

## Rulemaking Procedures: Science the Basis

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As students we've been taught that Parliament makes laws and the Executive implements them. Less widely known though is that before implementing the law – rulemaking must first be done.

Legislatures while enacting the law find it impractical to get into the level of detail or expertise required to establish complete standards. They delegate these powers to agencies; in this case the Food Safety & Standards Authority of India [FSSAI]: it is the regulatory agency that will make the rules.

Because legislative power is so copiously transferred to executive agencies, the bestowal of such statutory authority should be balanced with openness, transparency and public participation. While agency-made law is a reality, it is legitimate only where the agency scrupulously observes procedures specified for issuing legally binding rules. In this case the Food Safety and Standards Act 2006 apart from laying down food policy also provides for rulemaking procedures to be followed. These procedures are founded in the principles of responsible deliberations based on scientific evidence, open notice and public participation. It requires regulators to take a 'hard look' at the facts before making the rules.

Although judicial reviews are instrumental in discouraging poorly supported rules, it is not the main focus of our attention here. *The key point being made is that the rulemaking system should be self correcting. It can be so if all state actors faithfully implement the mandate of the Act with regard to rulemaking.*

### The Role of Science:

This article is focused on the principle of science based rulemaking. Put simply – what elements in the rulemaking process should provoke stakeholders and members of various constituted bodies to engage in science based deliberations. *For the system to be self correcting what are those clauses in the Act to be invoked when deliberations and outputs stray from the scientific path.*

The need of science based rulemaking is to minimize the influence of interests, because they introduce biases into decision making. Stakeholder interests frequently distort facts on the ground, ostensibly triggering a public display of action but in reality are unable to show impact on safety and health of the consumer.

Science on the other hand is a deliberate, rational process. Scientists strive to be dispassionate observers to prevent personal values from influencing the decision making process. *They are neutral examiners of scientific evidence – sifting for trends, contradictions ultimately reaching the best possible scientific consensus. This they do because of their scientific training that conditions them to deliberately blank out confounding factors e.g. randomized double blinding of research studies, independent peer review, etc. It is this bent of mind that the Food Authority is depending on when they request inputs from the Scientific Committee/Panels.*

Accordingly, under Section 13(1) the Food Authority has appointed independent scientific experts to the Scientific Committee and Scientific Panels. Members of the Scientific Committee/Panels are expected to fulfill their roles not as stakeholder representatives, but as independent experts whose expertise arises from their stakeholder surroundings.

### **Scientific Committee & Panels: Role and Remit**

The primary role of the Scientific Committee and Scientific Panels is to help collect scientific information and make judgments about it. They review scientific studies and offer independent expert judgment, including where facts are missing or uncertainties exist. Providing scientific input is the first step to assisting or framing of policy or the rule. *The Act defines the role expectation of the Scientific Committee in Section 14(2) where it states 'the Scientific Committee shall be responsible for providing the scientific opinions to the Food Authority and shall have powers where necessary of organizing public hearings. It does not have the role to provide rulemaking options – a task that falls within the domain of the Food Authority.*

The role differentiation is further strengthened to remove ambiguous interpretations in Section 14 (3): "The Scientific Committee shall be responsible for the general co-ordination necessary to ensure consistency of the scientific opinion procedure and in particular with regard to the adoption of working procedures and harmonization of working methods of the Scientific Panels. The functional separation of risk assessment and risk management is mandated in the Act. Members of the different constituted bodies under the Act should be clear about their role and remit while conducting their deliberations.

Scientific Committee or Scientific Panels providing scientific opinions would not undertake the role of framing of the rules. The task of rulemaking is essentially one for the Food Authority and can be thought of as working up practical options for responses to the problem on which scientific advice has been sought, analyzing those options and making decisions on them. This is precisely why Scientific Committee/Scientific Panels are not expected to fulfill their roles as stakeholder representatives, although individual members may have been appointed because of stakeholder associations that provide the expertise that is required. *The point to appreciate is that the Act has mandated a separation of science from policy; thereby segregating facts from interests. This is critical if other clauses in the Act are to be honored namely for rules to be proportionate and not too restrictive to trade and yet provides the appropriate level of protection to the consumer.*

In the previous system under PFA, members of the Sub Committees were often involved with the approval process of the Central Committee on Food Standards [CCFS]. This led to the inappropriate situation whereby CCFS in a sense reviewed its own previous decisions under various subcommittees. Also the Subcommittee and CCFS did not engage in separate deliberations of science or policy – more often in the absence of clear mandates engagements were an arbitrary mixture of both science and policy. This inherently was a lack of clarity in the Act; moreover members were chosen for their stakeholder interests rather than expertise.

#### The Agenda: How to seek Scientific Opinions:

The role and function of the Scientific Committee and Scientific Panels are set by statute. It is the Food Authority's responsibility to ensure that the Committee/Panels remit is clear and this may be specified by regulations. It is therefore the subsequent responsibility of the Committee/Panels to raise concerns if they believe there are ambiguities particular in the agenda setting. As a general principle, any required clarification required should be done before they begin their work. Under Section 15 (4) (d) the Food Authority shall specify by regulations the procedure for the operation and co-operation of the Scientific Committee/Scientific Panels in particular related to the manner in which tasks and requests for Scientific opinions are assigned to them.

Typically a request outlines what is being asked of the Scientific Committee or Scientific Panels, or any constituted body namely the issue, terms of reference, timeframe etc. A request normally results in the release of an **opinion** about each request, including supporting documents, the latter becoming the database for reference either at the WTO or judicial level as evidence of well supported rulemaking.

Agenda setting must not indicate or suggest a pre-settled position either in the language of the query on safety or the terms of reference. The background matter or data or reference giving rise to the query may be presented in an objective manner for the Committee/Panels to deliberate. This will ensure objectivity and transparency of the process.

#### **Delivering the Scientific Opinion:**

A Scientific Opinion is a scientific output in the form of a concise document adopted by the Scientific Committee/Scientific Panel that addresses a risk assessment or an evaluation of a risk on the opinion sought by the Food Authority.

The Scientific Panel shall rely on risk assessment which may among other considerations comprise information on risks identified, organized and analyzed in a systematic way to get a clear, consistent presentation of the data available for practical decision-making. The results of the risk assessment process shall form the basis for the risk management process.

An important factor for consistency in the scientific opinion procedure [Act 14(2) (3)] is that all Scientific Panels deliver scientific opinions in a predetermined format. This may be in the form of:

- The background and terms of reference as provided by the Food Authority or any other stakeholder.
- A summary opinion (with keywords), informative for the technical and non-technical reader summarizing which questions were addressed, which information was evaluated, the key issues that resulted to the opinion and conclusions based on the assessment.
- The assessment, i.e. the actual risk assessment section, addressing the questions posed, how the information was evaluated and which issues were considered of key-relevance for the opinion
- Conclusions and recommendations.
- A list of the references and documentation on which the opinion is based.

Opinions provided by the Scientific Committee and Scientific Panels are required by the Act to be made public as per Section 16(4)(a) wherein it states '*the Food Authority shall make public without undue delay – the opinions of the Scientific Committee/Scientific Panel immediately after adoption*'.

There are several reasons why the Food Authority would push forward the mandate of the law requiring risk analysis. The most fundamental reason would be to build a reliable structure of scientists and experts that conduct risk assessment in the most expedient fashion thus providing a sound framework from which rules are made.

Secondly rules that emerge from such a framework will provide a high level of consumer health protection. As food innovations take place in the market place, the Food Authority will face the challenge of balancing industry aspirations with the need to reduce the risk of adverse effects. Finding the correct balance for taking transparent and coherent actions requires a structured decisions making process, within the overall framework of risk analysis.

In other words regulations that are founded in science reflects the strong belief of the Food Safety and Standards Authority of India that science based food safety in the decision making process is the underpinning principle of consumer health.

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