SESSION 3 · CASE STUDY & FACILITATED DISCUSSION

Good Regulatory Practices

Food Additives as a Test of Regulatory Robustness

National Workshop "Advancing Indonesia's Food Regulatory System"
IPMI International Business School · Jakarta, Indonesia · 1 September 2026

Purpose of the Session

Food additives regulation provides perhaps one of the clearest illustrations of how a food regulatory system responds to requests from the food industry to introduce substances, new uses or new technological applications in food production. It requires the regulator to evaluate scientific evidence, assess safety and exposure, consider technological need, benchmark decisions against international standards, and communicate resulting requirements to industry and consumers.

For this reason, food additives will be used as a practical case study to explore the foundations of Good Regulatory Practices and how these principles operate in the Indonesian context — particularly transparency, predictability, efficiency, fair competition, international benchmarking, stakeholder confidence and innovation readiness.

How the Case Study Will Be Used

The discussion will consider food additive regulation from two complementary perspectives. The first is the review and approval of food additives and their conditions of use: how an application enters the regulatory system, how safety and technological justification are assessed, how Codex and international scientific assessments are considered, how stakeholders interact with the process, and how efficiently and predictably a decision is reached.

Introductory GFoRSS video: Food Additives – Regulatory Review and Approval

The second perspective concerns labelling as a regulatory and risk-management measure. The Southampton case will be used to examine how regulators may respond when emerging scientific evidence raises a possible concern, including whether mandatory labelling is justified, proportionate to the evidence, and consistent with the principles normally applied when labelling is made mandatory for risk-management purposes.

Case Study: The Southampton Study

In 2007, a randomized, double-blind, placebo-controlled study by McCann et al., commissioned by the UK Food Standards Agency, examined mixtures containing six food colours — tartrazine (E102), quinoline yellow (E104), sunset yellow FCF (E110), ponceau 4R (E124), allura red AC (E129) and carmoisine (E122) — together with sodium benzoate (E211). The study reported an association between the mixtures and increased hyperactivity in some children.

The subsequent regulatory response is particularly instructive. EFSA concluded that the findings did not provide a basis for altering the Acceptable Daily Intakes for the colours or sodium benzoate, noting inconsistencies among age groups and mixtures and uncertainty regarding the clinical significance of the observed behavioural changes. The UK Committee on Toxicology also identified important limitations. Health

Canada concluded that the weight of evidence suggested an association but did not establish causality and did not consider that the evidence warranted a change to its risk-management framework.

The European Union nevertheless introduced a mandatory precautionary statement for foods containing the six colours: "May have an adverse effect on activity and attention in children." Many other jurisdictions did not follow the European Union's approach and did not introduce an equivalent labelling requirement.

For the purpose of this workshop, the case illustrates a clear departure from the principles normally expected when labelling is made mandatory for risk-management purposes: the measure should be supported by the evidence, directly address the risk being managed, be clear and unambiguous, be proportionate, and avoid misleading consumers. The broader question is therefore how regulators should manage scientific uncertainty while maintaining the connection between risk assessment, risk management and credible consumer information.

Reference Principles for the Discussion

The workshop Discussion Paper proposes that robust food regulatory decisions should be made through a recognized risk-analysis framework and should be scientifically grounded, internationally benchmarked, proportionate, transparent, inclusive, predictable and timely. Good governance, scientific capacity, institutional functionality and collaboration among regulatory partners are indispensable enablers of that process.

Short Questionnaire for Facilitated Discussion

Please use the questions below to identify strengths, practical experiences and opportunities for continued modernization of Indonesia's food regulatory framework. Brief examples are particularly encouraged.

1. Food additive approval and predictability

How would you characterize Indonesia's current process for reviewing and approving a new food additive or a new use of an existing additive? Is the pathway sufficiently clear, science- and risk-based, transparent, predictable and timely for regulators and applicants?

2. International benchmarking and convergence

To what extent should Indonesia rely upon or take into account JECFA scientific assessments and Codex food additive standards when making national decisions? Where Indonesia adopts a different approach, what should constitute an adequate scientific or national justification?

3. Stakeholder participation and regulatory governance

Are there sufficiently clear and recognized mechanisms through which industry, academia, consumers and

other government partners can contribute scientific evidence, exposure information, technological justification and implementation considerations without compromising the independence of the regulatory decision?

4. Labelling as a risk-management measure — lessons from the Southampton case

Several jurisdictions reviewed the Southampton evidence but did not follow the European Union in requiring precautionary labelling for the food colours concerned. Can participants identify a comparable situation in Indonesia where a mandatory food labelling requirement may not have been sufficiently substantiated by the available scientific evidence or by the risk being managed, and where further discussion with the food regulator may therefore be warranted? More broadly, what principles should Indonesia apply before introducing mandatory labelling as a food risk-management measure to ensure that the requirement is evidence-based, proportionate, non-misleading and consistent with international good regulatory practices?

5. Indonesia and innovation readiness

Using food additives as a practical test case, what are the principal strengths of the Indonesian regulatory framework, and what one or two improvements would most enhance its ability to respond efficiently to food innovation while maintaining consumer protection?

Closing Question

If an innovative food ingredient or additive that has been scientifically assessed internationally and accepted through Codex were presented for use in Indonesia tomorrow, how confident are we that there is a clear, predictable and timely pathway to reach a scientifically sound regulatory decision?

Use of the discussion: The observations from this session will feed into the subsequent interactive assessment of Indonesia's food regulatory system and the development of the Jakarta Recommendations on food regulatory modernization.

Key Recommendation / Point to Carry Forward

What is the most important practical recommendation from this case study that should be considered in the Jakarta Recommendations?

Workshop background: Discussion Paper, "Foundations of a Robust, Predictable and Innovation-Ready Food Regulatory System"; Session 3 agenda; and GFoRSS Southampton Study case-study material.