COMMENTS & SUGGESTIONS ON FSSAI'S DRAFT NOTIFICATION ON FOOD SAFETY AND STANDARDS (GENETICALLY MODIFIED OR GENETICALLY ENGINEERED FOODS) REGULATIONS 2021 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 or Genetically Engineered Foods) Regulations, 2021

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**
	Kavitha Kuruganti, Kapil Shah, Dr Rajinder Chaudhary, Sridhar Radhakrishnan, Sreedevi L, Usha Soolapani, Rajesh Krishnan, Ananthoo, Ajay Etikala, Umendra Dutt, Kiran Vissa and others from Coalition for a GM-Free India. Email: indiagmfree@gmail.com; Phone: 8880067772		-	-	-	
			Chapter I General, 1	**ADD NEW POINT** (c) 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, 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.	
			Chapter I, 2 (1) (d)	**ADD** under 2 (1) (d) definition of Genetic Engineering towards the very end: "*and this includes genome editing techniques also"*	Genome edited organisms and products thereof are an integral part of "modern biotechnology" and must be included in definitions.	
			Chapter I General, 2, (e) and (f)	**ADD** to 2 (1) (e) and (f) after 'modern biotechnology' the	Genome edited organisms and products thereof are an integral part of "modern biotechnology" and must be included in definitions.	

				following: "*including obtained through genome editing"*		
			Chapter I General, 2 (1)	**ADD Definition of 2(1)(f)(A) "**GM (Animal/Poultry) Feed" means feed for animals and poultry, containing, consisting of or produced from GMOs.	**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, 2 (1)	**ADD Definition of Precautionary Principle as 2 (h):** 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. Prior Approval for manufacture,	**INSERT before 3 (1) :** GM Foods will be regulated by FSSAI in accordance with the precautionary principle, to	The regulations should be guided by the Precautionary Principle.	

			storage, distribution, sale and import	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.	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 Organisms (LMOs), after taking prior approval from GEAC, the application for the approval of	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.	

				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 (3)	**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 results of testing as prescribed. Such testing shall be independent, long term and	Regulation 4 (3) specifies mere scrutiny of documents along with application. This is completely inadequate. In addition, the GMFFSAC should be the body that should be the body conducting safety assessment as recommended in point 2.	

				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 where required, 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"		
			Chapter I General, 4 (4)	1. **REPLACE** the word <u>SHALL</u> **with** MAY, and **<u>ALTER</u>** phrase "WHERE REQUIRED". 2. Further, **the safety assessment protocols should be specified in the Regulations as a Schedule.**	Regulation 4 (4) using words like 'MAY' and 'IF REQUIRED' are deeply problematic as they imply optionality. On "**the safety assessment protocols should be specified in the Regulations as a Schedule", we have specified in the earlier point on 4(3) that guidelines for a testing regime should be mandatorily followed by every applicant.**	
			Chapter I General, 4 (5)	1. Regulation 4(5) 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(5) should also say/**add** that approval shall be	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</u>**	

				given only if state government provides an NOC. 3. Regulation 4(5) should say that approval will be given after a refundable security deposit of one crop rupees (which should be inflation-indexed as years pass by) is deposited with FSSAI as a compensation fund to victims of possible health implications.	**<u>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 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(9) **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	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.	

				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. Further, 4(9) should also have a sub-regulatory provision about grievance redressal mechanisms if citizen complaints are not responded to.		
			Chapter I General, 4 (8) and (9)	Regulation 4(8) and 4(9) **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 (10)	**<u>ADD</u>** - Regulation **4(10) (a) should specify** regulatory mechanisms related to random sampling and testing-based surveillance, to prevent unauthorised sale, import, storage, production etc.	**<u>Surveillance for, and action against illegal GM food sales</u>**: 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. 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(9) and 4(10). 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, and so on	
			Chapter I General, 4. (11)	**DELETE COMPLETELY** Regulation 4(11)	Regulation 4(11) 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 (12)	**Regulation 4(12) about no GMO in infant foods should be a general policy.**	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.	

				ALTER Regulation 4(12) as: 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 absolutely needed and no alternatives are available	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. 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 (2) under Foods Laboratory for Genetically Modified Foods Testing	**AFTER** "The laboratory shall have instruments for detection of DNA/ RNA by qRT-PCR, Protein by ELISA and Western blotting and GM organism by Fluorescent microscopy", **ADD** *"and such modern instruments as may be prescribed from time to time".*	New mechanisms and scientific methods are constantly evolving and so they should be prescribed according to the best available methods at the time.	
			Chapter I, 5 (4)	**AMEND** to: *"The GM food testing laboratory staff shall be well versed with these regulations and proficient with internationally recognised protocols related to biosafety and techniques related to molecular biology, protein biology and food testing."*	It is important for the staff to be well versed with internationally recognized protocols on biosafety	
			Chapter I, 5 on Foods Laboratory for GM Foods Testing	**ADD** New Regulation 5(5) about all labs having to be equipped with event-specific testing protocols, so that liability can be fixed on particular event developers.	All accredited labs should have event-specific testing protocols handed over to them, and any testing of samples should specify the event detected and the event developer should be made responsible for any illegal contamination detected.	
			Chapter I, 6 on Function of Foods Laboratory for Genetically	**AMEND 6 (c)** to ensure that FSSAI lays down SOPs for all labs for testing procedures	SOPs for labs should be created and prescribed by the FSSAI itself, and it should not be left to the labs to create their own differential SOPs.	

			Modified Foods Testing			
			Chapter I, 7 on GM Food Labelling	**REPLACE** figure 1% with **0.01 %** as the threshold for labeling.	1. Regulation 7 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.	
			FORM – I (See regulation 4) Point 7 (2)	DELETE Point 7(2)	It is completely unacceptable that the information submitted and approved in another country is automatically accepted India. This needs to be **deleted**.	
			FORM – I (See regulation 4)	In 7(3), **REPHRASE TO** "Long term, independent,	1. Points 7(3) and (4) cannot be the main determinants of safety - safety assessment has	

			Point 7 (3) and 7(4)	comprehensive, rigorous, and transparently generated data on the safety of GMOs derived food conducted within India" **DELETE** 7(4)	to happen within India in a transparent and independent fashion. 2. **<u>Independent, long term, comprehensive, rigorous and transparent testing and biosafety assessment as the basis of decision-making</u>**: We note with concern and a sense of disbelief that FSSAI is not proposing any mechanisms for independent, long-term, multigenerational, comprehensive, rigorous and transparent biosafety testing as the basis for decision-making on applications received for GM foods of any kind. This flies in the face of the need for utmost scientific rigour to be applied while adopting a technology or food, which will have far-reaching consequences on human and animal health. **This unscientific approach is unacceptable from the apex food regulator of the country, which is mandated to ensure food safety for all.** i. For every application that is submitted to FSSAI, biosafety data should be submitted as results of conducting third-party testing of the GM food, as per a set of prescribed tests (conducted by independent and accredited laboratories) as per prescribed rigorous test protocols, to prove long term and comprehensive safety of that GM food product. **FSSAI has to evolve such a comprehensive testing regime to begin with, and the same should be applied as guidelines to be followed without exception for all applicants. Applications that do not provide data generated in India should not be accepted.** FSSAI choosing to accept data generated and submitted to regulators elsewhere outside India, and going by the regulators' decisions	

					elsewhere is simply unacceptable and a clear abdication of the responsibility of the Indian regulator. If FSSAI is to simply adopt this kind of a procedure, it may as well clear all those foods that have already been approved elsewhere! Why does it even have to specify these regulations? ii. There should be **independent** testing and scrutiny of biosafety data provided by the applicant. The entire **biosafety dossier should be uploaded and comments sought from the public** and specifically various independent biosafety experts. These inputs should form part of the assessment that is done by a newly-constituted GM Foods & Feed Safety Appraisal Committee (GMFFSAC). In Point E below, we have elaborated some more about this GMFFSAC. iv. Biosafety assessment should be **long term and multigenerational**, with appropriate testing for at least three years if not more, for chronic impacts. Acute and so-called sub-chronic testing is not enough. Such a testing regime should be mandatory on all applicants and FSSAI should begin processing an application only after such a testing regime is followed.	
			FORM – I (See regulation 4) Point 8 (13)	**REPHRASE TO** "What is the basis for claiming safety of the product being applied for with regard to animal toxicological studies." Share the entire data of testing carried out within India.	Questions 13 is set up for an applicant to give a cryptic yes or no answer without any details. No applicant is likely to give an adverse response to this question. The questions need to be rephrased where the applicant has to provide exhaustive and scientific details on the biosafety being claimed by them.	

			FORM – I (See regulation 4) Point 8 (14)	**REPHRASE TO** "What is the basis for claiming safety of the product being applied for with regard to the allergenicity of the newly expressed protein(s)?" Share the entire data of testing carried out within India. **ADD SIMILAR QUESTIONS TO OBTAIN DATA ON OTHER HEALTH AND FOOD SAFETY PARAMETERS THAT ARE PART OF THE TESTING REGIME LAID DOWN**	Questions 14 is set up for an applicant to give a cryptic yes or no answer without any details. The questions need to be rephrased where the applicant has to provide exhaustive and scientific details on the biosafety being claimed by them.	
			FORM – I (See regulation 4)	**ADD NEW POINT 8 (19) – "**Why does this food need to be produced or imported into India? What are the alternatives present in India and what would happen if this food is not produced or imported? Has this food have consumer preference? Does this food have NOC from state governments where it is intended to be sold"	1. **Needs Assessment and establishing lack of alternative:** The final approval for an GMO/GEO/LMO ingredient / food should be based on assessment of needs and alternatives of safer ingredients / foods that can serve the same purpose as the GM ingredient/ food under consideration. This should happen at the GEAC end and thereafter also at the FSSAI end whenever applications are received. 2. **Public opinion:** The final approval for an application should be based on obtaining public opinion. Just like these regulations have been put in the public domain to invite feedback, similarly each and every application made to the FSSAI for approval of such foods must also be put in the public domain to invite feedback. 3. **State Governments' NOCs and views** also to be gathered here.	

			After Form II	**<u>Add a Form III</u>** specifically for any GM feed application with all relevant details sought, related to biosafety data generated within India.	**<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, and there is no reason why GM feed should be left out of the current regulations.	

Date: Jan 14, 2022

Place: Bangalore, Chennai, Vadodara, Wayanad, Trivandrum, Delhi and other places

Name and Signature:

Kavitha Kuruganti on behalf of everyone sending this response