Operationalizing the Regulation of Genetically Modified Foods in India

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1 OPERATIONALIZING THE REGULATION OF GM FOODS IN INDIA

In India, the regulation of all activities related to GMOs and products derived from GMOs is governed by "*Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989"* (commonly referred to as *Rules, 1989*) under the provisions of the *Environment (Protection) Act, 1986* through the Ministry of Environment and Forests (MoEF). The *Rules, 1989* are primarily implemented by MoEF and the Department of Biotechnology (DBT), Ministry of Science and Technology through six competent authorities: the Recombinant DNA Advisory Committee (RDAC); the Review Committee on Genetic Manipulation (RCGM); the Genetic Engineering Approval Committee (GEAC); Institutional Biosafety Committees (IBSC); State Biosafety Coordination Committees (SBCC), and; District Level Committees (DLC). The *Rules, 1989* are very broad in scope and essentially capture all activities, products and processes related to or derived from biotechnology including foods derived from biotechnology, thereby making GEAC as the competent authority to approve or disapprove the release of GM foods in the marketplace.

The *Food Safety and Standards Act, 2006* (*FSSA, 2006*).

Following the promulgation of the *Food Safety and Standards Act, 2006*, which empowers the Food Safety and Standards Authority of India (FSSAI) to regulate genetically modified (GM) foods, MoEF published Notification No. S.O. 1519(E) dated 23-8-2007 in the Gazette of India. This notification exempted "food stuffs, ingredients in foodstuffs and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organism" from Rule 11 of the *Rules,1989.* At the time of Notification No. S.O. 1519(E), the FSSAI had yet to publish rules that described how GM food stuffs (*i.e*., processed foods containing one or more ingredients derived from a genetically modified organism) would be regulated under the *FSSA,* 2006 and consequently MoEF published a series of additional notifications that have kept Notification No. S.O. 1519(E) in abeyance so that GM foods could, as an interim measure, continue to be regulated under *Rules, 1989*.

The FSSAI now intends to meet its regulatory obligations by implementing a safety assessment and approval process for GM foods that leverages existing regulatory capacity within the Government of India, notably within DBT, MoEF and the Indian Council of Medical Research (ICMR). The responsibility of the FSSAI relative to other governmental authorities involved in the regulation of GM organisms in India (excluding pharmaceutical applications) is shown in Table 1 and Figure 1.

Table 1. Responsibilities of governmental authorities as regards the regulation of GMOs in India (excluding pharmaceutical applications).

Activity	Responsible Authority
Contained research (laboratory and greenhouse)	RCGM (DBT)
Event selection trials/BRL 1 trials	RCGM and GEAC (MoEF)
Food safety assessment of GM foods (viable and processed)	FSSAI
Environmental risk assessment of GM organisms	GEAC
Approval for commercial release of GM foods (processed)	FSSAI
Approval for commercial release of GM foods (viable *i.e.* LMOs)	GEAC
Approval for environmental (commercial) release of GM organisms	GEAC

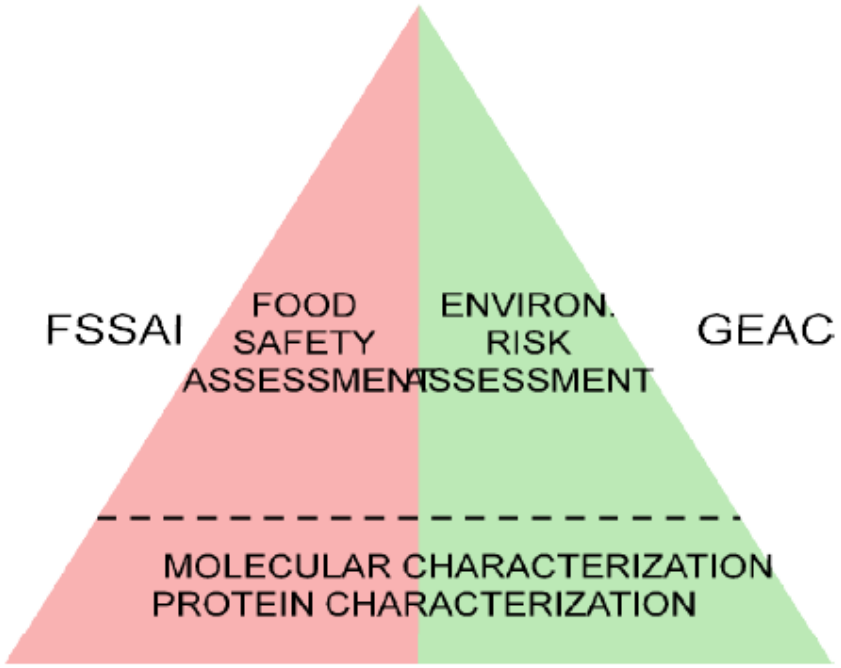

Figure 1. The food safety assessment and the environmental risk assessment of GM organisms are separate and distinct evaluations that share some common elements of information provided through the molecular characterization of the GM organism and characterization of the expressed, transgenic proteins.

1.1 ORGANIZATIONAL STRUCTURE

In order to manage the administration of the regulatory program for GM foods, the FSSAI will establish a new secretariat within the FSSAI, namely the Office of GM Foods and the GM Food Safety Assessment Unit (see Figure 2).

Initially staffed with two Scientific Officers, the Office of GM Foods will be responsible for:

- Coordinating the receipt of GM food safety applications;
- Conducting administrative reviews of applications;
- Verifying submitted documents;
- Managing communication and correspondence with applicants;
- Managing the tracking of applications;
- Providing a secretariat function for the GMFSAU and Expert Committee on GM Foods (*e.g.*, meeting coordination, report taking, document tracking); and
- Managing communications and outreach with stakeholders and the public (*e.g.*, ensuring that information about GM food regulation, policy and decisions are made promptly available on the FSSAI website).

The GMFSAU will be comprised of a multi-disciplinary team of scientists trained in GM food safety assessment and will include each of the following (at a minimum): molecular biologist; biochemist; immunologist; food allergenicity specialist; toxicologist; nutritionist. The GMFSAU will be situated at the National Institute of Nutrition, Hyderabad. NIN has experience in GM food safety assessment and already provides science advice to RCGM and GEAC in this regard. Further the Scientist at GMFSAU will have to access to the library and other facilities at NIN for accessing the latest literature on the subject. The GMFSAU will report administratively to the Director, NIN and operationally to the FSSAI. The FSSAI and NIN will be committed to ensuring that the member scientists of the GMFSAU have the appropriate combination of subject-matter expertise, are free from conflicts of interest, and are provided with opportunities to maintain and enhance their scientific knowledge and safety assessment experience.

The FSSAI will also establish the Expert Committee on GM Foods which will: oversee a public consultation process[1]; consider and respond to comments received during public consultations; and recommend any conditions to be stipulated for product approvals keeping in view the safety assessment report by GMFSAU. The Expert Committee on GM Foods will be comprised of the following members:

- Chief Executive Officer (CEO), FSSAI (acting as Chair of the Expert Committee on GM Foods);
- Principal Scientific Officer, FSSAI;
- Chair, Scientific Panel on GM Organisms and Foods;
- Director, National Institution of Nutrition;
- Advisor, Department of Biotechnology;

[1] This will include the publication of draft decision documents for a period of public comment before final decisions are taken to approve/not approve applications.

- An eminent scientist with experience related to food safety;
- An expert in socioeconomic and/or consumer issues related to food safety.

The process for selection of scientists and experts will be laid down separately.

An organizational chart based on the above is provided in Figure 2 which also shows the relationship of the Office of GM Foods to the Scientific Panel on Genetically Modified Organisms and Foods, the Expert Committee on GM Foods and the GMFSAU. All of these are within the FSSAI.

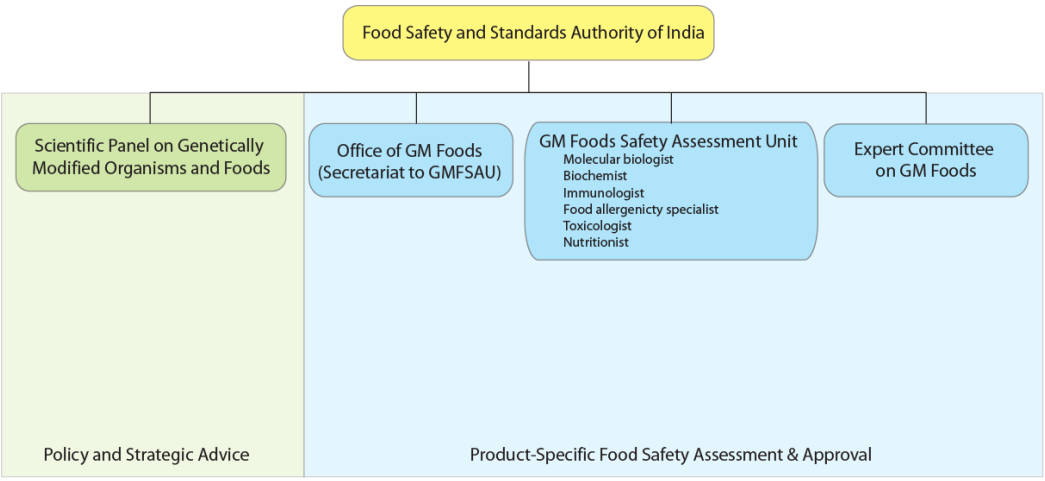

Figure 2. Organizational relationships within the FSSAI for the regulation of GM foods in India.

1.2 THE INTERIM PROCESS: APPLICATION, SAFETY ASSESSMENT AND DECISION MAKING

The steps in the interim process are as follows (see also Figure 3):

1. Applications for a GM food safety approval will be submitted to the Office of GM Foods. Applications must meet the information and data requirements as described in the "2008 Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants" and companion protocols[2]. A proforma will be developed by FSAAI to standardize the format of the application.
2. The same application and assessment procedure applies to GM events that may be developed domestically or imported (see section 1.3 below).
3. The Office of GM Foods will complete an administrative review of each application to verify submitted documentation and to ensure that each required section of an application has been completed (*e.g.*, applicant name and address). This is not a technical review. Applications that are deemed complete will be entered into an

[2] http://igmoris.nic.in/files/Coverpage.pdf and http://igmoris.nic.in/files/Coverpage1.pdf.

application tracking system and an acknowledgement will be provided from the Office of GM Foods to the applicant within 10 days. Applications that are deemed incomplete will be returned to the applicant with an explanatory letter also within 30 days. Applicants will be permitted to re-submit applications without prejudice when errors or omissions have been corrected.

4. The application is provided to the members of the GMFSAU and the safety assessment process begins.

   Applicants will not be permitted to communicate directly with members of the GMFSAU and vice versa. Communications between applicants and the GMFSAU will be facilitated by the Office of GM Foods and may occur during one or more of the following three stages:

   - During product development and prior to submission of an application to the FSSAI (*e.g.*, during BRLI and BRLII confined field trials) when product developers may seek guidance or clarification about experimental protocols and design, data collection and/or data interpretation relevant to the "2008 Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants" and companion protocols;
   - Dossier development; and/or
   - During the GM food safety assessment by the GMFSAU when the Unit may seek clarification or additional information from the applicant.

   It is common that during a safety assessment, the evaluators may require clarifications about information, data or studies and these can be requested from the applicant. Additionally, the evaluators may encounter deficiencies in the information provided by the applicant (*e.g.*, a required study may not have been provided or required data may be missing). In both of these cases (clarifications and deficiencies) the safety assessment stops until the additional information is provided by the applicant. If the applicant cannot or does not provide this information within a reasonable amount of time, the application will be returned to the applicant and the file will be closed.

5. Upon completion of the safety assessment, the GMFSAU will prepare a Safety Assessment Report that summarizes the information that was taken into account during the safety assessment and states the decision of the GMFSAU as to whether the GM event that is the subject of the application may be considered as safe as its conventional (non-GM) counterpart in the context of its proposed uses as food. The safety assessment, preparation and submission of the Safety Assessment Report should be completed within the prescribed period of time (90 days) excluding the time required by an applicant to address any clarifications and/or deficiencies (which may extend the total time of the assessment to 6-12 months).

In cases where NIN is involved in performing any studies for safety assessment of GMOs, the GMFSAU will co-opt two or three additional excerpts from outside NIN to give opinion.

6. The Safety Assessment Report will be submitted to the FSSAI.
7. The CEO, FSSAI will convene the Expert Committee on GM Foods which will consider the Safety Assessment Report , oversee the public consultation process and make a recommendation to approve/not approve the subject event. This recommendation will be taken in a timely fashion (within 90 days of receiving the Safety Assessment Report).
8. In the case of **GM foods that are not LMOs**, the FSSAI will take a decision to approve/not approve the subject event based on the recommendation of the Expert Committee on GM Foods.
9. In the case of **GM foods that are also LMOs**, the FSSAI will forward the recommendation of the Expert Committee on GM Foods to the GEAC.
    a. GEAC will take a decision to approve/not approve the subject event based on the recommendation of the Expert Committee on GM Foods provided by the FSSAI. This decision will be taken in a timely fashion.
    b. Decision-making should be determined by the recommendation provided by the FSSAI to the GEAC. However, if it is decided that other non-safety considerations should also be included in the decision-making process, GEAC will ensure that these are consistent with the *Rules, 1989*, the *FFSA, 2006* as well as any other pertinent obligations that India has under international agreements. The inclusion of non-safety considerations must be carefully considered as a matter of policy and then defining regulations and guidance should be developed. This is essential to ensure that there is consistency and impartiality in how such considerations may be used to inform product-specific decisions.
    c. The GEAC will communicate its decision to the FSSAI.
10. The FSSAI will publish decision summaries of all GM food approvals and these will be posted on the FSSAI website.
11. The approval of an event by FSSAI or GEAC will apply to all foods that contain that event, whether imported or produced domestically. This will exempt the need for food importers and processors to submit applications to the FSSAI for the safety assessment of the same event.

1.3 OTHER KEY OPERATIONAL ELEMENTS

1. The FSSAI will assess GM foods at the level of an "event[3]". Approvals will apply to foods derived from the event, its progeny (including derived hybrids and varieties produced through conventional plant breeding) and any food stuffs that contain ingredients derived from the approved event and its progeny.
2. The safety assessment of an event will include the evaluation of the whole or primary food product in the forms that are commonly consumed in India. For example, the food safety assessment of a GM soybean event may include compositional and nutritional data for raw soybean seed **as well as** processed fractions of soybeans, such as toasted meal, defatted non-toasted meal, protein isolate, protein concentrate and oil. It will not include the safety assessment of biscuits that include soy oil as an ingredient (see point 1 above) as the soy oil will have been evaluated during the approval process for the subject soy event to be as safe as conventional soy oil.
3. Processed foods that contain ingredients derived from an approved GM event will not be subject to further regulation.
4. The Scientific Panel on Genetically Modified Organisms and Foods will have the responsibility of discussing issues related to regulatory policy and will provide strategic advice to the FSSAI. The Panel will have no responsibility for, or role in, product-specific safety assessments and subsequent decisions to approve/disapprove these products.
5. While applications to approve GM livestock feeds are submitted to GEAC, GEAC may seek comments based on GM food safety assessment from FSSAI on such applications as these feeds may potentially enter into the food chain.
6. All rules, regulations, policies, standards, guidance and decisions related to the regulation of GM foods will be made publicly available by the FSSAI and GEAC.

1.4 THE DEVELOPMENT OF GUIDELINES

The FSSAI will notify guidelines that clearly describe the regulatory framework for GM foods. These guidelines will provide details about the interim process for the regulation of GM foods as described below and will be in place until such time as new regulations are notified under the *FSSA, 2006*:

- The scope of the interim process;
- Application procedures and process;
- GM food safety assessment procedures and process including the format of the safety assessment report

[3] A genotype produced from the transformation of a single plant species using a specific genetic construct. For example, two lines of the same plant species transformed with the same or different constructs constitute two events.

- Decision-making procedures and process;
- Time standards;
- Protection of information;
- Draft standard for GM foods for incorporation in regulations;
- The role of the Scientific Panel on Genetically Modified Organisms and Foods;
- The purpose, constitution and operations of the Office of GM Foods, FSSAI; and
- The purpose, constitution and operations of the GMF SAU,

The "Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants" and the complementary GM food safety protocols that were approved by GEAC and RCGM in 2008 are will be adopted and implemented by the FSSAI. The 2008 Guidelines provide a safety assessment framework that is consistent with international standards developed by Codex Alimentarius. Additional guidance will also be developed for documentation and quality standards for applications submitted to the FSSAI.

1.5 CAPACITY BUILDING

The FSSAI is committed to ensuring that sufficient institutional, financial and human resource capacity is put in place to implement this interim process and will work to achieve this by participating in, and building upon, initiatives already taken up by MoEF and DBT. In particular, the FSSAI will provide the necessary administrative and technical training to establish:

- The Office of GM Foods;
- The GMFSAU, including advanced training in GM food safety assessment for the GMFSAU member scientists;
- Diagnostic laboratories for detection of unapproved GM events, including advanced training in sampling and detection methodologies, test validation and potentially developing a nationally (or internationally) accepted laboratory certification scheme.

The capacity that is built under the interim system will be transitioned to the permanent food safety assessment and approval process for GM foods that will be established when the necessary rules and/or regulations for GM foods are notified under the *FSSA, 2006*.

Figure 3. The administrative, food safety assessment and approval procedures for GM foods produced domestically or imported.