Environmental Social Justice & Governance Initiatives

1572, 36th Cross, 100 Feet Ring Road,
Banashankari II Stage,
Bangalore 560070. INDIA
Tel: 91-80-26713560
Voice/Fax: 91-80-26713316
Email: esg@esgindia.org
Web: www.esgindia.org

Email/RPAD

To:

Shri. Arun Singhal, IAS
Chief Executive Officer,
Food Safety and Standards Authority of India,
FDA Bhawan, Kotla Road, New Delhi – 110 002

January 15, 2022

Subject: Objections to and Comments on the draft Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021

Dear Sir,

Please find enclosed our objections to the draft Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021 ("**draft Regulations**"). We believe that they pose a grave risk to food sovereignty and also the country's food, public health and ecological securities, and must be withdrawn immediately. We provide reasons hereunder and also in the annexed table containing section-wise comments:

1. **Infringement of States' power to make laws on agriculture:**
    a) To trace the source of the Union's power to legislate on genetically modified foods, it is critical to look at the scheme distributing legislative competence in Schedule 7 of the Indian Constitution.
    b) Food finds a mention in Entry 33 of List III, the Concurrent List in Schedule 7. The power to make laws on trade and commerce in, and the production, supply and distribution of "foodstuffs" is located in Entry 33. This entry also deals with the power to make laws on trade and commerce in, and the production, supply and distribution of "the products of any industry where the control of such industry by the Union is declared by Parliament by law to be expedient in the public interest, and imported goods of the same kind as such products".
    c) In fact, "industries" as a subject is placed within the legislative domain of states (Entry 24, State List). But the Union has power to legislate on industries when it pertains to defence or public interest (Entries 7 and 52, Union List). This exceptional power is not given to the Union when it comes to agriculture, which is squarely within the state's domain (Entry 14, State List). Indeed, a look at the legislative history of Entry 33 reveals that as far as food items were concerned, its purpose was to deal with issues of scarcity, hoarding and black-marketing. It was in this context that legal experts criticised the Union Government's decision to interpret Entry 33 as a general entry on food-related matters to introduce the controversial farm laws in Parliament in 2020, which have since been repealed in response to almost a year long protests by farmers at Delhi's borders [1].
    d) Given the close interconnections between food production and agriculture, the Union should always exercise restraint in using its powers under Entry 33 of the Concurrent

List, or under Entry 52 of the Union List, to legislate on matters related to food. This restraint appears to have been grossly ignored in proposing the instant Regulations.

e) In this context, it is also deeply disconcerting that the Union used its power under Entry 52 of the Union List to enact the Food Safety and Standards Act, 2006 **("FSSA Act")** declaring in Section 2 that the entire food industry is being brought under its control, in public interest [2]. Perhaps this concern was raised at the time, perhaps not. But we feel compelled to highlight this now, because this power continues to be unilaterally employed by the Union Government, as was the case when the Ministry of Health and Family Welfare ("**MoHFW**"), the nodal ministry for the Food Safety and Standards Authority of India **("FSSAI")**, sought to amend the FSSA Act in 2020 to bring the "animal feed" industry within the control of the Union and within the ambit of a statute about human food safety [3].

f) Given that the stated objective of the FSSA Act, 2006 is to "ensure availability of safe and wholesome food for human consumption", several critical questions arise: can a legislation for food safety be used to declare the entire food (and animal feed) industry within the control of the Union? What is the "food industry"? How do we delineate it from agricultural operations?

g) The Union Government, in a futile attempt to avoid legislative overreach with FSSA Act into the realm of agriculture, incorporated a section which states the Act does not apply to farmers, fisherfolk, farming operations, crops, livestock, aquaculture, supplies used or produced in farming, or to the products of crops produced by a farmer at farm level or a fisherman in his operations (Section 18(3)). But at the same time, the law applies to "primary food" (Section 2(j) defines "food" as including "primary food"). "Primary food" itself is defined in Section 2(zk) in an absurd manner - as "produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form", but carried out by persons other than farmers and fishermen. Meanwhile, who qualifies as a farmer or fisherperson is not defined in the Act. This whole exercise of evading application to agriculture is nothing but an unlawful colourable exercise of power, as the Union Government through the FSSA Act is indeed regulating matters intrinsically linked to agriculture, which it is not competent to do at all.

h) During the Lok Sabha debate on the Food Safety and Standards Bill [4], many MPs like Shri Prabodh Panda from Midnapore pointed out that the law could not effectively regulate food safety, since it could not be applied to the stage of primary production, often the point of entry for hazardous substances and technologies such as fertilizers, pesticides, and genetic modification. Some like Shri M. P. Veerendra Kumar of Kozhikode called out the bill, which was actually introduced in Parliament by the then Minister of the Food Processing Industry, for "*deregulating the industrial food processing which causes health hazards and diseases through chemicals, artificial synthetic additives and genetic engineering*". Shri Bikram Keshari Deo from Kalahandi noted, perhaps prophetically, that the FSSAI was being vested with a host of arbitrary powers that could turn disadvantageous to the farmer in the future. Shri B Mehtab, MP from Cuttack, noted:

> "The modern food law should recognize that our country's decentralized food economy enhances nutrition, safety, culture and livelihood. We need laws to

protect our diverse local food cultures from the disease causing homogenous, centralized industrial food culture of the West. **Do we need food police through pseudo safety standards which serve global business?** We need society-led, participatory, democratic systems to enrich our food systems, promote health and nutrition, and guarantee food safety. Let the Government regulate agri business. **There is a need for food sovereignty, food freedom.**" (Emphasis supplied.)

i) Seen in this light, it is clear that the parent legislation of the draft Regulations, the FSSA Act itself very much stomps upon States' legislative power concerning agriculture. It makes a colourable attempt at avoiding to do so by locating the power to legislate on the subject in Entry 52 of the Union List, and then attempting to disentangle the scope of the law from agricultural operations. The fact of the matter is that food safety (including through the regulation of GM food) cannot be ensured without regulating agriculture, the legislative competence for which lies with the State Governments alone. Thus, there is no constitutional backing to the FSSA Act, let alone to the power of the FSSAI under Section 22 of the FSSA Act to regulate matters fundamental to the production and consumption of GM food.

2. Inadequate inter-ministerial consultation:

a) A cursory look at the collated comments from the inter-ministerial consultation conducted for the Draft Regulations reveals that the Ministry of Science and Technology, and the Department of Biotechnology ("**DBT"**) in particular, have not been consulted or involved in the drafting process [5]. This violates the principle of coordinated and harmonious decision-making as enshrined in the Allocation of Business Rules, 1961 and the Transaction of Business Rules, 1961 and invalidates the process of drafting the proposed draft Regulations undertaken without essential inter-ministerial consultative processes. This is particularly because the Allocation of Business Rules specifically states in Entry 69 of the Second Schedule that DBT shall be the central agency for the import or production of biotechnology-based products in India.

b) Furthermore, given the critical role played by committees such as the Genetic Engineering Appraisal Committee ("**GEAC"**) and the Review Committee on Genetic Manipulation ("**RCGM"**) in the regulation of genetically modified organisms ("**GMOs**") in India, it is shocking that these and other such committees critical to the implementation of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms/Genetically Engineered Organisms or Cells, 1989 ("**1989 Rules**") have been entirely left out from the drafting process.

3. Draft Regulations Undermine the Protection of Human and Environmental Health:

a) As we highlight in the section-wise comments below, the entire scheme of the Draft Regulations appears to be an effort to deregulate GMOs in food and of foods derived from GMOs ("**GM Foods**") in India. This is when other countries are tightening their restrictions on GM Foods due to a growing recognition of their potential risks and also public disapproval. For instance, on August 4, 2020 a recall order was issued by American food corporation Mars Wrigley for a batch of its M&M's Crispy's on grounds that it was contaminated with rice flour that contained unauthorised GMOs, rice flour

believed to be sourced from India. The contamination was first flagged by the European Commission's Rapid Alert System for Food and Feed and it is believed that it may have resulted from cross-contamination arising due to cultivation in India, even though GM rice is not permitted to be grown in the country [6]. In the United States, the Environment Protection Agency also proposed to phase out many Bt corn and Bt cotton varieties in 2020 in an effort to curb increasing insect resistance [7]. This is a significant change in policy, as the United States is the country where GMOs were first conceived and aggressively promoted.

b) From the impacts of vegetative dispersal at the stage of production, to environmental contamination through the gut-sewer-water passageway, it is undeniable that a lax regulation of GM Foods will cause unprecedented and irreversible impacts on environmental and human health, and seriously obstruct the objectives of the Environment (Protection) Act 1986 ("**EP Act**") and the Biological Diversity Act 2006 ("**BD Act**"), and not least the objectives of the FSSA Act itself.

c) If operationalised along with the proposed amendments to the BD Act, the proposed Regulations will also seriously undermine the protection of the biological resources of India, the sovereign control that local communities have over these resources, and usher in further commercialization and commodification of food and food resources.

d) Moreover, as is shown in the section wise comments below, the proposed scheme exhibits absolute lack of scientific and technical knowledge, and gross ignorance of the principles of safety and risk assessments. The draft Regulations thereby display grave callousness and utter disregard for the protection of public health and the environment. They do not adequately account for many complex human health and environmental factors. Such a lackadaisical approach in legislative and regulatory drafting as is evident with the draft Regulations betrays an absolute lack of concern for irreversible environmental consequences.

4. In summary

a) Given what is stated above, we find it plausible that these Regulations are being promoted at the behest of giant agribusinesses and food corporations who stand to gain from such gross weakening of food standards in India. It is critical, therefore, that the MoHFW as the nodal Ministry of the FSSAI must withdraw the draft Regulations forthwith and take steps to ensure that the food regulator protects India's sovereignty, and the health and environment of the country for posterity.

b) We also wish to state that the draft Regulations ought to have been widely circulated with all State Governments first and foremost, providing every district within the states the opportunity to cogently engage with the implications of the draft Regulations. This has obviously not been undertaken given the manner in which the draft Regulations are being rushed through a ritual of online public consultation, which fails to reach the large numbers of farmers and consumers in the country.

c) We also record our strong protest and disapproval of the ongoing stand of the Speakers of the Parliament denying Parliamentary Standing Committees to adapt to the pandemic over the past two years and hold online/hybrid proceedings, as is being done by the Judiciary, which has resulted in the draft Regulations being rushed through a superficial process of consultation without due Parliamentary oversight. We

unequivocally state that these draft Regulations must be placed before the Parliamentary Standing Committee on Subordinate Legislation forthwith to test its legality. The implications of the draft Regulations must also be overseen by a Joint Parliamentary Committee given that the subject has cross-cutting implications across the entire country, has intergenerational implications and directly affects the sovereignty of the people and their biological and food resources. To this end, please find our detailed section-wise comments on the draft Regulations annexed.

Signed for and on behalf of Environment Support Group

Leo F. Saldanha, Malvika Kaushik, Vani Sharma and Bhargavi S. Rao
Environment Support Group

References:

[1] Amit Jaiswal, What Will the Legal Challenge to the Modi Government's Farm Bills Look Like?, The Wire, 5 October 2020, available at <https://thewire.in/law/farm-bills-legal-challenge-constitution-seventh-schedule-supreme-court>.

[2] M.R. Madhavan and Kaushiki Sanyal, Legislative Brief: The Food Safety and Standards Bill, 2005, ecosocialsceinces.com, Working Paper, January 2006, available at <https://www.researchgate.net/publication/23778229_Legislative_Brief_The_Food_Safety_and_Standards_Bill_2005>.

[3] Public notice No. P. 15025/195/2015-DFQC dated 23 September 2020 issued by the Department of Health and Family Welfare, Ministry of Health and Family Welfare, Government of India, available at <https://main.mohfw.gov.in/NEWSHIGHLIGHTS-16>.

[4] Further discussion on the motion for consideration of the Food Safety and Standards Bill, 2005 moved by Shri Subodh Kant Sahay on 22 May, 2006 (Motion adopted and Bill passed), Proceedings of the session dated 26 July 2006 of the 14th Lok Sabha, available at <https://eparlib.nic.in/bitstream/123456789/727670/1/5552.pdf>.

[5] Comments Received During Interministerial Consultation on the Draft Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021, Ministry of Health and Family Welfare, available at <https://fssai.gov.in/upload/uploadfiles/files/Comments_Interministerial_Consultation.pdf>.

[6] Priscilla Jebaraj, EU food recall linked to GM rice exports from India, The Hindu, 19 October 2021, available at <https://www.google.com/url?q=https://www.thehindu.com/news/national/eu-food-recall-linked-to-gm-rice-exports-from-india/article37078352.ece&sa=D&source=docs&ust=1642238529957137&usg=AOvVaw3Gjl4WuemGPpWVWDxa7o_t>.

[7] Environmental Protection Agency, Draft Proposal To Improve Lepidopteran Resistance Management, 8 September 2020, available at

<https://www.regulations.gov/document/EPA-HQ-OPP-2019-0682-0001>.

Annexure

Section wise comments on the Draft Regulations

S. No.	Section of draft notification commented upon	Comments/ suggestion	Rationale
1.	Section 4: Procedure for Grant of Prior Approval	• The safety standards that should be the basis for approval have not been laid out. • There is no requirement for a speaking order to be issued by the FSSAI while granting approval. • No provision is made for independent verification of the claims made in the application form for approval, and for public hearing.	In addition to our unequivocal rejection of the draft Regulations for reasons cited before, we wish to highlight that the manufacture, import, storage, sale and distribution of GM Foods in India cannot be permitted without instituting the highest level of scrutiny and the most diligent process of risk assessment and mitigation. As is noted above, the draft Regulations appear to be virtually toothless and are likely doomed to fail to meet the aforesaid objectives. **<u>Unguided power to grant approval:</u>** Firstly, it is essential for any regulatory procedure to clearly lay down the **grounds and standards** on which a given instance of the action being regulated may be permitted or prohibited. When discretionary power is vested in any authority, the exercise of this discretion must be limited by a set of clear criteria or guidelines, otherwise the vesting of such discretion would violate Article 14 of the Constitution for being arbitrary. In the case of GM products, there must be safety standards in place meeting which is a prerequisite for grant of approval. The draft Regulations do not specify any such standards. It is important to note that the FSSA Act is premised on the development of **standards based on adequate risk assessment, management and communication**, and while no standard is laid

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			down in the statute itself, it is clearly the FSSAI's duty to develop standards for ensuring the protection of human life and health, as well as consumer interest (Sections 16 and 18). Indeed, the FSSAI is also empowered to develop specific regulations pertaining to how it carries out risk assessment, which it has not done till date. Given the immense risks that GM products can pose to human and environmental health, it is necessary for such regulations to be in place before the FSSAI proceeds to open the floodgates to GM food production and import in India, as appears the intent of the Draft Regulations. Regulation 4(5) states that the Food Authority may either grant approval or reject the application on the basis of the "safety assessment of the article of food or food ingredient of processing aid". This procedure of "**safety assessment**" is neither described in the draft Regulations nor in the parent statute. Indeed, the draft Regulations make no reference to the 2008 Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants evolved by the Indian Council for Medical Research ("**ICMR Safety Assessment Guidelines 2008**") in its capacity as the scientific and technical advisory body to the MoHFW, based on the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants 2003 (CAC/GL 45-2003 prepared by the Codex Alimentarius Commission). Thus, critical aspects such as current dietary exposure and possible effects of the GM food on population sub-groups, nutritional assessments (especially in case of an intended nutritional

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			modification), and the cumulative safety assessment of food items containing multiple GMO components find no mention in the draft Regulations. **<u>No requirement for speaking order:</u>** It is also essential that any order granting or rejecting approval must clearly **explain the reasons** for doing so, i.e. the authority must demonstrate clearly that it is aware of the risks of the given item and has taken adequate measures to ensure that the manufacturer/importer of the item mitigates such risk. These requirements should have been explicitly incorporated in the draft Regulations concerning GM Foods, but do not even find a cursory mention therein. This is also in violation of Section 18(1)(f) of the FSSA Act, which requires that "*where there are reasonable grounds to suspect that a food may present a risk for human health, then, depending on the nature, seriousness and extent of that risk, the Food Authority and the Commissioner of Food Safety shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or type of food, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk*." Non-disclosure of potential risks and the steps taken to eliminate those risks through a speaking order, in case of an approval, would be in gross violation of this fundamental statutory requirement and the principles of natural justice. **<u>No mechanism for independent verification of applicant's</u>**

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			<u>claims and public hearing:</u> We staunchly oppose the reliance on **self-reporting mechanisms** in the draft Regulations based on the deeply problematic concept of "*utmost good faith*" promoted by the now-rejected Report of the TSR Subramanian High Level Committee to review various Acts administered by the MOEFCC. These are bound to be exploited by applicants in the absence of a clear structure of independent verification. Regulations 5 and 6 deal with the functioning of 'Foods Laboratories for Genetically Modified Foods Testing', but nowhere is there a requirement that a sample of any GM food that is the subject matter of an approval application has to be sent to such a lab for **independent verification** of the claims made by the applicant regarding such food. Moreover, there are many claims that cannot be verified through testing samples, most importantly those regarding evidence of the safety of the food from other countries, or the extent of their regulation internationally. An important way of ensuring that true and full disclosures are made in the application is to make the application process subject to **public hearing**. Even the FSSA Act requires that the public must be fully aware of potential risks of foods proposed to be introduced in the country, as is evident from Section 18(1)(f) mentioned above. Public consultation would thus be a key way not only to let the wide public hold applicants for GM foods accountable, but also for the public to stay informed of the risks they are being exposed to.

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			It is a matter of gravest concern that the draft Regulations make no provision whatsoever for public consultation.
1.	Section 4(9): "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."	1. A specific mention of the power of consumers to make complaints outlined in Regulation 5(4) of the Food Safety and Standards (Food Recall) Regulations, 2017 should be incorporated. 2. The wider public must also be given the power to lodge complaints/concerns about GM Foods. 3. Further, the liability to be incurred by the food business operator for failure to suspend manufacture/ import/ sale/ distribution or to take steps for recall has not been specifically set out.	1. The draft Regulations do not explicitly lay down that a consumer may lodge a complaint against GM food subsequent to the grant of approval by the FSSAI. Therefore, consumers who may wish to raise a complaint with the food business operator or with FSSAI may not find it accessible to do so. 2. Further, given the experimental nature of GM Foods, in the event that they are allowed, the wider public must also have the power to raise complaints and flag concerns based on emergence of subsequent evidence of risk. 3. The lack of clear, stringent criminal consequences specific to the failure to comply with this regulation will also embolden food business operators to not make necessary recall arrangements in case any risk is later discovered by them.

S. No.	Section of draft notification commented upon	Comments/ suggestion	Rationale
4.	Section 4(10): "Food Safety Officers and Designated Officers shall immediately inform the Food Authority of any complaint received regarding safety of any product approved by the Food Authority under these regulations."	There is no clarity on the consequences of any complaint received in respect of products approved under the draft Regulations, both in respect of recall of products and in respect of consequences for the food business operator.	This section is indicative of the opening of doors for irrational exercise of power in the functioning of FSSAI and its regulatory committees and could easily be a route exploited to corrupt the regulatory processes.
5.	Section 4(12): "Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms shall not be used as an ingredient in any infant food."	1. The intent of this clause, i.e., to prevent infants from being exposed to GMOs/ LMOs in their food, is subverted by allowing GMOs/ LMOs in food and foodstuffs even for adults. 2. Further, it creates a loophole where "Food or Processed food containing Genetically	1. Prevailing laws governing infant food, such as the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply And Distribution) Act, 1992, and the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020, are limited to governing packaged infant food, which is easier to regulate. However, packaged infant food is expensive and not readily available. Indeed, infants are often fed softer, easier-to-eat versions of the same food that adults in the household eat (e.g. mashed brinjal, soaked grains, etc.). If GMOs are allowed to enter general foodstuffs, the prohibition on using GM ingredients in infant food shall be meaningless in practice. Further, even if infants are not directly fed food containing GMOs,

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		Modified ingredients produced from but not containing LMOs or GEOs or GMOs" as defined in Section 1(2)(b) are not prohibited from being ingredients in infant food.	maternal consumption of GMOs during pregnancy and nursing periods would still expose them to GMOs.
6.	Section 5 (Foods Laboratory for Genetically Modified Foods Testing)	The laboratory standards for testing of GM foods are ill defined compared to other similar regulations.	The standards make no reference to existing laboratory standards under the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017, which set out four levels of Biosafety Labs depending on the risk posed by the material being studied. In addition, the required skill level of the laboratory staff is vaguely defined through meaningless terms like "well versed with these regulations" and "proficient with techniques".
7.	Section 7 (GM Food Labelling)	1. There is no scientific basis for 1% to be the required threshold at which food and foodstuff are to be labelled as GM Food. 2. Further, assuming that there is a scientific basis for the same, the intent	1. Comparable regulations, such as Regulation (EC) No. 1829/2003 of the European Union, have 0.9% as the required threshold for food to be labelled as GM Food. Those regulations have also not provided a scientific basis for these requirements. However, they have the additional requirement that the presence of GMOs in food below that threshold is to be adventitious or technically unavoidable, which needs to be demonstrated by ample evidence before approval. If no scientific basis can be found for having a 1% threshold for food to be labelled as GM Food, then the

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		of the clause to promote consumer awareness is subverted by not having explicit requirements for GM Food Labelling in regional languages.	operation of the precautionary principle would require that any percentage of GMOs in any food product in India should be disclosed. 2. There is no requirement of GM Food Labelling in regional languages, without which labelling in India is meaningless and contemptuous of the linguistic diversity of this county, making it also wholly insufficient for consumer awareness and undermines people's right to make an informed decision at every step.