COMMENTS & SUGGESTIONS ON FSSAI'S DRAFT NOTIFICATION ON FOOD SAFETY AND STANDARDS (GENETICALLY MODIFIED FOODS) REGULATIONS 2022 AS PER FORMAT SUGGESTED BY FSSAI, FROM COALITION FOR A GM-FREE INDIA (http://indiagminfo.org)

Subject: Draft Notification on Food Safety & Standards (Genetically Modified Foods) Regulations, 2022

Sr No	**Name and Address of the organisation/person, contact number and E-mail**		**Relevant section in the draft notification on which comments are being provided**	**Comments/suggestion**	**Rationale**	**Remarks**
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			Chapter I General, 1 Short Title and Commencement - 2(a)	**ALTER to** "(2) a. Genetically Modified Organisms (GMOs) or Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) intended for direct use as food or for processing."	This was how it was in 2021 version as well, this was a more comprehensive definition.	
			Chapter I General, 1 Short Title and Commencement - 2 (b)	**ALTER to** "(2) b. Food or Processed food containing Genetically Modified ingredients produced from but not containing LMOs or GEOs or GMOs."	This was how it was in 2021 version as well, this was a more comprehensive definition.	

			Chapter I General, 1 Short Title and Commencement - 2 (c)	**INSERT** after GMOs **"**or LMOs or GEOs.**"**	Makes coverage more comprehensive	
			Chapter I General, 1 Short Title and Commencement -2 (d)	**ADD NEW POINT** (d) GM Animal and Poultry Feed	**Since GM animal/poultry feed affects human food chain, it must be included in the regulation**: The draft regulations have ignored GM feed, even though GM feed also affects safety of human food chain. FSSAI in the past has not hesitated to issue regulations with regard to some aspects of animal feed, and there is no reason why GM feed should be left out of the current regulations.	
			Chapter I General, 1 Short Title and Commencement - 4	**DELETE COMPLETELY (2) (4)** "They shall not apply to genome edited crops of SDN1 and SDN2 category."	FSSAI might not have taken into account that SDN1 and SDN2 genome editing techniques have shown impacts from emerging research in other countries — on-target mutagenesis other than off-target mutations, single nucleotide mutations, mutations in non-coding regions of the genome, more widespread mutations, on-target/near-target/off-target effects including unintended insertions/deletions/mutations/DNA rearrangements. Whilst GEAC is making a big mistake in excluding genome editing from the scope of GM regulation, FSSAI must not repeat the same mistake. In addition in SDN-1, when gene-editing tool is introduced into the plant cells as plasmids encoding it, either the whole plasmid or fragments thereof – a type of foreign DNA – could be incorporated into the genome by accident. In this case, the product could end up being an unexpected transgenic GMO.	

					In SDN-2 as well, there is a high likelihood of the repair template DNA unintentionally being incorporated into the genome, either in part or as a whole. The intended repair might be there, however in addition, the repair template DNA could have been integrated into the genome at the intended edit site at off-target sites. In these cases, as with SDN-1, an unexpected transgenic GMO could be the result too. Such changes may not be spotted by the developer and without regulatory checks and its health impact GEAC and FSSAI won't even be looking as is being proposed currently. GMO developers should also be asked to carry out transcriptomics, metabolomics, and proteomics analyses and share the information – to ensure that no unintended and potentially dangerous functional and compositional changes have taken place. If they have, these would indicate that the plant's biochemistry has been altered in unexpected ways. These could include the production of toxins or allergens, higher levels of existing toxins and allergens, or altered nutritional value.	
			Chapter I, 2 (1) (b)	**ADD NEW DEFINITION** under Regulation 2 (1) (b) (i) GM Foods & Feed Safety Appraisal Committee (GMFFSAC): A Committee of independent biosafety experts devoid of any conflict of interest set up within FSSAI for appraisal of applications for comprehensive and long-term biosafety	**GMFFSAC must be constituted as the safety assessment body in FSSAI:** The draft regulations only refer to the "Authority" deciding on applications. This is something that is not possible, given that the Authority is not even properly constituted as per Sec.5 of the Food Safety & Standards Act 2006 right now, and importantly, does not meet often enough, nor has biosafety experts. The Authority also does not have Environment Ministry representatives, and coordination with GEAC will be difficult in this situation. The Authority, as per FSS Act 2006 is	

					also not mandated to give routine regulatory approvals etc. The regulations should therefore have to specify which body in FSSAI would be taking decisions on applications received. This is why a GM Foods and Feed Safety Appraisal Committee (GMFFSAC) would have to be set up in FSSAI consisting of independent biosafety experts, devoid of any conflict of interest. This Appraisal Committee must peruse all applications on GM foods after clearance by GEAC in the MoEFCC, and run processes of biosafety assessment, based on which decision-making by the Authority can take place. Such biosafety assessment will take place after testing data as per laid down testing regime is submitted.	
				ADD NEW DEFINITION under Regulation 2 (1) (b) (i) Genetic Engineering: means the technique by which heritable material, which does not usually occur or will not occur naturally in the organisms of cell concerned, generated outside the organism or the cell is inserted into said cell or organism, or it shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material. This includes genome editing techniques as well.	The definition of Genetic Engineering was in 2021 regulation draft as well. A regulation on GM food must keep this definition too.	

			Chapter I General, 2, (1) (f) and (g)	**<u>ADD</u>** to **Definition of 2 (1) (f) and (g)** after 'modern biotechnology' the following: "*including obtained through genome editing"*	Genome edited organisms and products thereof are an integral part of "modern biotechnology" and must be included in definitions.	
			Chapter I General, 2 (1)	**<u>ADD</u> Definition of 2(1)(g)(A) "**GM (Animal/Poultry) Feed" means feed for animals and poultry, containing, consisting of or produced from GMOs.	**<u>Since GM animal/poultry feed affects human food chain, it must be included in the regulation</u>**: The draft regulations have ignored GM feed, even though GM feed also affects safety of human food chain. FSSAI in the past has not hesitated to issue regulations with regard to some aspects of animal feed (https://www.fssai.gov.in/upload/advisories/2021/01/6013fd4bd1a62Direction_Animal_Feed_29_01_2021.pdf), and there is no reason why GM feed should be left out of the current regulations.	
			Chapter I General, 2 (1)	**<u>ADD Definition of Precautionary Principle as 2 (l):</u>** Precautionary Principle means an approach to decision-making as defined in the Cartagena Protocol on Biosafety which states that Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent appropriate decision-making in order to avoid or minimize such potential adverse effects.	India is a signatory to the international agreement called Cartagena Protocol on Biosafety. One of the key decision-making principles/approaches of the CPB is the Precautionary Principle. This Principle should guide FSSAI's decision making too. Therefore, including it in the definition, and later on under actual regulations becomes important.	
			Chapter I General, 3.	**<u>INSERT before 3 (1) :</u>**		

			Prior Approval for manufacture, storage, distribution, sale and import	GM Foods will be regulated by FSSAI in accordance with the precautionary principle, to protect citizens from risks of modern biotechnology on human health as well as animal health which could in turn result in affecting human food chain.	The regulations should be guided by the Precautionary Principle. This is the most critical part of regulation. The decision-making around approval should have policy directives in place, keeping in mind India's conditions of production, consumption and health, and should not be based on other countries' decisions. It should be based on needs and alternatives assessment.	
			Chapter I General, 3 (1) Prior Approval for manufacture, storage, distribution, sale and import etc.	**INSERT** 3 (1) 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 or containing any Living Modified Organisms, **except with prior approval first from Genetic Engineering Appraisal Committee (GEAC) and then of** prior approval of the Food Authority.	FSSAI has to harmonise regulation under FSSA 2006 with other regulations/regulatory bodies, including ones with more competence and experience, and make it into sequential regulation. In view of the complexity with regard to GM foods and its ramifications with regard to environment and animal well-being in addition to human health, it is important and imperative that the regulation of GM foods developed by FSSAI is harmonised with the regulations of GEAC under Ministry of Environment, Forest & Climate Change under EPA 1989 Rules and EPA 1986, and of DGFT. GEAC and FSSAI have an explicit responsibility for all GM foods in that order. The EPA 1989 Rules have a mandate imposed on GEAC to regulate all GM foods. FSSAI has to allude to that, just as it has done for Regulation 4(1). Applicants can come to FSSAI only after GEAC clearance even for Regulation 3(1).	
			Chapter I General, 4 (1) Procedure for grant of prior approval	**DELETE "for Environmental Safety"** and instead say: 4 (1) In case a Genetically Modified or Engineered Food contains any Living Modified	The Environment Protection Act 1986 and the Rules of 1989 already govern the regulation happening for GMOs. FSSAI cannot, under regulations formulated under FSS Act 2006, dictate the regulatory regime contours for GEAC.	

				Organisms (LMOs), after taking prior approval from GEAC, the application for the approval of the Food Authority may be submitted…..		
			Chapter I, General, 3 Prior Approval for manufacture, storage, distribution, sale and import etc, (1) Chapter I, General, 4, Procedure for grant of prior approval, (1), (2), (3), (4), (7), (8), (10)	From Regulation 3 onwards, wherever Food Authority is mentioned, **ADD** the following: "Food Authority, based on the appraisal of GMFFSAC including through consultations with, and NOC of state governments and through public opinion, and by ensuring bodies and processes devoid of any conflict of interest".	See full remark under point 2, titled: **GMFFSAC must be constituted as the safety assessment body in FSSAI:** Here, the rationale is also about preventing Conflict of Interest in regulation which has eroded the credibility of FSSAI in the past. The current mechanisms of preventing conflict of interest in regulatory decision-making in FSSAI are inadequate and unacceptable. The appraisal and decision-making bodies within FSSAI which will scrutinise and decide on each application should be completely devoid of any conflict of interest (GMFFSAC and the Authority). Conflict of interest can't be defined narrowly only as one related to any particular application under discussion, since regulators end up influencing the entire regulatory regime in the course of their work. No GMO developer and no one with any immediate family member involved in GMO development, or imports of GM foods can be a regulator deciding on applications. There should be strict norms around cooling-off period of at least five years both before and after any post related to GMO development, for any regulator.	
			Chapter I General, 4 (4)	**FULLY ALTER TO:** "The Food Authority should lay down the guidelines for comprehensive testing regime for assessing safety of any GM Food. Any applicant wanting to get approval for GM Foods should submit	Regulation 4 (4) specifies scrutiny of documents along with application and that it will examine whether food is safe for human consumption. How this is to be done is not mentioned.	

				results of testing as prescribed. Such testing shall be independent, long term and multi-generational, comprehensive and rigorous. The documents submitted shall be put out in the public domain for independent public scrutiny and feedback to be obtained by GMFFSAC. Such public feedback shall also be used by GMFFSAC for its appraisal of every application. GMFFSAC shall also commission independent testing, at the cost of the applicant. GMFFSAC shall also obtain feedback specifically from state governments where the GM food is intended to be sold and their NOCs"	In addition, the GMFFSAC should be the body that should be the body conducting safety assessment as recommended in point 2.	
			Chapter I General, 4 (8)	1. Regulation 4(8) should **<u>specify</u>** that approval is for an initial period of 1 year and then extend it incrementally, only if post-approval surveillance does not find any problems. 2. Regulation 4(8) should also say/**add** that approval shall be given only if state government provides an NOC. 3. Regulation 4(8) should say that approval will be given after a refundable security deposit of one crop rupees (which should be inflation-indexed as years	1. Any **approval should be for a specified time period** of one year initially and certainly not more than three years, as regulatory science is constantly co-evolving and all applications need to be reviewed automatically in the light of evolution of scientific methods and evidence. 2. **<u>Federal polity should be upheld with state government's views and policies taken on board</u>**: In these regulations, the FSSAI should explicitly mandate that no GM foods will be sold or imported into any state unless the concerned state government gives an NOC for the same, given that this is a matter of public health. A majority of states in India have adopted policies that are against GMOs in our food and farming systems as of now, on the basis of public	

				pass by) is deposited with FSSAI as a compensation fund to victims of possible health implications.	interest. Therefore, every application should be processed after obtaining inputs and recommendations from state governments. The processing of and decision on an application for approval of a GM ingredient should also ensure that the "No GM Foods Policy" of any state government is completely and inviolably protected and upheld. Therefore, the regulatory mechanisms that will be adopted by the FSSAI should take into account the federal polity and the rights of the states. This also means that there should be fool proof mechanisms put into place to ensure that there is no sale or import of these into states which do not want GM foods. 3. Applicant should deposit one crore rupees (which should be inflation-indexed as years pass by) with FSSAI as a deposit for compensation to victims of possible health impacts of GM foods. This deposit is returnable after ten years after approval, depending on the health outcomes of the said GM food.	
			Chapter I General, 4 (9)	Regulation 4(11) **should have provisions** where any citizen can complain or present evidence about impacts of anything approved, which should trigger an investigation and action; there should be procedures for recall laid down right here where approval is suspended or revoked and here, the existing Food Recall regulations have to be re-visited by FSSAI to check the ready applicability of the same in the context of GM foods, especially GMOs.	Such a post-marketing response should also include a citizen complaint channel, upon which also, a response should be made mandatory. The regulations should specify **grievance redressal mechanisms** if citizen complaints are not responded to.	

				Further, 4(11) should also have a sub-regulatory provision about grievance redressal mechanisms if citizen complaints are not responded to.		
			Chapter I General, 4 (12)	Regulation 4(12) **should specify post-marketing surveillance** as per scientifically sound protocols, that is taken up routinely and not just as alerts by the applicant or FBOs when there is a problem.	Post marketing surveillance cannot be left to the applicant or FBOs alone as alerts that get triggered in certain cases "*if a FBO has reason to believe that the GM food poses any risk to health*(!!)", but must be taken up routinely as per a laid-down protocol that is scientifically sound. **Post approval market surveillance mechanisms** should be part of the regulations. The surveillance needs to be taken up along prescribed protocols by FSSAI as well as the applicant.	
			Chapter I General, 4. Procedure for grant of prior approval	A section on Post-Approval regulatory procedures is needed to be **added** after Section 4, for cases when there is evidence of adverse impacts or risk to health as detected either by the operator, or by the general public, when complaints are raised, or when the Food Safety Officers/ Designated Officers detect such issues.	Presently, post approval regulatory procedures very inadequately addressed in 4(12). Such a section should spell out all the actions that have to be taken by FBOs and the applicant, such as how to constitute an enquiry, alert consumers, call back products, address the risk and health issues, provide compensations if any.	
			Chapter I General, 4 (12)	**ADD** - Regulation **4(12) (a) should specify** regulatory mechanisms related to random sampling and testing-based surveillance, to prevent unauthorised sale, import, storage, production etc.	**Surveillance for, and action against illegal GM food sales**: The regulations cannot be just about procedures for receiving and taking decisions on applications, and should have **pro-active regulatory mechanisms spelt out about how to prevent and protect the public from illegal GM food sales/imports etc.** At present, the draft regulations are completely silent about it.	

					i. We suggest that active surveillance through random testing of samples be taken up for those products which are imported from GMO-growing countries with those ingredients present in the food products, and also for those foods for which India has allowed GM crop field trials. ii. Apart from lab-based testing, such a surveillance mechanism should also keep a watch out for supply chain points including import points that are likely to contaminate the food chain with GM material and domestic production units (for cotton seed oil that is part of the food chain in India, without FSSAI safety assessment and clearance, for example). iii. Once again, citizen complaint channel should also be kept open for such a surveillance system.	
			Chapter I General, 4. (13)	**<u>DELETE COMPLETELY</u>** Regulation 4(13)	Regulation 4(13) is completely unacceptable and **should be deleted fully**. There is no guarantee that GMOs as well as GM ingredients approved elsewhere are appropriate for human consumption in India. For instance, GMO corn elsewhere might be approved for bio-fuel - how can we accept that for food or feed here without our own in-country assessments?	
			Chapter I General, 4 (14)	**Regulation 4(14) about no GMO in infant foods should be a general policy.** **<u>ALTER Regulation 4(14) as</u>**: No GM Foods shall be allowed into the food chain in India, unless they are proven to be safe through the processes run as per these regulations, and are	1. The fact that FSSAI put in a provision of this sort clearly indicates that it has the power to do so, of prohibiting certain kinds of foods. 2. It is also clear that it is not just infants who are a vulnerable community when it comes to toxic foods. There are other citizens like malnourished, ones with co-morbidities etc., who are vulnerable. 3. The main duty given to the Food Safety Authority under Sec. 16 (1) of the Food Safety and Standards Act of 2006 is to ensure safe and wholesome food.	

				absolutely needed and no alternatives are available	4. It is not practically possible to implement a special approach specific to vulnerable groups like under-nourished, infants etc. in the country. Except under exceptional circumstances (that too after NOC from a majority of states), no GM Food should be allowed in our food chain in a preventive and precautionary approach. 5. As mentioned earlier, it is important that the Precautionary Principle is embedded into the regulations: The precautionary principle is at the core of the Cartagena Protocol on Biosafety which India ratified. Based on that, **FSSAI should explicitly mention that GM foods will not be allowed into India by way of production or imports**, based on sound reasoning drawn from a variety of important reasons. GM foods have negative preference among the public and are not unavoidable. It is fraught with potential biosafety risks during production and health risks during consumption. Also, as stated in the earlier section Indian public should avoid the ingestion of such foods, especially for vulnerable sections of the public such as infants, children, pregnant and lactating mothers, the elderly and people with health issues. Plant, animal and human health are deeply connected and it is important that FSSAI adopt this "One Health" concept. In short, the mandate should be to adopt the precautionary approach and the regulatory framework should be evolved basically to fulfill this.	
			Chapter I, 5 (1) on GM Food Labelling	**REPLACE** figure one per cent with **0.01 %** as the threshold for labeling.	1. Regulation 5 (1) on "GM Food Labelling" should be 0.01% threshold clearly, especially given that the event-specific testing protocol being asked for is at 0.01% detection level. Mandatory Labelling requirement, therefore, can kick in at the same level. A 100-fold	

					dilution is not acceptable. 2. Labeling is not a matter of safety and cannot replace required biosafety assessment. However, labeling as a mechanism of providing a limited set of consumers their right to know and right to informed choices, should not be diluted in any way and should be mandatory. The labeling requirement should kick in by keeping the threshold at 0.01% when the detection mechanism is able to provide this at 0.01% threshold. Therefore, labeling should become mandatory if any food contains individual GM ingredient/ material at 0.01% threshold. This applies to genome editing also, since techniques for detection have been evolved for genome edited materials. However, as mentioned earlier, India's unique consumption conditions and existing health/under- nourishment conditions should govern the fact that labeling is not an easy answer to even the issue of consumer's right to know and right to informed choices.	

Date: Jan 18, 2023

Place: Coimbatore

Name and Signature: Sreedevi Lakshmikutty on behalf of everyone sending this response