



FOOD INNOVATION-READY REGULATORY SYSTEMS INITIATIVE

SECOND WORKING MEETING



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Non-nutrient claims in Asia: from substantiation to predictability

Reflections following the presentation by Prof. Tee: positive lists, risk-based options and a collaborative pathway

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What Prof. Tee's presentation showed us

Asia has countries with a clear framework that is open to the acceptance of non-nutrient claims — but openness is not the same as predictability.

1

Clear frameworks exist

- Several Asian countries operate a defined framework for non-nutrient (function) claims
- Frameworks are open in principle to accepting new claims

2

Substantiation is required

- Every framework states that scientific substantiation is needed
- The requirement is a condition of acceptance in each jurisdiction

3

But no clear guidance

- No framework spells out what evidence is expected, or how it is weighed
- Applicants cannot anticipate the outcome of an assessment

4

Result: no predictability

- Acceptance is managed through positive lists
- Anything outside the list has no visible route to acceptance

Frameworks are open, substantiation is mandatory, guidance is missing — so the outcome of a claim submission cannot be predicted.

Positive lists: the questions on the table

The positive list gives certainty on what is already accepted, but says nothing about how something new gets there.



Should everything be managed by a positive list?

A list is transparent and easy to enforce, but it freezes innovation at the date of the last update and gives no route for ingredients or claims that are not yet listed.



Should the approach be risk-based?

Claims differ widely in the health stakes involved. A proportionate, risk-based route could reserve the heaviest scrutiny for claims with the highest potential to mislead or to affect vulnerable groups.



Is there a way to a more collaborative approach?

If several jurisdictions ask for the same science, the evidence review could be shared rather than repeated — provided the type of data and the format of the outcome are agreed in advance.

These three questions are open for discussion — the pilots can help answer them with evidence rather than opinion.

Building blocks of a collaborative approach

Three practical steps would turn “scientific substantiation is required” into something an applicant and a regulator can both work with.

1

Codify the type of data needed

- Agree the categories of evidence expected for a non-nutrient claim: human studies, mechanism, dose, target population
- Publish it as a common data template usable across jurisdictions
- Predictability starts with a known checklist

2

Generalise the results of assessments

- Write assessment conclusions so they apply to an ingredient–claim pair, not to a single product file
- Allow another authority to rely on the conclusion rather than re-do the review
- Reduce duplicated effort and divergent outcomes

3

Third-party supported effort

- Thai example: the authority recognises third parties to evaluate claim dossiers — a model that already works nationally
- Can this recognition be generalised to a regional third party, with regulators keeping the decision?
- GForSS / AFIRS can host and coordinate this effort

Codified data + generalisable conclusions + a shared scientific effort = a claims pathway that is predictable without being closed.

Asia-FIRN / GFIRN with a pre-clearance house

A network-based process for the acceptance of claims — and a source of guidance for countries that have no process today.

- 1 Submission**
Applicant files the dossier once, using the codified data template
- 2 Shared review**
Third-party scientific panel assesses the evidence for the ingredient–claim pair
- 3 Pre-clearance opinion**
Generalised conclusion issued by the network, with the wording and conditions of use
- 4 National acceptance**
Each participating authority relies on the opinion to accept the claim under its own framework

Where no process exists

- Some countries in the region have no route at all for non-nutrient claims
- Is there a possibility for guidance on that? The network opinion could serve as reference guidance
- A country can adopt the pre-clearance outcome as its interim process rather than building one from scratch
- Thailand's recognition of third-party evaluators shows the mechanism is workable — the question is whether it can be generalised

One dossier, one shared review, one generalised opinion — usable by countries with a framework and by those still without one.

Nutrient profiling: an option to discuss

Offers have been made to introduce nutrient profiling alongside claims. The question is how it is designed — not whether it is worth discussing.

The concern

- A nutrient profile applied as a gate would negate claims on whole categories of foods
- Dairy products are the clearest example: yogurt and other fermented products carry well-substantiated functional claims but may fail a profile on fat, sugar or sodium
- The result would be to block claims that are scientifically valid, on foods with an established place in the diet

The principle

- A nutrient profile should function hand in hand with claims, not negate them
- Profiling can inform how a claim is presented and on which products, without cancelling the underlying substantiation
- Design options to discuss: category-specific profiles, conditions of use rather than exclusion, and coherence with the claims substantiation route

Discuss nutrient profiling as a companion to the claims framework — a tool that complements substantiation rather than overriding it.

What this forum can do, and what the pilots give us

Turning today's discussion into deliverables that the AFIRS work programme can carry forward.

What this forum can do

- Agree that the claims substantiation gap is a priority workstream
- Draft the codified data template for non-nutrient claims
- Define the pre-clearance house concept within Asia-FIRN / GFIRN
- Prepare interim guidance for countries with no claims process
- Frame the nutrient profiling discussion so it works with, not against, claims

What we gain from the pilots

- GABA and goji test whether a shared evidence review can produce a generalisable claims conclusion
- They reveal which data types are decisive and which are missing
- They show how one opinion can be relied on across several jurisdictions
- They give a concrete case for a risk-based route rather than a positive-list-only route
- They produce the first reusable outputs of the pre-clearance model

From the pilots to a predictable, collaborative claims pathway: this is the outcome Zhangzhou can commit to.



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Thank you

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