Policy Brief No. 13

National Academy of Agricultural Sciences

Regulation for Genetically Modified (GM) Foods and Detection of Unauthorized GM Food Events

New Delhi
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Preface

Regulation of genetically modified (GM) foods and food products derived from GMOs is a globally recognized requirement to ensure safety to humans, animals and the environment at large. Such regulations have evolved and been adopted by many countries across the world. In India, GMOs and products derived therefrom are regulated by the Environment (Protection) Act, 1986, under the Rules 1989 - "Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989", and administered by the Ministry of Environment and Forests (MoEF), and Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India.

In 2006, India promulgated the Food Safety and Standards Act (2006), and empowered the Food Safety and Standards Authority of India (FSSAI) to regulate GM foods. Accordingly, the FSSAI, as required under sub-section (1) of section 92 of the said Act, published the draft regulation 'Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021', dated November 15, 2021 and invited comments from the public.

The National Academy of Agricultural Sciences (NAAS) organized a national stakeholders' consultation on January 10, 2022 to discuss the FSSAI's Draft Regulation for Genetically Modified (GM) Food, 2021 and also the Detection of Unauthorized GM Food Events, involving more than 50 national experts/stakeholders from both public and private sector organizations. Based on the discussions, the NAAS has come out with this Policy Brief containing key recommendations on the draft GM Foods Regulations, 2021, and on Detection of Unauthorized GM Food Events.

I am thankful to all the experts and stakeholders, who actively participated and gave valuable suggestions. I am especially thankful to the Convener, Prof K.C. Bansal, and Co-convener, Dr Gurinderjit Randhawa for taking initiative to organize the discussion and develop this Policy Brief. Thanks are due to the reviewer Dr N. Bhaskar for his useful comments and suggestions. The editorial support of Dr P.S. Birthal and Dr Malavika Dadlani is duly acknowledged.

(Trilochan Mohapatra)
President

Dated: 31 December, 2022

Round Table Discussion: Regulation for Genetically Modified (GM) Foods and Detection of Unauthorized GM Food Events

Chairman : Dr Trilochan Mohapatra, President, NAAS

Co-Chairman: Prof Swapan K. Datta, Former DDG (CS), ICAR and Former VC, Visva Bharati University, West Bengal

Convener : Prof K.C. Bansal, Secretary, NAAS

Co-Convener : Dr Gurinderjit Randhawa, Head, Division of Genomic Resources, ICAR-NBPGR, New Delhi

Reviewer : Dr N. Bhaskar, Director, CSIR-IITR, Lucknow

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4. Dr Malavika Dadlani, Editor, NAAS, New Delhi
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11. Dr Sesikeran Boindala, former Director, ICMR NIN, Hyderabad
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Regulation for Genetically Modified (GM) Foods and Detection of Unauthorized GM Food Events

Background

Science-driven growth in agriculture has contributed immensely in making available the desired quantity of food for the ever-growing population. Concerted efforts by agricultural science experts from various disciplines, particularly the geneticists and plant breeders paved the way for the development and deployment of high yielding, disease resistant and nutritionally rich crop varieties bringing self-sufficiency in food production in India. Although traditional plant breeding has been largely instrumental and continues to play the key role in developing improved crop varieties, the new crop improvement technologies that include targeted genetic engineering for the development of genetically modified (GM) crops, and genome editing hold great promise in accelerating the pace of variety development and in addressing different challenges due to climate change, degradation of the natural resource base and low sustainability and profitability of the production system that agriculture is facing today. Thus, it is imperative to deploy cutting-edge technologies to find solutions to these challenges, and to increase food production to meet the ever-increasing demand and to achieve sustainable food and nutrition security.

Genetic engineering efforts by both public and private sector institutions in the country have led to the development of several genetically modified/engineered GM crops with improved traits though the insect resistant Bt cotton is the only crop approved commercially for cultivation in India[1]. Recently, GM mustard hybrid DMH 11 and its GM parental lines have been granted permission for the environmental release by the Government of India[2].

Research is in progress in public as well as private sector laboratories for genetically modifying a number of crops with improved traits such as enhanced yield, resilience to insect pests and diseases, tolerance to abiotic stresses, improved nutritional quality and tolerance to herbicides.

Genetically modified food and feed products derived through genetic engineering approaches are regulated and their manufacture, import, and storage require approval from GEAC (Genetic Engineering Appraisal Committee), as per the Rules, 1989 (Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989) of the Environment (Protection) Act, 1986 (EPA 1986). In 2006, the Government of India enacted an integrated law, namely the Food Safety and Standards (FSS) Act of 2006 that empowered the Food Safety and Standards Authority of India (FSSAI)as the single authority responsible for establishing and implementing science-based standards for food safety, including that of GM foods. Post enactment of FSSA, 2006, the Rules, 1989were amended in 2007 to exclude GM foods from the purview of GEAC.

[1]NAAS Policy Brief # 1, 2017

[2]http://www.geacindia.gov.in/Uploads/MoMPublished/MoMPublishedOn20221025200345.pdf

Need for the Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations

According to the Rule 11 of Rules 1989 "Food stuffs, ingredients in food stuff and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Appraisal Committee (GEAC)".

However, Ministry of Environment, Forest & Climate Change (MoEF&CC) vide Notification No. SO1519(E) dated 23.08.2007 exempted "Food stuff, ingredients in food stuffs and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organisms" from the purview of Rule 11 of the Rules, 1989 implying that approval of GEAC is not required for such foods. Since FSSAI had not published any rules for regulating GM foods, a series of supplemental notifications were issued by the MoEF&CC to keep the above notification (Notification No. SO1519(E) dated 23.08.2007) in abeyance. On the expiry of this notification, the provision was not renewed, thereby disrupting the import approval process.

Since the GM Foods - related regulations under the FSS Act, 2006 were not yet ready, the MoH&FW and FSSAI requested the MoEF&CC to put on hold the gazette notification, dated 23.08.2007. Accordingly, a series of supplemental notifications were issued by the MoEF&CC to keep the above notification in abeyance and the GEAC continued providing approval for the processed foods including processing aids between the period 2007 and 2016. However, on the expiry of this notification, the provision was not renewed, and the GEAC stopped assessing and/or clearing any of the processed foods or ingredients including processing aids derived from GMOs, thereby disrupting the import approval process. This caused delays in approvals and the burden of regulations presented multiple challenges for the trait developers and importers of GM food products. Finally, the said amendment was enforced by the MOEf&CC with effect from 01.04.2016.

In August, 2017, Hon'ble Supreme Court directed the Government of India to put in place the required regulatory framework under Section 22 of the FSSA, 2006. Therefore, the FSSAI developed and notified the draft Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021[3] on November 15, 2021 and placed these for public consultation for 60 days.

Key Features of the Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021

- The proposed Regulations, 2021 will apply to Genetically Modified Organisms (GMOs) intended for food use.
- The draft regulations require mandatory prior approval for the genetically modified food, to manufacture, sell, and import, and for the ingredients produced from genetically-modified organisms.

[3]https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_GM_Food_17_11_2021.pdf

- The regulations also cover the food ingredients produced from GMOs that contain modified DNA and the food ingredients produced from GMOs that do not contain modified DNA but include ingredients/additives/processing aids derived from GMOs.
- According to the draft regulations "No person shall manufacture, store, distribute, sell or import in the country any food or food ingredient, as the case may be, derived from Genetically Modified Organisms, except with the prior approval of the Food Authority".
- All food products (GMOs intended for food use and food ingredients produced from GMOs that contain modified DNA) must be labelled if the product contains one per cent or more of the GM ingredient considered individually, as 'contains genetically modified organisms'. However, the labelling requirement will not be applicable to such GM-food products in which the modified DNA is not detectable.
- Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms shall not be used as an ingredient in any infant food.

Procedure for Grant of Prior Approval of FSSAI: Key Points

- In case a Genetically Modified or Engineered Food contains any Living Modified Organisms (LMOs), after taking prior approval from GEAC for Environmental safety, the application for the approval of the Food Authority may be submitted in Form-I along with the documents and fees as specified by the Food Authority from time to time.
- In case a Genetically Modified or Engineered Food does not contain any LMOs, the application for the approval of the Food Authority may be submitted directly in Form-II along with the documents and fees as specified by the Food Authority from time to time.
- The food business operator shall, after grant of approval, apply for license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
- Post approval, if a food business operator has reason to believe that the Genetically Modified or Engineered Food poses any risk to health, he shall immediately suspend the manufacture, import, sale, or distribution of such article of food and take steps to recall the same in accordance with the provisions of the Food Safety and Standards (Food Recall) Regulations, 2017.
- Food Safety Officers and Designated Officers shall immediately inform the Food Authority of any complaint received regarding the safety of any product approved by the Food Authority under these regulations.
- Once a Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms having a unique identification Code provided by the Biosafety Clearing House, Organisation for Economic Co-operation and Development etc, is approved by FSSAI, approval for the same will not be required for any other Food Business Operator. Approval will also not be required if it is used as an ingredient in any product.

Laboratory for Testing of Genetically Modified Foods

Any food laboratory notified in accordance with section 43 of the Food Safety and Standards Act, 2006 may be designated for testing of Genetically Modified Foods having the following pre-requisites: (1) The laboratory shall have a designated GM food testing area that should be well segregated from the general laboratory working area and should have four physically separated and contained areas for Reagent and Sample preparation, DNA and Protein extraction, Product Analysis, and Data analysis and storage with air conditioning/ventilation. Airflows should be maintained within the Genetically Modified food testing area. (2) The laboratory shall have instruments for the detection of DNA/ RNA by qRT-PCR, Protein by ELISA and Western blotting and GM organism by fluorescent microscopy. (3) The laboratory shall be able to assess multiple batches of samples. (4) The GM food testing laboratory staff shall be well versed with these regulations and proficient with techniques related to molecular biology, protein biology and food testing.

GM Food Labelling

All food products having 1% or more individual Genetically Engineered (GE) ingredient shall be labelled. The labeling shall be as: 'Contains GMO/Ingredients derived from GMO'.

Recommendations

With the above background the National Academy of Agricultural Sciences (NAAS) organized a National Level Stakeholders Consultation on "Draft Regulation for Genetically Modified (GM) Food and Detection of Unauthorized GM Food Events" on 10th January 2022 involving more than 50 national experts/stakeholders from both public and private sector organizations (List of participants: Annexure 1)., The following recommendations emerged on: (A) GM Foods Regulations, 2021, and (B) Detection of Unauthorized GM Food Events, which were submitted to the FSSAI on January 15, 2022.

A: Food Safety and Standards (Genetically Modified Foods) Regulations, 2021

1. Food safety aspects of all GMOs or GEOs, whether produced locally or imported, be dealt with by FSSAI. The three terms – GMO, GEO, and LMO are used interchangeably, creating confusion. FSSAI may continue to use the terms "genetically modified or engineered food" as per the definition of Food given in the article 22 of FSSA, 2006. The term LMO has not been used in FSSA and Codex hence, it is recommended that the mention and use of LMO should be deleted from the **Sections 1(2) (a) and (b).**

2. With regard to the '**Definitions**', it is suggested that the definition of Modern Biotechnology be used as given in the Codex Alimentarius Commission, which is given below: "Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection". Further, it was also suggested

that Genome Editing products should be exempted, and this may be clarified in the definition of genetic engineering itself. No mention is to be made of Genome Editing as inferred from definition 2(d) of genetic engineering. Definition 2(d) should be deleted as it is beyond article 22 of FSSA, 2006,

3. In case a Genetically Modified or Engineered Food contains any LMOs, after taking prior approval from GEAC for environmental safety, developer of the product shall submit an application for the approval of the Food Authority in Form-I along with the documents and fees as specified by the Food Authority from time to time.

4. In case of processed food containing genetically modified or engineered organisms or derived from, but not containing genetically modified or engineered organisms, the application for the approval of the Food Authority may be submitted directly in Form-II along with the documents and fees as specified by the Food Authority from time to time. Processed food containing genetically modified or engineered organisms or derived from but not containing genetically modified or engineered organisms for an approved event(s) – single or stacked event(s), under **Section 4(1)** to be regulated in the same way as conventional foods without any requirement for subsequent GM food safety assessments.

5. Once the GMO is found as safe as its non-GM counterpart, food safety and food quality considerations and associated laws, regulations, standards and guidance will apply to GM and non-GM foods alike. The licensing regulations as specified in the **Section 4(6)** may be applied accordingly.

6. Once a Genetically Modified or Genetically Engineered Food or Living Modified Organisms having a unique identification Code provided by the technology developer is approved by FSSAI, and included by Biosafety Clearing House, approval for the same will not be required for any other Food Business Operator as required under **Section 4(11)**. Approval will also not be required if it is used as an ingredient in any product.

7. With respect to the use of Genetically Modified or Genetically Engineered Organisms as an ingredient in any infant food under **Section 4(12),** it was felt that such restrictions be placed only on a case-by-case basis, provided there is enough scientific evidence that suggests that the above has been found to have some safety concerns specifically for infants.

   Further, it was reiterated that a GM crop is approved only after a detailed case-by-case assessment based on established scientific principles and national/international guidelines. The safety evaluation process includes a detailed evaluation of toxicity, and allergenicity of expressed proteins/ metabolites at much higher levels than the likely presence in GM crops or final products. The guidelines indicate that safety must take into account any specific considerations for sub-populations including infants. If in any specific case, such restrictions are required as a follow-up of the safety assessment process, the same can be specified as a pre-condition in the approval letter.

8. With regard to the identification and function of 'Laboratory for Testing of Genetically Modified Foods' under **Section 5, 6**, it is recommended that only the existing accredited GMO laboratories for the detection, identification and quantification, located at ICAR/ICMR/CSIR/SAUs and

upgraded by MOEF&CC under the Global Environment Facility (GEF) project be considered. It was felt that there is no need to give details of the laboratory design, equipment, etc. It will be sufficient to say that the-State-of-the-Art and NABL accredited labs for GM Food Testing shall be developed.

9. The labelling requirements as given in **Section 7**, need to be elaborated to clarify that only detectable and quantifiable levels would require labelling. For example, products like refined oil, sugar, starch, etc. cannot be labeled, as the current detection techniques cannot detect transgenic DNA or proteins in the final products. There is a need to define not only the nature of the message but also the precise means of conveying the selected message such as front or back label of a product, as part of the list of ingredients or separated from other labeling sections, the use of a potential logo (with color/ font), the font size for the message, etc. It is recommended that all food products having individual Genetically Modified or Engineered (GE) ingredient 2% or more shall be labelled. The suggested labelling should be as 'Contains GMO'.

10. A requirement of three-year use in country of origin as mentioned in **Section 7(3) Form 1,** is unwarranted and could delay the introduction of new products beneficial for human health and nutrition into the Indian market. In cases where sufficient multi-year feeding data is already taken into consideration at the time of approval, such products are to be exempted from a three-year safe use data requirement.

11. In cases, where the certificate is issued by the concerned authority of the country of origin, a certificate of endorsement or authentication by the Indian Embassy/High Commission/Consulate in that country/Embassy of the country of origin in India as mentioned in **Section 9 Form I** may not be required as the GM events are approved by the concerned regulatory agencies of exporting countries with unique identifier code available on Biosafety Clearing House (BCH) database for verification.

12. With regard to shipment details, Food Authority should recognize existing international food and feed approvals for GM event(s) approved by GEAC and products already in commerce, e.g., those events which have undergone food safety assessment in OECD countries should be approved with minimal documentation.

13. For the three years' data requirement as per **Section 6(2), Form II** on the safe use of the GMOs derived food in the country of origin, it is recommended that a requirement of three years of use in the country of origin is unwarranted and could delay introduction of new products beneficial for human health and nutrition into the Indian market. In cases where sufficient multi-year feeding data have already been taken into consideration at the time of approval, such products are to be exempted from a three-year safe use data requirement.

14. As per the requirement in **Section 7, Form II** of Biosafety Description of Items applied for approval, it is recommended that the Biosafety description of processed food containing or derived from LMOs should not be required from any other Food Business Operator for an approved event(s) under section 4(1), as only the LMOs approved by GEAC and/or listed by the Biosafety Clearing House (BCH) will be allowed for import.

Revision of the Food Safety and Standards (Genetically Modified Foods) Regulations, 2021 by FSSAI

In the light of the comments and suggestions received from various stakeholders including the recommendations submitted by NAAS on January 15, 2022 on the Food Safety and Standards (Genetically Modified Foods) Regulations, 2021, the FSSAI has since revised and published the draft regulations on November 18, 2022, called as Food Safety and Standards (Genetically Modified Foods) Regulations, 2022[4].

Importantly, the FSSAI has accepted majority of the comments / suggestions given by the NAAS; the notable one being that the regulations shall not apply to genome edited crops of SDN1 and SDN2 categories.

B: Detection of unauthorized GM food events

The FSSAI issued an order 1-1764/FSSAI/Imports/2018(Part-1) dated 21 August 2020, stating the requirements of non-GM-cum-GM-free certification issued by the competent national authority of the exporting country for imported food consignments of 24 crops. In such a scenario, stringent diagnostics and policy options need to be streamlined so as to track the occurrence of unapproved/unauthorized GM events and avoid their entry into the environment.

The detection of unauthorized GM brinjal in the farmer's fields in the recent past, and newspaper reports of the unauthorized presence of GM brinjal and cotton in some of the states of India have necessitated the need for efficient GM diagnostics and their utilization to detect the unauthorized events. Detection of such events is important to track GMOs in the supply chain as well as in the imported consignments, particularly in case of lack of transgene sequence information, non-availability of reference material, and low-level presence, which is beyond the detection limit.

Recommendations

1. The following policy options need consideration to ensure the tracking of unauthorized events/ incidents:
    - While submission of application for field trials or import of a GM event, transgenic construct sequence details along with the event-specific test protocol with estimated limit of detection as well as reference material need to be submitted by the developer to a designated GM reference laboratory as per the directions of the RCGM, which may be made mandatory. A similar mechanism is being followed by the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF), Joint Research Centre, European Commission, Ispra, Italy.

[4]https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_GM_Food_21_11_2022.pdf

- The voucher samples of GM crops generated by public/private research institutes need to be submitted along with the detection protocols for validation at the designated institution by RCGM. This would allow tracking the escape of any GM event to the environment.
- Publication/patent covering any GM crop needs to be processed after the voucher samples are submitted to the designated institute. Further, in case of transfer or superannuation of any scientist developing GM crops, the voucher sample has to be submitted at the RCGM-designated reference laboratory as a condition for granting relief.

2. A functional network of GM detection laboratories is required to be in place along with a central reference laboratory/facility, with the role to sensitize/extending technical support to the network of laboratories for the detection of GM through a harmonized mechanism and to develop a Rapid Alert System.
3. There is a need for the adoption of science-based consistent policies and time-bound approval of GM products for food, feed, or processing usage, so as to benefit the relevant stakeholders across the value chain.

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