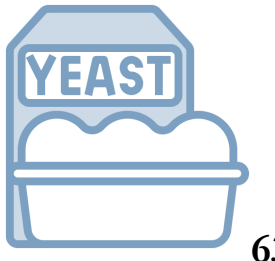
*Must comply with: CXS 193-1995

*Maximum limits apply

Food Hygiene

*Follow: CXC 1-1969 (General Principles of Food Hygiene)

*Meet: Microbiological criteria (CXG 21-1997)



Analysis

Labelling

*Product name: “Baker’s yeast”

“Yeast” allowed: If not misleading

*Non-retail: CXS 346-2021 applies

Packaging & Storage

Packaging must:

*Prevent contamination

*Preserve quality

*Be odorless

Conclusion & Recommendations

Conclusion

Draft standard prepared reflects:

- EWG discussions
- Member feedback
- Ready for advancement in Codex process

Recommendations

CCFA56 to:

- Consider draft standard
- Progress through Codex steps
- Review GSFA amendments

المبادرة العربية للدستور الغذائي
ARAB CODEX INITIATIVE

Agenda Item 10

Discussion paper on the development of a guideline for the conduct of food safety assessment of cell culture media components used in the food safety assessment of cell culture media components used in the production of cell-based foods

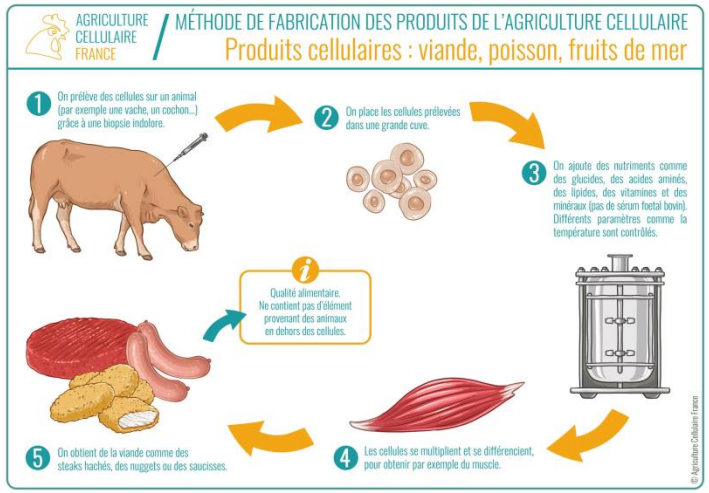
Documents :CX/FA 26/56/11

Prepared by : Tunisia & Qatar

Background: Agenda item 10

General context: The emergence of cell-cultured foods

Definition: Agricultural animal products grown *in vitro* from isolated cells (cattle, poultry, fish, etc.).
They require **culture media** containing nutrients, growth factors, and additives.



Market Status (Mid-2025): Regulatory approvals already obtained in Australia, Israel, New Zealand, Singapore and the United States.
Outlook: Evaluations are underway in the European Union, the United Kingdom, Switzerland and Thailand.

Strategic Objective: To complement conventional livestock farming systems to meet the challenges of global food security.

Background: Agenda item 10

History of the Work on the Codex (The Chronology)

Origin (CCFA53/54): Initial discussions on the suitability of the current additives framework for "New Food Production Systems" (NFPS).

The Turning Point (CCFA55, 2024): Submission by Singapore and China of a formal proposal for further work. The Committee recognizes the urgency of a harmonized framework to avoid trade barriers.

Current mandate (2025-2026): Creation of the Electronic Working Group (EWG) chaired by **Singapore** and co-chaired by **China, the Republic of Korea and Saudi Arabia** .

Objective: To develop guidelines for assessing the health safety of components of environments, and not of the finished products themselves (which fall under other bodies).

Analysis : Mandate of the EWG

CCFA mandate (55th session): Review the project document and establish a categorization framework.

Key Objectives:

Develop a guideline for conducting the safety assessment.
Categorize the components according to the level of evidence required.
Identify areas requiring scientific advice from the FAO/WHO.

Participation: 32 member countries and 6 committed observer organizations

Reminder: Codex Procedure Manual

Discussion Document (Appendix 1) . Its role is to:

Justify the need: Demonstrate that there is a scientific basis and a real need for international standardization.

Define the scope: Clarify the scope to avoid any overlap with existing standards.

Assess maturity: Analyze whether the available data allows for unambiguous normative work to begin.

Project Document (Annex 2): This is the formal instrument required for the Commission to approve a new project. Its importance lies in:

Planning: It sets clear objectives and a precise timetable (2026-2028 in our case).

Impact Analysis: It assesses how this new job will facilitate international trade and protect consumer health.

The Critical Consensus: It is on the basis of this document that the members decide to allocate resources and commit the technical responsibility of the committee.

Analysis : Presentation of Document CX/FA 26/56/13

Working document for the 56th session, summarizing the contributions of 32 member countries and 6 observer organizations.

Document structure:

- **Body of text:** Progress of discussions and sticking points (e.g., nomenclature).
- **Appendix 1:** Draft revised working document.
- **Appendix 2:** Proposal for new work (the "Project Document").
- **Annex 3:** Methodological framework for safety assessment (the technical core).

Analysis : Presentation of Document CX/FA 26/56/13

Appendix 1: Draft revised working document.

Scope:

Focus: Limited exclusively to components of culture media for animal cells (meat and seafood).

Exclusions: Plant cells, microorganisms (biomass) and support matrices (scaffolds) are excluded at this stage to ensure rapid progress of the dossier.

Antimicrobial Resistance (AMR):

Precautionary principle: Strict prohibition of the use of antibiotics in the final phase of production.

Management: Need for rigorous aseptic production protocols to avoid any dependence on antimicrobial agents.

Safety and Assessment:

Lack of historical data: Consensus on the need to rigorously assess components that have never been consumed by humans.

Transparency: The importance of sharing security data while respecting the intellectual property of companies.

Analysis : Presentation of Document CX/FA 26/56/13

Appendix 2: Draft revised working document.

Trading Volumes:
Current situation: Although trade volumes are currently low and localized, rapid growth is anticipated.
Proactive Approach: The Codex has chosen to act now to harmonize standards before international trade becomes widespread, thus avoiding future technical barriers to trade (TBT).
Durability (Sustainability):
Committee position: The document maintains a neutral and cautious tone.
Need for evidence: Although the potential for reducing the environmental footprint is often highlighted (water consumption, land), the Committee awaits further empirical evidence and full life cycle assessments (LCAs) before making a decision.

Analysis : Cultural Environments ...
The Challenges of Health Security

Complexity of the Environment: Mixture of salts, vitamins, amino acids, but also **growth factors, hormones and small molecules** .

Identified Risks:

- No consumption history available for some components.
- Potential presence of chemical or biological residues in the final product.
- Need to manage the use of antimicrobials to avoid resistance (AMR).

Challenge: To ensure that the components used during proliferation or differentiation do not compromise ultimate safety

Analysis : Methodological Framework for Evaluation (Appendix 3)

Tiered Approach Approach): Graduation of the level of scientific evidence according to the potential risk of the component.
Inverted pyramid.
Step 1: Components already authorized. Step 2: Components with a history of use. Step 3: New molecules.

"This approach avoids overloading the evaluators. Scientific resources are concentrated on the most uncertain substances."

Analysis : Methodological Framework for Evaluation (Appendix 3)

Scientific Tools: The VAT Threshold

Use of the **Toxicological Concern Threshold (TCT)** .

In vitro models for simulating human digestion

Assessment of residual exposure in the finished food.

"For components present in trace amounts, TTC is a robust tool. We also recommend the use of bioinformatics to predict allergenicity . "

Principle: Strict alignment with the Codex risk analysis principles

Analysis : Cultural Environments ...
The Challenges of Health Security

Why a specific framework for cultural environments?

The culture medium is the critical input: it dictates growth (proliferation) and structure (differentiation).

Complexity: A mixture of >100 molecules (amino acids, vitamins, mineral salts, hormones).

Challenge: Transitioning from "laboratory" use to large-scale human consumption.

"We cannot apply the standards for conventional additives because these components interact dynamically with living cells."

Analysis : Methodological Framework for Evaluation (Appendix 3)

The Tiered Approach Approach)

graduated assessment strategy . It allows not all components to be treated in the same way, in order to concentrate scientific resources and complex tests on the most uncertain substances.

Step 1: Sorting and History (Screening)

We check if the component is already known. If it is an additive already authorized by the Codex, a standard nutrient (vitamin, mineral salt) or a substance with a history of safe consumption (GRAS status), the evaluation is simplified.

Step 2: Exposure Assessment

The amount of substance that actually remains in the finished food after rinsing the cells is calculated. If this amount is minimal (traces), the analysis proceeds via the TTC threshold (see below).

Step 3: In-depth testing

For new or complex molecules (such as growth factors produced by biotechnology), if exposure exceeds safety thresholds, comprehensive toxicological tests (*in vitro* or *in vivo*) are required to prove safety.

Analysis : Methodological Framework for Evaluation (Appendix 3)

Threshold of Toxicological Concern (TTC) Concern)

The TTC is a scientific screening tool used by experts (JECFA, EFSA) to assess the safety of a substance when toxicological data are limited but human exposure is **very low** .

The principle: It is considered that below a certain dose of exposure (a "threshold"), the risk to human health is negligible, even if the toxicity of the molecule is not fully known.

Application to culture media:

In cellular production, many components (hormones, cytokines) are used in infinitesimal quantities.

If the analysis shows that the residue in the final product is below the TTC threshold corresponding to its chemical class, we can conclude that there is no risk without needing to conduct tests on animals.

Cramer's Classes: Substances are classified from I to III according to their chemical structure (from least toxic to most suspect), and each class corresponds to a specific safety threshold (expressed in micrograms per day).

Analysis : Other technical proposals by the CCNEA : consumer protection through information (labeling) and biosafety (cell bank)

key challenges related to input safety and process control in cultured meat production, with a focus on emerging risks and assessment requirements.

Nutritional assessment required: ensure compliance (Vit A, salt, trans fats) after intensive washing processes

Non-target hazard analysis: detect unknown toxins and compounds

Input evaluation:

- Specifications & certificates of analysis
- Safe-use limits
- Scaffolds and microcarriers

Residues & contaminants:

- Antibiotics, chemicals, bioaccumulation
- Adaptation of analytical methods (complex matrices)

Stability & transformation:

Effects of cooking/digestion

Formation of harmful metabolites

Media recycling: risk of contaminant concentration

TTC approach: needs adaptation to bioactive substances

Analysis : Other technical proposals by the CCNEA : consumer protection through information (labeling) and biosafety (cell bank)

health control measures, manufacturing requirements, and final product characteristics to ensure safety, quality, and regulatory compliance.

Adventitious agents (contaminants):

- Identification of microorganisms
- Facility monitoring (biomapping)
- Advanced testing (sequencing)

Manufacturing practices:

- Impact of novel technologies on safety
- Implementation of HACCP, GMP, specific programs
- Management of process changes

Waste management:

- Identification of hazardous waste (e.g. washing water)
- Safe disposal procedures

Final product:

- Shelf life & storage conditions
- Nutritional composition vs conventional meat
- Nutrient bioavailability
- Development of non-animal testing methods

Analysis : Other technical proposals by the CCNEA

Technical Safety and Regulatory and ethic Compliance

To bridge the gap between technical safety and market acceptance in the Arab-CCNE region, the following pillars must be integrated:

Total Traceability (Cell-to-Fork):In fact, safety is not limited to the media. It requires "Total Chain" traceability, starting from the **Cell Bank** to the final product.

Mandatory Halal Integrity: Safety and Suitability are inseparable. must ensure that the cell lineage and all media components (including recombinant proteins) are free from non-halal derivatives.

Transparent Labeling: Terminology must be precise to prevent consumer confusion, clearly distinguishing "Cell-Based" products from traditional meat.

Conclusion: By adopting the **Decision Tree** within a framework that mandates **Halal Integrity**, we ensure a standard that is scientifically robust and culturally inclusive

Analysis : Implementation challenge

Operational Challenges and Capacity

The question is whether member countries have the resources to implement the directives.

1. Standardization of Analytical Methods:

The problem: To assess safety, it is necessary to be able to measure trace amounts of components (e.g., hormones) in the finished food. However, current methods vary from one laboratory to another.

The issue: Without reference methods (ISO or Codex), a product could be deemed "safe" in one country and "non-compliant" in another, creating commercial disputes.

2. Evaluator Training (Capacity Building):

The challenge: Evaluating cell culture media requires hybrid skills: classical toxicology, biotechnology and process engineering.

The solution: Document CX/FA 26/56/13 underlines the need for FAO and WHO to help developing countries train their experts so that they are not excluded from this new market.

3. Access to industrial data (Trade secrets):

The conflict: Companies consider the formula of their culture medium their most closely guarded trade secret. However, the authorities require the complete composition to ensure safety.

The operational challenge: To create protocols for submitting confidential data that protect intellectual property while allowing for rigorous scientific review.

Analysis : Collaboration with JECFA and FAO/WHO

.1. The request for a scientific opinion:
The Committee (CCFA) cannot decide on its own what is toxic. It must ask the JECFA to conduct independent studies.
Key question: "What are the safe exposure levels for recombinant growth factors?"
2. The creation of a Global Database:
The document proposes that FAO/WHO centralize data on components already evaluated.
The objective: To avoid each country having to start the evaluation from scratch for common components (e.g. standard vitamins or amino acids), which would speed up approval procedures.
3. Definition of "Grades of Purity":
Currently, specifications exist for additives (Food Grade). However, none yet exist for complex biotechnological components used in cell culture.
The mission of JECFA: To establish specific monographs (purity standards) to ensure that these components do not contain dangerous impurities from their own manufacturing process (e.g., bacterial toxins).
4. Positioning within the food category system:
The collaboration must determine whether these products fall into existing categories (e.g., Meat) or whether a new category, "Foods derived from cell cultures," needs to be created in the General Standard for Food Additives (GSFA).

Analysis : Strategic Directions and Discussion Points

Scope of Application: Limited for the time being to animal cells (excluding matrices/scaffolds and plant cells at this stage).

Trade and Innovation: Although trade volume is still low, the Codex is taking a **proactive approach** to avoid technical barriers to trade.

Sustainability: Adopting a neutral tone pending further empirical evidence on environmental impact.

Recommendations

The following recommendations may guide the regional coordination at CCFA56:

Approve the New Work proposal (Annex 2): Official launch of the development of guidelines for adoption planned for 2027-2028.

Validation of the Methodological Approach (Appendix 3): Confirm the use of the " Tiered Approach " (step-by-step approach) as a working basis for risk assessment.

Request for Scientific Advice (FAO/WHO): Launch a formal request for expert advice on critical issues:

- Definition of purity criteria (Food Grade).
- Validation of digestion models for growth factors.

Creation of a Database: Study the feasibility of a global directory of pre-evaluated components to support countries with fewer technical resources.

https://gforss.org/networks/arabcodex/