COMMENTS RECEIVED DURING INTERMINISTERIAL CONSULTATION ON THE DRAFT FOOD SAFETY AND STANDARDS (GENETICALLY MODIFIED OR ENGINEERED FOODS) REGULATIONS, 2021.

S.NO	COMMENTS RECEIVED FROM DIFFERENT MINISTRIES	RELEVANT CLAUSE	COMMENTS	RATIONALE	PANEL RECOMMENDATIONS
1.	**Ministry of Commerce and Industry** – Department for Promotion of Industry and Internal Trade - IPR – Copyrights Section		No comments		Not Applicable
2.	**Ministry of Commerce and Industry** – Department for Promotion of Industry and Internal Trade - Patents Section		No comments		Not Applicable
3.	**Ministry of Consumer Affairs, Food and Public Distribution** – Department of Consumer Affairs - Legal Metrology Division		No comments		Not Applicable
4.	**Ministry of Consumer Affairs, Food and Public Distribution** – Department of Food and Public Distribution		No comments		Not Applicable

5.	**Ministry of Law and Justice** - Legislative Department	General Comment	As per the Government of India (Allocation of Business) Rules, 1961, providing of legal comments/suggestions does not come within the domain of the legislative Department. Therefore, Administrative ministry in requested to prepare the final draft notification on the subject and forward this department for vetting.		No action needed at this stage.
6.	**Ministry of Agriculture and Farmers Welfare** – Department of Agriculture, Cooperation and Farmers Welfare	General Comment	As per the provisions of Chapter-II. Clause 6 of PQ Order 2003, import of Genetically Modified Organisms (GMO)/ Living Modified Organism (LMO) for agriculture research purpose is entrusted with NBPGR. New Delhi. Genetically modified/ Genetically engineered food products are not regulated in PQ Order, 2003.		Agreed. Genetically modified/ Genetically engineered food products are not regulated in PQ Order, 2003.
7.	**Ministry of Environment, Forests and Climate Change –** CS III (Biosafety) Division	**Clause 4 -**Procedure for grant of prior approval **4(11)** Once a Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms having unique identification Code provided by Biosafety Clearing House, Organisation for Economic Co-operation and Development etc., is approved by FSSAI, approval for the same will not be	Under procedure for grant of prior approval point No. (11) " Once a Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms having unique identification Code provided by 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", this Ministry is of view that since Biosafety Clearing House is a database platform under Cartagena		Agreed. The following may be incorporated in the draft regulation in Clause 4(11). 'A GMO with unique identification code when approved by FSSAI will be communicated to the Ministry of Environment, Forests and Climate Change for inclusion in the Biosafety Clearing House.'

			required for any other Food Business Operator. Approval will also not be required if it is used as an ingredient in any product.	Protocol on Biosafety, indicates the list of approved GMOs of all the countries, therefore, FSSAI may be request to follow the same procedures for dealing with approved GMOs listed on Biosafety Clearing House as per Form 1 of the regulations. Further, this Ministry is in the process of seeking comments from all the members of Genetic Engineering Appraisal Committee (GEAC) members and would be sharing further comments of this Ministry in due course.		
8.	**Ministry of Food Processing Industries** (Received from Industry Associations **CII -** Confederation of Indian Industry **FICCI -** Federation of Indian Chambers of	**FICCI**	**Clause 1** - Short title and commencement **1(2)(b)** Food or Processed food containing Genetically Modified ingredients produced from but not containing LMOs or GEOs or GMOs.	Clause 1(2) - The phrase "processed food" in clause 2(b) may be replaced by "Food Ingredients".	• Definition of Food includes processed food. • Food ingredients added to bring more clarity.	Agreed. The Panel further recommended that to bring clarity, clause 1(2) may be as follows: **(a)** GMOs / GEOs / LMOs intended for use as food after approval from GEAC, Ministry of Environment, Forests and Climate Change**.** **(b)** Food containing ingredients derived from GMO/ GEOs / LMOs. **(c)** Food ingredients derived from GMOs but not containing modified DNA. It includes Food ingredients/additives/processing aids derived from Genetically Modified Organisms (GMOs).

	Commerce and Industry **ICC -** Indian Chamber of Commerce)	**CII**	**Clause 2**—Definitions	The definitions under these regulations may be aligned with global best practices for better implementation of the regulation.	• Definition of "Genetically Modified or Engineered Food" is very broad, which may also cover food and food ingredients derived from advance technologies like gene editing. This technology is different from GM organism. There are several enzymes, vitamin and nutrients, which are produced using GMO processing aid wherein the ingredient i.e. enzymes or vitamin nutrients does not contain any GMO. Such ingredients are not considered GM as per global best practices.	The definitions are as per the provisions in the FSSAI Act (2006) as it is existing today. However, with the revised definition proposed as part of revising the act (i.e., in sub-section 2 of Section 22 of the Act, the definition of "genetically engineered or modified food" shall be substituted with "*genetically engineered or modified food means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology*"), the issue raised will be addressed.
					• There is no provision to take into account the presence of adventitious traces of GMO in food products, which is technically unavoidable during farming, harvesting and distribution process.	The Adventitious presence and low level presence) is only applicable for Non- GMO certification which is not the mandate of this Regulation.
					• There is ambiguity with respect to highly Processed Material, which may have been derived from GMO but no longer contain GM DNA/protein after processing. Such materials are accepted in many countries like USA, Japan, Taiwan, Thailand etc.	The revised definition as proposed in the paragraph above addresses this issue.

		FICCI	**Clause 2**—Definitions **2 (1) (e)** "Genetically Modified or Engineered Food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;	The Clause 2(1)(e) may be revised as under:- "Genetically Modified or Engineered Food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology."	To align with the global definitions viz. • USDA -"Bioengineered foods" (ii) Such a food does not contain modified genetic material if the genetic material is not detectable. • Similar definitions in Korea, Australia, Taiwan, Indonesia, Japan, Malaysia, Vietnam. • FINAL Rule for National Bioengineered Food Disclosure Standard (Dec 2018).	Not Agreed. Definitions are as per the provisions in the FSSAI Act. Definition of 'Modern Biotechnology' as in Codex (CAC/GL 44-2003) may be included in the draft regulations.
		CII	**Clause 3**- Prior Approval for manufacture, storage, distribution, sale and import etc.	An exemption may be considered for approval in cases, where level of GM traces, are within the proposed threshold value of 1%.	• The regulation does not contain clarity w.r.t any provisions for adventitious contamination during food handling and processing. Though, FBOs always take appropriate measures to avoid unintended presence of GMO in their products. The product sometimes may contain traces of GM as a result of adventitious or technically unavoidable presence in the food chain during farming, harvesting and distribution.	Agreed. The Panel observed that Adventitious presence and low level presence is only applicable for Non- GMO certification which is not the mandate of this regulation. In addition, this has been addressed in the provision of 1% threshold in clause 7- GM Food Labelling. The following clause may be added at 3(2): 3(2): In case of food or food ingredient contain adventitious or

						low level presence (LLP) of GMO or GEO or LMO as per clause 7(1) under this regulation, no prior approval is required.
		FICCI	**Clause 3**- Prior Approval for manufacture, storage, distribution, sale and import etc.	The following may be incorporated as Clause 3(2) &3(3) under Clause 3: Clause3(2): In case of food or food ingredient contain adventitious or technically unavoidable traces of GMO or GEO or LMO as per clause 6(1) under this regulation, no prior approval is required. Clause 3(3): In case of documentary evidence available for the food or food ingredient including manufacturer or ingredient supplier certification or traceability documentation shall not require prior approval.	• The above provisions have been proposed for inclusion in alignment with the EU legislation EC 1830/2003 and EC 1829/2003 and many and many regulations recognize documentation to declare IP like USA.	Clause 3(2) Agreed with minor change. The following clause 3(2) may be added: 3(2): In case of food or food ingredient contain adventitious or low level presence (LLP) of GMO or GEO or LMO as per clause 7(1) under this regulation, no prior approval is required. The issue has been addressed in clause 3(2).

			Clause 3- Prior Approval formanufacture, storage, distribution, sale and importetc. **3(2)** The provisions of these regulations are in addition to, and not in derogation of, any other rules or regulations made under the act.	The serial number of the existing Clause, i.e. Clause 3(2) in the draft Regulations, may be renumbered as Clause 3(4).		It is editorial comment.
		FICCI	**Clause 4**- Procedure for grantof prior approval **4(11)** Once a Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms having unique identification Code provided by 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.	The Clause 4(11) may be revised asunder: "Once a GMO or GEO or LMO having unique identification code provided by Biosafety Clearing house, organization for Economic Cooperation and Development etc. or Food ingredients produced using these 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".	• To bring clarity about use of food ingredients produced using GMO.	Agreed. Revised with minor change. It is already addressed in S. No. 7 above and it is also reproduced below: It may be incorporated in the draft regulation in Clause 4(11). 'A GMO with unique identification code when approved by FSSAI will be communicated to the Ministry of Environment, Forests and Climate Change for inclusion in the Biosafety Clearing House'.

		ICC, Kolkata	**Clause 5**- Foods Laboratory for Genetically Modified FoodsTesting **5(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 separate and contained areas for Reagent and Sample preparation, DNA and Protein extraction, Product Analysis, and Data analysis and storage with a ir conditioning/ventilation. Airflows should be maintainedwithin the Genetically Modified food testing area.	Clause 5(1): The segregated Clean Rooms are mandatory for (1) Pre-PCR, (2) PCR & (3) Post PCR Jobs. There should be unilateral flow in Lab are as to prevent cross contamination.		Not Agreed. "Clean rooms" are not mandatory for GMO analysis. Such rooms are required only for microbiological labs. All these aspects and requirements for GMO analysis are covered in ISO/IEC 17025:2017 and laboratories doing analysis for regulatory compliance are mandated to comply with ISO/IEC 17025: 2017 standard for NABL accreditation. The Panel recommended to delete Clause 5(2), 5(3), 5(4) and clause 6 since all these aspects are covered in ISO/IEC 17025:2017.

		FICCI	**Clause 5**- Foods Laboratory for Genetically Modified Foods Testing **5(2)** 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.	Clause 5(2): 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 or by any other internationally recognized method.	• To bring more clarity and align withInternational best practices.	Not Agreed. All these aspects are covered when a lab is accredited as per ISO/IEC 17025:2017. The following provision has been recommended in Clause 5(2): The laboratory should be accredited by NABL as per ISO/IEC 17025 for GMO testing in their scope.
		ICC, Kolkata	**Clause 5**- Foods Laboratory for Genetically Modified Foods Testing	Clause 5(5): The following provision may be incorporated suitably in Clause5(5) of the draft Regulations: "The personnel involved in Testing should have at-least 01 Year of Hands on Training experience in detection of GMOs from any FSSAI notified GMO Lab".		Not Agreed. These are all covered under ISO/IEC 17025:2017 which is in clause 5(2).
		ICC, Kolkata	**Clause 6** - Function of Foods Laboratory for Genetically Modified Foods Testing **6(a)** Analyse samples of food sent by any officer or organization authorized by the Food Authority for the purpose of Genetically Modified testing and submission of the certificate of analysis to the authorities concerned. Each sample of Genetically Modified	Clause 6(a): Testing each sample should be duplicate.	• Testing each sample in triplicate may be b • Moreover, Clients would not be willing to pay for 03 analysis charges for same sample to Labs. • Since each run will invariably have positive and negative control CRMs,	Not Agreed. In any analytical procedure repeatability and reproducibility are required for the reliability of the result which can be achieved only by doing analysis in triplicates or more. This aspect is also addressed under ISO/IEC 17025:2017 which is in clause 5(2).

			Foods shall be tested in triplicate.		the issue pertaining to false positives and false negatives can easily be addressed".	
			Clause 6 - Function of Foods Laboratory for Genetically Modified Foods Testing	Incorporation of new clause 6(g): The following may be incorporated as Clause 6(g): "A minimum level for detection of GMOs may be established. It can be 0.1% or 0.5% so that labeling 1% can be reliably done as the laboratory's LOD can be 0.1% or 0.5%".		Not Agreed. Clauses in the ISO/IEC 17025:2017 takes care of this aspect. Also, FSSAI approval and both FSSAI and NABL audit of its notified laboratories also takes care of this.
		FICCI	**Clause 6** - GM Food Labeling	This clause may be renumbered as Clause 7 as the serial number of this clause has typographical error.		Agreed.

		ICC, Kolkata		Thefollowingprovisionsmayalsobeincorporatedas Clause7(1) and7 (2): - Clause 7(1): The phrase "Contains GMO / Ingredients derived from GMO" may be given if the Lab has tested for the presence of Promoter (e.gCAMv 35S or FMV), Terminator (e.g T-NOS) as well as gene responsible for expression of a particular trait (e.g RR Soya). Clause 7(2): In case the Lab only tests for Promoters and Terminators and does not test for the gene responsible for expression of a particular trait, it can be labeled as "Genetic elements such as "CAMv 35S Promoter" and "T-NOS terminator" detected with LOD at x%. This will have more clarity as to what actually was tested.		Not Agreed. This is not relevant to the current trends in GMO testing. 35S / FMV /T-NOS are only detection methods. Currently identification and quantification is required for compliance. This is carried out by using "event based testing" (host genome integration site) which is more reliable.
		ICC, Kolkata	Forms I & Form-II	Seem exhaustive and o.k.		No action needed.

9.	**NITI Aayog** (inputs of **ICMR-National Institute of Nutrition, Hyderabad CSIR-Central Food Technological Research Institute, Mysore**)	FORM-I (See regulation 4): Application for Approval for Food or food ingredient or processing aid containing Living Modified Organism (LMOs) **8.** Bio-safety Description of items applied for approval	**8.(6)(c)** Annotated complete DNA sequence of the integrated gene construct along with flanking region (from RB to *LB)*a relevant (editable) format *{e.g.,.txt. fasta*,.fsa,.doc). **Modification suggested:** in place of (from RB to LB)…….**(Left Border to Right Border)** **8.(7)(c)** Briefly describe any target site rearrangement(s), addition(s), or deletion(s) occurred at the gene construct insertion locus in host organism's genome DNA *in compare the type pre-insertion locus.* **Modification suggested:** in place of *in compare the type pre-insertion locus….**"in*** **comparison to pre-insertion locus".** **8.(7)(e)** Describe genomic (chromosomal) location of the integration site and flanking region endogenous gene(s) of *the hostplant.* **Modification suggested:** to add - "of the host plant or **animal**".		The Panel felt that the two forms need to be revisited to make them simpler and in line with global practices.

			8.(8) Details of event specific experimental methods to detect the presence of the transferred gene construct(s) (and gene(s)) at 0.01% Limit of Detection (LoD0.01) in recipient plants or animal/progeny of recipient plants or animal. **Modification suggested:** to add - "**recipient plant or animal/ progeny of recipient plant or animal**" **8.(12)** Whether the genetic modification intended to alter *plant* nutrient composition? **Modification suggested:** to add - "plant or **animal**".		
		Additional Points	• GM Labelling provisions are generally meant to give consumers the right to choose between GM and non-GM food. At 1 % threshold GM labelling legislation has been proposed, does this mean that products derived from GMOs that no longer contain any trace of DNA or proteins resulting from the genetic modification (for *e.g.,* oil derived from genetically modified chops) are exempt from labelling? In such a scenario, label will not give any		Yes, any product having less than 1% of GMO content is not required to be labelled.

			information about the genetic modification;		
			• GM testing is an expensive proposition; financial resources and trained human resources are matters of concern and need to be suitably addressed to ensure compliance with the proposed GM labelling legislation;		Irrespective of the cost, testing is mandatory for regulatory compliance.
			• GM food wastage and its consumption by animals, impact on environment, soil health and water resources were not discussed in the draft. Adequate emphasis on measures for safe disposal of GM food may be included.		GM food wastage and its consumption by animals, impact on environment, soil health and water resources do not fall under the purview of FSSAI.
			• The concept of history of safe use is pivotal in the context of GMO safety assessment. As per the proposed legislation, applicants are to provide three years' data of the safe use of the GMOs derived food in the country of origin. Rationale for asking 3years' data may be included, why not more than 3 years considering safety of GM food;		

			• The use of CRISPR-CAS and other gene-editing techniques to develop crops with desirable traits is a very advance field of research. At this stage, it is not clear whether the scope of the proposed GM legislation includes food derived from crops through the emerging technologies as well. If it falls under the scope, then how are they going to be regulated?		Genetic engineering is the direct manipulation of an organism's DNA. Whereas gene editing is a precise method of genetic engineering. Hence gene editing is just another form of genetic engineering. As such the provisions for genetically engineered food will apply for gene edited food.