



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

FAO/WHO COORDINATING COMMITTEE FOR ASIA

Twenty-third Session

DISCUSSION PAPER ON NOVEL FUNCTIONAL INGREDIENTS, AND CLAIMS – THE ROLE OF CCASIA IN GUIDING FOOD REGULATORY PRACTICES

(Prepared by China and the International Union of Food Science and Technology - IUFoST¹)

Executive Summary

Asia has emerged as the world's leading hub of food innovation, spanning novel functional ingredients derived from traditional diets, functional foods, new food production systems, and health-related claims. These innovations respond to consumer demand for sustainability, nutrition, and diversity, but they also present significant regulatory challenges. Fragmented national approaches, divergent definitions, and inconsistent requirements for pre-market safety assessment risk undermining both consumer protection and innovation.

Codex offers an indispensable foundation for guiding regulators in this fast-evolving field. CCASIA, as the region most actively generating functional ingredients and associated health applications, as well as novel foods and processes, is uniquely positioned to pilot a coordinated approach—anchored in Codex principles—to establish predictable, transparent, and science-based regulatory pathways. This would include identifying triggers for oversight, clarifying data requirements for safety assessment, and fostering regional mechanisms for information exchange on evaluations conducted outside Codex but guided by Codex-consistent principles.

This CRD therefore invites CCASIA23 to consider advancing work toward harmonized regional guidance with an initial focus on functional ingredients, building mutual confidence across Member States, and ensuring that Asia contributes substantively to shaping global Codex deliberations on new food sources and production systems.

Background and Problem Statement

Novel foods, ingredients, and processes—including precision fermentation, cellular agriculture, functional compounds derived from traditional diets, and advanced processing methods—are reshaping the food sector.

Of particular importance in Asia is the growing focus on functional ingredients, many of them rooted in traditional diets and increasingly associated with health applications; these ingredients are now being incorporated into novel food formulations to deliver specific functionalities or address targeted dietary objectives, reflecting both consumer demand and the region's rich heritage of food–health linkages.

However, national regulatory frameworks across Asia vary widely:

- Definitions of novelty differ, creating uncertainty.
- Pre-market approval processes range from highly prescriptive systems to limited or no oversight.
- Data requirements for safety assessment and claims are inconsistent, complicating applications across markets.

For innovators, this lack of predictability delays market entry and raises investment risks. For regulators, rapid innovation pipelines create pressure to evaluate new products efficiently while ensuring consumer safety. For consumers, fragmentation risks inequitable protection and uneven access.

Without convergence, Asia's innovation potential risks being hampered by duplicated efforts, fragmented trade, and reduced consumer confidence.

Relevance to Codex and to CCASIA

Codex provides internationally agreed principles for risk analysis, transparency, and scientific rigor that are essential for guiding the regulation of novel foods, ingredients, processes, and claims. At CAC46, Members

¹ Through IUFoST Disciplinary group for Food Regulatory Science, the Global Food Regulatory Science Society (GFoRSS)

confirmed that New Food Sources and Production Systems (NFPS) can be addressed through existing Codex structures, with Members encouraged to bring forward concrete, science-based proposals.

For CCASIA, this agenda is of particular importance because many of the region's most dynamic innovations are **centered on functional ingredients**, often derived from traditional diets and increasingly linked to health-related claims. These ingredients are not only shaping new formulations of foods and beverages but also responding directly to consumer demand for nutrition, wellness, and dietary solutions that resonate strongly across Asia.

Given this, it is both timely and strategic for CCASIA to first develop a shared, regionally grounded framework for functional ingredients—clarifying when they should be considered novel, how their safety should be assessed, and how related claims should be substantiated—before advancing proposals to the global Codex level.

Such preparatory work would ensure that any future Codex actions are grounded in Asia's specific realities, reflecting its innovation ecosystems, consumer patterns, and regulatory experiences.

Accordingly, CCASIA has the opportunity to lead by:

- Translating Codex's horizontal principles into regional guidance on the regulation of functional ingredients, particularly those with new or enhanced health functionalities;
- Clarifying triggers of novelty that determine when functional ingredients require additional oversight from food regulators;
- Defining core safety data requirements and evidence standards for functional ingredients, including toxicological, nutritional, and efficacy data relevant to substantiating claims; and
- Supporting information-exchange platforms where regulators can share assessment outcomes on functional ingredients, thereby reducing duplication, strengthening mutual confidence, and accelerating safe and equitable access to innovation.

This work is further inspired by the recommendations of the 2025 Asia Codex and Food Regulatory Forum held in Bangkok in August 2025, the outcomes of which are summarized under CRD 05.

Opportunities for CCASIA Collaborative Action

As a first step, CCASIA would commission a discussion paper—developed through structured, multi-stakeholder dialogue (industry, SMEs, academia, consumer groups, and regulators)—that reviews the current environment of functional ingredient regulation in Asia, within the broader context of novel foods. The paper would identify needs for guidance and highlight the benefits of regional harmonization, including the aspirations of the production sector for predictable, innovation-friendly pathways. It would pave the path forward by framing a project document under CCASIA to develop regional guidance on: (i) principles for identifying **novelty in functional ingredients**, including **triggers that warrant added regulatory oversight**; and (ii) requirements for safety assessment, expressed as general principles and, where relevant, tiered approaches for priority applications linked to health functionalities.

Building on that foundation, CCASIA could:

1. Develop CCASIA Guidance on principles for **identifying novelty and oversight triggers in functional ingredients**, alongside requirements for their safety assessment (general and tiered for priority categories).
2. Establish **regional mechanisms for joint or coordinated reviews**, focusing initially on **high-demand categories such as functional ingredients** derived from traditional diets, while also extending to precision-fermented proteins and cell-based foods.
3. Create a **CCASIA-wide database of authorized functional ingredients** and other novel foods, along with **completed assessments**, to enhance transparency, reduce duplication, and accelerate safe market entry.

Cross-cutting enabler: Institutionalize the structured dialogue process so it continuously informs the discussion paper, guidance development, collaborative reviews, and database updates—ensuring inclusivity, better data availability, and sustained mutual confidence among authorities.

Recommendations to CCASIA23

CCASIA23 is invited to:

1. Acknowledge Asia's central role in food innovation, and in particular the **region's leadership in developing and commercializing functional ingredients** derived from traditional diets and associated with health applications, while noting the regulatory challenges created by fragmented approaches.

2. Initiate work through **a discussion paper, prepared via structured multi-stakeholder dialogue**, to review the current regulatory environment for functional ingredients (within the broader category of novel foods), identify needs for regional guidance, and outline the benefits of harmonization. This paper should serve as the basis for a project document on CCASIA guidance covering: (i) principles for identifying novelty in functional ingredients, including triggers requiring oversight; and (ii) requirements for safety assessment, articulated as general principles and, where relevant, tiered approaches for priority applications.
3. **Advance collaborative mechanisms**—such as joint or **coordinated reviews, shared databases of authorized functional ingredients and other novel foods**, and coordinated data-generation initiatives—to build mutual confidence, reduce duplication, and accelerate safe access to innovation.
4. **Support sustained capacity building**, with particular emphasis on SMEs and emerging regulators, to ensure inclusive participation and effective implementation of innovation regulation across the region.