EVENT 1: REGIONAL THINK TANK ON INNOVATION-READY FOOD REGULATORY SYSTEMS IN ASIA

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SESSION 2
GUIDED DISCUSSION QUESTIONNAIRE PRIORITIZING FUNCTIONAL INGREDIENTS AND CLAIMS FOR CONVERGENT REGULATORY PATHWAYS IN ASIA

1. Framing the Scope of Prioritization

- Which categories of functional ingredients should be in scope for the pilot (e.g. traditional medicine-derived, bioactives, microbiome-related, novel extracts)?
- Should prioritization focus on “near-market” ingredients (already approved somewhere) or include emerging/novel candidates?
- What level of scientific maturity is sufficient for inclusion in the pilot?

2. Developing Prioritization Criteria (Ingredients)

Which criteria are most critical when selecting priority ingredients?

- Existing approval/use in Asia?
- Strength of safety and/or efficacy data?
- Economic/market relevance?
- Link to traditional knowledge systems?
- How should we weigh traditional use vs. modern scientific evidence?
- What constitutes a “credible regulatory starting point” (e.g. approval in ≥1 jurisdiction, GRAS-like status, published risk assessment)?
- Should scalability and supply chain feasibility be explicitly considered?

3. Identification of Priority Functional Ingredients

- Which specific ingredients meet the agreed criteria?
- Are there ingredients that:
  - Already face market access barriers across multiple jurisdictions?
  - Have high regional relevance but fragmented regulatory status?
- Which ingredients could serve as "low-risk / high-impact" pilot candidates?
- Are there examples from prior novel foods discussions that could be revisited for prioritization?

4. Prioritization of Non-Nutrient Claims

- Which types of claims are most suitable for convergence?
  Non-Nutrient Claims with aspects related to:
  - Structure/function claims?
  - Risk reduction claims?
  - Traditional use-based claims?
- Which claims already have strong scientific substantiation but inconsistent regulatory acceptance?
- Should claims be prioritized only if linked to selected ingredients, or considered more broadly?
- What level of evidence should be considered "sufficient for alignment discussions"?

5. Linking Ingredients and Claims

- For each shortlisted ingredient, what are the most relevant associated claims?
- Are there claim categories that could be standardized across multiple ingredients?
- Where do we see the greatest mismatch between:
  - Scientific evidence.
  - Regulatory acceptance.
  - Market practice.

6. Understanding Market Access Barriers

- What are the main regulatory bottlenecks affecting prioritized ingredients/claims?
  - Novelty classification triggers?
  - Divergent safety data requirements?
  - Claims substantiation thresholds?
- Which barriers are:
  - Technical (data-related) vs.
  - Procedural (approval pathways) vs.
  - Policy-driven (risk perception, precautionary approaches)?
- Which barriers are most feasible to address in a pilot phase?

7. Enhancing Regulatory Predictability

- Where do regulatory requirements already converge across jurisdictions?
- What elements could be aligned relatively quickly:
  - Definitions of functional ingredients?
  - Data requirements for safety?
  - Claims substantiation frameworks?
- Could a common minimum data set be envisaged for pilot ingredients?

8. Access to Scientific Assessments and Data

- What are the current challenges in accessing:
  - Existing risk assessments?
  - Claims evaluations?
- Would a shared repository of scientific opinions be feasible?
- What level of transparency is acceptable for regulators and industry?
- Are there existing models (regional/international) that could be leveraged?

9. Prioritizing Actions for Barrier Reduction

- Which 2–3 priority actions would most effectively improve market access?
  - Should the focus be on:
  - Guidance development?
  - Data harmonization?
  - Mutual reliance / recognition mechanisms?
- What can realistically be achieved within a 2-year pilot timeframe?

10. Models for Regulatory Cooperation

- Which cooperation model is most appropriate for the pilot:
  - Informal information sharing?
  - Sequential review?
  - Joint assessment?
- What lessons can be drawn from existing initiatives (e.g. FIRN)?
- What are the minimum conditions for trust and reliance between jurisdictions?

11. Role of the Asia Food Innovation Initiative

- How can the initiative best support:
  - Coordination between regulators?
  - Technical exchange and expert mobilization?
  - Pilot implementation and follow-up?
  - What should be its first concrete deliverable post-session?