GFORSS | GLOBAL FOOD REGULATORY SCIENCE SOCIETY

AFIRS
ASIA FOOD INNOVATION-READY REGULATORY SYSTEMS INITIATIVE

DISCUSSION PAPER - OUTPUT OF SESSION 1

Enabling Non-Nutrient Health Claims in Asia

Toward more predictable, risk-based and collaborative pathways for scientific substantiation and regulatory oversight

PURPOSE AND OBJECTIVE OF THIS DISCUSSION PAPER

This paper records the outcome of Session 1 and sets out key considerations for a possible path forward toward a more predictable, transparent and enabling framework for the management of non-nutrient health claims in Asia. It reflects the issues raised during the discussion and identifies practical options that could improve clarity around scientific substantiation, reduce uncertainty for applicants seeking authorization of new claims, and create stronger conditions for cooperation, information sharing and regulatory reliance among Asian authorities.

Asia Innovation-Ready Food Regulatory Systems Initiative

Second Working Meeting · Zhangzhou, China · 14–15 September 2026

Working paper for discussion — Session 1: Non-Nutrient Health Claims in Asia

Executive Summary

Non-nutrient health claims describe beneficial physiological effects associated with foods or food constituents that are not conventional nutrient-content claims. Codex provides a broad conceptual framework for nutrition and health claims, including 'other function claims', but leaves substantial room for national implementation. Across Asia, this has produced a range of regulatory regimes with differing positive lists, submission pathways and evidentiary expectations.

The regional picture presented at the meeting shows that several jurisdictions have formal systems and require scientific substantiation, yet applicants often have limited practical guidance on how evidence will be weighed, what level of human evidence is sufficient, how product-specificity is treated, and how conflicting studies are reconciled. The result is an environment that can be formally open to new claims but **still difficult to navigate and predict.**

This paper proposes a pragmatic regional response. Rather than seeking immediate harmonization of all national rules, Asian regulators could work toward greater convergence through: (i) a tiered, risk-based model of oversight; (ii) a shared information platform linking existing positive lists to the scientific basis for their acceptance; (iii) common, detailed guidance for substantiation of non-nutrient health claims; and (iv) recognized third-party scientific review mechanisms, while leaving the final regulatory decision with national authorities.

These options build directly on current Asian experience, including the **use of positive lists** in several jurisdictions and Thailand's model of recognized assessment centers. They also fit the objectives of the Asia Innovation-Ready Food Regulatory Systems Initiative, which can use the Goji berry and GABA pilots to test how common evidence requirements, shared reviews and reliance mechanisms could work in practice.

> **PROPOSED DIRECTION**
>
> Preserve the predictability offered by positive lists while strengthening them through transparent and shared scientific substantiation, and complement them with a proportionate, risk-based pathway for new claims. Such an approach could allow lower-risk claims to be managed without mandatory pre-market approval, supported by clear substantiation requirements and appropriate post-market oversight, while reserving pre-market assessment for claims of greater health significance. The resulting scientific assessments could also be shared and relied upon across jurisdictions.

1. Context: What Are Non-Nutrient Health Claims?

Non-nutrient health claims are statements linking a food or a food constituent other than a conventional nutrient to a beneficial physiological function or health effect. In Codex terminology, these claims fall principally within the broader concept of health claims and, in particular, 'other function claims' describing beneficial effects on normal functions or biological activities of the body. They are distinct from nutrient-content claims and should also remain distinct from therapeutic claims relating to the treatment or prevention of disease.

Codex provides important principles: claims should be **truthful and not misleading**, should be supported by scientific evidence, and should be considered in the context of the total diet. However, Codex does not provide the level of operational detail needed to answer many of the questions that determine the outcome of an application: what constitutes sufficient evidence, how many human studies are needed, which endpoints are acceptable, how product-specific the evidence must be, how systematic reviews should be weighted, and how uncertainty or conflicting findings should be handled.

Developing more detailed global guidance through Codex may remain difficult. The extended discussions around probiotics and related terminology in the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) illustrate the challenge of achieving consensus when scientific, regulatory and market approaches differ substantially. This creates a strong rationale for **Asia to develop practical, regionally grounded approaches that remain Codex-consistent** but are responsive to the region's own regulatory experience and innovation priorities.

2. The Current Asian Environment: Open in Principle, Uncertain in Practice

The information presented during Session 1 demonstrates that there is no single Asian model. Several Southeast Asian jurisdictions have regulations or guidance addressing other function claims and maintain positive lists of accepted non-nutrient substances or claims. Others follow Codex more generally or are still developing formal lists. In most systems, claims not already listed may be submitted for review, and scientific evidence is required. Yet the route from 'scientific evidence is required' to an actual regulatory decision is often insufficiently described.

Jurisdiction	Current approach	Implication for new claims
Indonesia	Regulated framework; positive list; written approval possible for new claims	Formal submission path exists, with scientific evidence and expert review.
Malaysia	Positive list of other function claims; prior written approval possible	Ingredient acceptance and claim acceptance may be sequential, adding complexity.
Singapore	Positive list with case-by-case application for new claims	Application format exists, but assessment expectations remain partly case-specific.
Thailand	Positive lists plus recognized assessment centers for new claims	Provides an operational precedent for third-party-supported assessment under regulator oversight.
Philippines / Vietnam	Codex-based or developing systems	Opportunity for regional guidance to provide a clearer pathway where national detail is limited.

The core obstacle is therefore not simply the absence of regulation. In many cases, the system is formally open but insufficiently predictable. Positive lists offer certainty for what has already been accepted, but they do not necessarily provide a transparent pathway for the next ingredient or the next claim. This can discourage investment in evidence generation, lead to variable dossier quality, and force regulators to repeat similar scientific reviews across jurisdictions.

3. A More Enabling Regulatory Model

A more enabling environment does not require lowering scientific standards. It requires making the level of oversight more proportionate, the evidence expectations more explicit, and the results of scientific reviews more reusable. Four complementary approaches could be advanced through the Asia Innovation-Ready Food Regulatory Systems Initiative.

3.1 A tiered, risk-based model of oversight

Not all health claims create the same level of consumer risk. A claim relating to a modest, reversible physiological effect does not carry the same public-health consequence as a claim that could materially

influence the behavior of a person with hypertension, impaired glucose control, cognitive decline or another condition where reliance on the claim could affect health outcomes.

A tiered model could therefore distinguish claims according to the consequence of a claim being false, overstated or misunderstood. Lower-risk claims could be managed through notification, defined substantiation requirements and strong post-market oversight. Claims with greater potential health consequence, claims directed at vulnerable populations, or claims that approach disease-risk reduction or therapeutic territory would remain subject to pre-market scientific review and authorization.

Illustrative tier	Possible oversight	Regulatory logic
Lower-risk function claims	Notification / defined self-substantiation + post-market verification	Low consequence if effect is modestly misstated; regulator retains enforcement power.
Intermediate claims	Pre-clearance against common guidance, potentially supported by recognized third-party review	Greater scientific complexity or consumer reliance warrants structured review.
Higher-risk claims	Pre-market review and explicit regulator authorization	Potential for significant health consequence, vulnerable populations or proximity to disease-related claims.

3.2 Make existing positive lists scientifically reusable

Positive lists across the region represent an underused regulatory asset. They document claims and ingredient–claim relationships that have already passed through national regulatory systems, but the scientific reasoning supporting those decisions is not always accessible in a form that another authority can readily use.

A practical collaborative project would be to compile the positive lists used by participating regulators and, where possible, link each accepted claim to the scientific evidence, assessment rationale, conditions of use, target population and any warnings or limitations that supported the original decision. This would create a regional evidence map rather than simply a list of permitted wording.

> **REGIONAL INFORMATION-SHARING OPPORTUNITY**
>
> Create a regulator-facing repository of accepted ingredient–claim pairs, the evidence supporting them, the conditions of use and the regulatory reasoning. The objective is not automatic mutual recognition, but better-informed reliance and less duplication.

3.3 Develop common guidance for substantiation

The second major opportunity is the development of **a common Asian guidance document for substantiation of non-nutrient health claims**. Such guidance could be built from the existing requirements and practices of participating authorities, while providing greater operational detail than is currently available in many national instruments.

The guidance should address, at minimum, characterization of the food or functional constituent; definition of **the claimed beneficial physiological effect**; relevance of the target population; human intervention evidence; study design and duration; appropriate biomarkers and endpoints; dose and conditions of use; totality and consistency of the evidence; treatment of systematic reviews and meta-analyses; product or ingredient comparability; conflicts of interest; evidence both supportive and non-supportive of the claim; and the relationship between the final claim wording and the strength of the evidence.

The Goji berry and GABA pilots provide immediate test cases. They can be used to identify which evidentiary elements are decisive, where existing national approaches converge, and where further guidance is needed before a claim conclusion can be considered transferable across jurisdictions.

3.4 Recognized third-party scientific review with regulator oversight

Thailand provides an important operational precedent. Claims outside the established lists can be assessed by nutrition and health-claim assessment centers recognized by the Thai Food and Drug Administration, with the assessment report then submitted to the regulator for approval. This separates scientific dossier evaluation from the final exercise of regulatory authority without transferring accountability away from the regulator.

A regional adaptation could establish **criteria for recognized third-party scientific panels** or assessment centers. These could combine independent academic expertise, technical experts from the food sector, and, where appropriate, participation or observation by regulators. Their role would be to apply regulator-developed guidance, improve dossier quality, perform transparent scientific assessment and issue a pre-clearance opinion. National authorities would retain the power to accept, reject, condition or revisit the claim.

> **KEY SAFEGUARD**
>
> Third-party review should support regulatory capacity, not replace regulatory authority. Regulators would define the rules, recognition criteria, conflict-of-interest controls, evidence standards and conditions for reliance, while retaining the final decision and post-market enforcement powers.

4. From National Approval to Regional Reliance

The longer-term opportunity is to move from isolated national approvals toward a system of mutual confidence. A shared assessment does not require identical laws or automatic recognition. It requires a sufficiently transparent scientific record that another competent authority can understand what was assessed, under what conditions, and why the conclusion was reached.

The Asia Innovation-Ready Food Regulatory Systems Initiative can serve as the neutral platform for this transition. Through the GABA and Goji pilots, it can test common dossier templates, common evidence-grading principles, generalized ingredient–claim assessment reports, and a process through which participating authorities may choose to rely on a prior assessment while retaining national legal responsibility.

5. Proposed Work Programme Following Zhangzhou

1. Map existing positive lists and pathways	Compile accepted non-nutrient claims across participating Asian jurisdictions and identify the underlying evidence and conditions of use where these are available.
2. Draft a tiered oversight model	Develop criteria distinguishing claims suitable for notification/post-market control from claims requiring pre-market review.
3. Prepare common substantiation guidance	Translate existing national requirements into a more detailed, regulator-led guidance covering evidence quality, human studies, endpoints, dose, target population, totality of evidence and claim wording.
4. Define a recognized third-party review model	Develop criteria for recognition, governance, expertise, independence, conflict-of-interest management, transparency and regulator interaction, building on the Thai experience.

5. Build the information-sharing platform	Create a structured repository of accepted claims, assessment summaries and supporting science to facilitate reliance and reduce duplication.
6. Use GABA and Goji as validation pilots	Apply the proposed guidance and review model to the two current pilots and identify where the framework needs refinement before broader use.

6. Questions for Regulatory Discussion

- **Can Asian regulators agree on a small number of evidence categories and minimum dossier elements that would apply across jurisdictions?**
- **Which claim types are sufficiently low risk to be managed primarily through notification and post-market oversight, and which should always remain subject to pre-market review?**
- **Can existing positive lists be converted into a regional evidence resource by linking accepted wording to the scientific basis and conditions of use?**
- **What level of transparency is needed for one authority to rely on, or give weight to, an assessment conducted elsewhere?**
- **What criteria should govern recognition of third-party scientific assessment bodies, and how should conflicts of interest be managed?**
- **How can the GABA and Goji pilots be used immediately to test the feasibility of a common claims-substantiation framework?**

7. Conclusion

Asia already has many of the building blocks required for a more enabling claims environment: national regulations, positive lists, expert review structures, scientific assessment experience and, in Thailand, an operational model of recognized third-party assessment. The principal opportunity is to connect these elements so that evidence expectations become clearer, scientific work can be reused, and regulatory oversight can be proportionate to the actual health significance of the claim.

The objective is not to lower the threshold for health claims. It is to make the threshold visible, scientifically coherent and operationally achievable. A risk-based system, shared substantiation guidance, a regulator-facing evidence platform and carefully governed third-party pre-clearance could together provide a more predictable pathway for responsible innovation while preserving consumer protection and national regulatory authority.

These proposals should therefore be carried forward as part of the next phase of work under the Asia Innovation-Ready Food Regulatory Systems Initiative, with the GABA and Goji pilots serving as the first practical tests of the proposed approach.

Reference Documents

- Codex Alimentarius. Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997, as amended).
- Tee, E-Siong. Non-Nutrients Health Claims in Southeast Asia – Overview of Current Situation. Presentation to the Asia Innovation-Ready Food Regulatory Systems Initiative, Zhangzhou, September 2026.
- AFIRS. Non-nutrient claims in Asia: from substantiation to predictability. Session 1 discussion slides, Zhangzhou, September 2026.
- Indonesia Food and Drug Authority (BPOM). Regulation No. 1 of 2022 concerning monitoring of claims on labels and advertisements of processed foods.

- Malaysia. Food Regulations 1985, including Regulation 18F on Other Function Claims.
- Thailand Ministry of Public Health. Notification No. 447 B.E. 2566 (2023) on health claims made on food labelling.
- Singapore Health Promotion Board. A Guide to Nutrition Labelling for Food Products, revised August 2024.
- Tee ES, Chan P. Regulatory status of bioactive non-nutritional food components in Southeast Asian countries. Malaysian Journal of Nutrition. 2022;28(3):461–505.