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The Chief Executive Officer
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Subject: My objections to and comments about the draft regulation called the Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021.

Section 1, intent of the regulations

At the outset, I completely reject modern biotechnology in India's farming and food. There is no case now, and there never has been a case, for its inclusion, based both on sound science and on public interest. Genetically modified/edited seed and crop of any kind is a threat to the health of Indian citizens. It is a threat to the environment and to the existing agricultural biodiversity of India. It is a threat to the socio-cultural traditions that our agriculture and food rests upon. The Union Government of India and every state and union territory government must prohibit genetically modified/edited seed and crop. There can be no compromise on this matter.

What then is this draft legislation brought for? Nowhere in the text of the draft legislation do I find any reference to any work carried out by the FSSAI or commissioned by it from independent authorities, nor any reference to such work carried out by either the Ministry of Agriculture or the Ministry of Environment - as both these are subject areas associated with the subject of this draft legislation - that assesses the need for such products in India.

In the same way, nowhere in the text of the draft legislation do I find evidence of the precautionary principle applied. The precautionary principle is central to the Cartagena Protocol on Biosafety which India has ratified. Thus the precautionary principle is an obligation, hence a draft legislation about genetically modified or engineered foods must explicitly state that such foods manufactured from, and such foods that contain ingredients derived from (whether in small part or larger part) genetically modified/edited seed and crop will under no circumstances be allowed into India, whether by import of finished goods, or by manufacture (food processing) based on such ingredients or by cultivation within India.

There is a voluminous international record of more than 25 years which shows conclusively that GM foods carry with them biosafety risks during production and health risks during consumption. No Indian citizen should be presented such foods, in whatever form, for consumption. Vulnerable sections of the public such as infants, children, pregnant and lactating mothers, the elderly and people with existing morbid conditions should more particularly be protected from such foods.

I find there is no recognition whatsoever - let alone the provision to act upon such recognition - of these first principles in the text of the draft legislation.

Where something can cause serious irreversible harm, it is right and proper for scientists to demand evidence demonstrating that GM is safe beyond reasonable doubt. This is also an approach that is contained by the precautionary principle (for scientists and for the public, it is just common sense). Scientific evidence is no different from ordinary evidence, and should be understood and judged in the same way. Evidence from different sources and of different kinds has to be weighed and combined to guide policy decisions and actions. That's good science as well as good sense.

Genetic modification/ engineering/ editing involves recombining, that is, joining together in new combinations, DNA from different sources, and inserting them into the genomes of organisms to make 'genetically modified organisms'. GMOs are unnatural, not just because they have been produced in the laboratory, but because many of them can only be made in the laboratory, quite unlike what nature has produced in the course of millions of years of adaptation and change. Thus, it is possible to introduce new genes and gene products, many from bacteria, viruses and other species, or even genes made entirely in the laboratory, into crops, including food crops. We have never eaten these new genes and gene products, nor have they ever even been part of our food chain.

The artificial constructs are introduced into cells by invasive methods that result in random integration into the genome, giving rise to unpredictable, random effects, including gross abnormalities in both animals and plants, unexpected toxins and allergens in food crops, and unknown effects on humans and animals. This problem is compounded by the overwhelming instability of transgenic lines, which makes risk assessment virtually impossible.

None of these risks are acknowledged by the draft legislation which therefore fails completely to establish why in the first place the provisions and mechanisms it contains are needed or are suitable for India. It also fails as a protective legislation by not prohibiting foods based on or derived from genetically modified/edited seed and crop.

Section 2, contextualising industry interest

Genetically modified crops (GM or GMO crops) still run far ahead of our understanding of their risks. The citizens of India, first, followed by the scientific community and specialists, must better appreciate the complexity of biological organisms and the capacities of these organisms which may benefit us or may harm us. The scientific community especially - both in centres that are publicly funded and those that belong to industry - need to learn much more humility about the capacity of science to do more than scratch the surface in its understanding of the deep complexity and diversity of the natural world.

Both the Bt brinjal and GM HT mustard public debates, as well as consumer surveys in the past, have made it amply clear that Indian citizens do not want GM foods entering their diets. Most state governments have also taken a policy stand against GM technology in food and farming systems.

FSSAI is a government regulator, and my experience of observing government regulatory agencies and bodies for more than 30 years is that they overwhelmingly tend to rely on

data produced by, and assurances given by, the commercial beneficiaries of regulations, and that means industry. For years, the FSSAI sidestepped its responsibility for the presence of illegal GM foods in the Indian food chain. FSSAI's constitution of a scientific panel on GM foods had conflicts of interest and excluded experts on biosafety. Members of the FSSAI Scientific Panel were active in GM crop development. Even when the panel was reconstituted several earlier members were retained. No rationale was given for the selection of the experts into the Scientific Panel.

The Bt corn and soya plants that are now common in many ecologies around the world are registered as insecticides! How are these insecticidal plants regulated? Have their proteins been tested for safety when ingested as food products and in the environment? In India the answer is a resounding 'no'. This is because independent GMO crop risk research is rare in India, not being supported financially by even the agencies of the Government of India (which should, but do not) and also as the agricultural biotechnology (ag-biotech) industry uses its patent-based control of GM crops to restrict independent research. Research that has been suppressed includes assessments of health and environmental safety and agronomic performance of GM crops.

In contrast, the international scientific literature is full of studies showing that genetically engineered corn and soya contain toxic or allergenic proteins. Fully contrary to the claims of the agricultural biotechnology (ag-biotech) industry in India and internationally, genetic engineering (or modification or editing) is imprecise and the results are thoroughly unpredictable, with mutations changing the nutritional content of food, crop performance, and releasing toxic effects into the environment. Worse, every generation of GMO crop interacts with more organisms, creating more opportunities for unwanted side effects when introduced into foods and toxic effects in the environment.

I am very well aware that powerful agricultural multinational corporations and their subsidiaries and partner companies in India want to use new genetic engineering techniques to force GM food into our fields and onto our tables either without public scrutiny, or through a compromised regulatory process such as the one the FSSAI has drafted in this proposed legislation. I am well aware that seeds produced with older and new generation GM techniques (like CRISPR/Cas) are fundamentally different from non-GM seeds and in no way can food products derived from GM seed and crop be considered similar to non-GM seed and crop.

Section 4, the 'gene' myth-making

What in the first place is the origin of the term or concept 'gene' which is the basis for the 'genetically modified' or 'genetically engineered' terms that are the subject of this draft legislation Such organisms were developed based on exaggeratedly simplified premises from molecular biology and the very recent science of genetics. According to these, a 'gene' codifies for a certain protein the performing of a certain function. Thus it was believed that simply transferring a gene from one organism (donor) to another organism (receptor) would be enough for desired function to be performed.

In the case of the human genome, such a simplified interpretation gave rise to the notion until some years ago, that most of it was "waste DNA". From around a decade ago, it came to be thought that some 80% of the genome would have biochemical functions as regulators of unpredictable and unknown complex systems. Thus modern science does not

know what a 'gene' is, and all that is known is that earlier ideas of what it is were incorrect. Thus, an understanding of
the basic biological mechanisms inherent to the life requires much more study. This small group of papers illustrate the great gaps in understanding:

a) El-Hani, C. 2007. 'Between the cross and the sword: the crisis of the gene concept.' Genet. Mol. Biol., vol.30, nº 2. São Paulo.
"Challenges to the gene concept have shown the difficulty of preserving the classical molecular concept, according to which a gene is a stretch of DNA encoding a functional product (polypeptide or RNA). The main difficulties are related to the overlaying of the Mendelian idea of the gene as a 'unit': the interpretation of genes as structural and/or functional units in the genome is challenged by evidence showing the complexity and diversity of genomic organization."
[see http://www.scielo.br/scielo.php?pid=S1415-47572007000300001&script=sci_arttext]

b) Encode Project Consortium. 2007. Identification and analysis of functional elements in 1%
of the human genome by the Encode pilot project. Nature, v.447, p. 799-816.
"We report the generation and analysis of functional data from multiple, diverse experiments performed on a targeted 1% of the human genome as part of the pilot phase of the ENCODE Project... integration of these new sources of information, in particular with respect to mammalian evolution based on inter- and intra-species sequence comparisons, has yielded new mechanistic and evolutionary insights concerning the functional landscape of the human genome. Together, these studies are defining a path for pursuit of a more comprehensive characterization of human genome function."
[see http://www.ncbi.nlm.nih.gov/pubmed/17571346]

c) Encode Project Consortium. 2012. An integrated encyclopedia of DNA elements in the human genome. Nature, Vol 489, 57-74.
"The human genome encodes the blueprint of life, but the function of the vast majority of its nearly three billion bases is unknown. Overall, the project provides new insights into the organization and regulation of our genes and genome, and is an expansive resource of functional annotations for biomedical research."
[see http://www.ncbi.nlm.nih.gov/pubmed/22955616]

Section 4, FSSAI acting as an adjunct of industry

This draft legislation by FSSAI comes after years of dithering on the prohibition of GM seed and crop and of foods based on their use, but when it has come, it is in opposition to what is meant by 'safety'. Between the Genetic Engineering Appraisal Committee in the Ministry of Environment, Forest and Climate Change and the FSSAI under the Ministry of Health and Family Welfare, GM foods have been left virtually unregulated in India from April 2016. It was only under public pressure that FSSAI put in a new system for all importers of some select crops (apple, eggplant, maize, wheat, melon, pineapple, papaya, plum, potato, rice, soybean, sugarbeet, sugarcane, tomato, sweet pepper, squash, flax-seed, bean plum and chicory) for a mandatory "non-GM-origin-cum-GM-Free" certification, from 1 January 2021, but this is not applicable to processed GM foods, which is the subject of this draft legislation.

I am listing some of the many paragraphs that illustrate the objections I have given in this letter:

(a)
In Chap 1, Sec 1: these apply to
"(a) Genetically Modified Organisms (GMOs) or Genetically Engineered Organisms (GEOs) or Living Modified Organisms (LMOs) intended for direct use as food or for processing.
(b) Food or Processed food containing Genetically Modified ingredients produced from but not containing LMOs or GEOs or GMOs."

On what basis is such text even included as draft text? When GMOs/GEOs/LMOs are under strict regulation in countries all over the world, it is grossly irresponsible to place draft legal text that includes them as "food or for processing".

(b)
In Chap 1, Sec 3: here we find the term "prior approval":
"Prior Approval for manufacture, storage, distribution, sale and import etc. (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, except with the prior approval of the Food Authority."

The term "prior approval" has no place in a legislation for food safety. Prior approval is the creation of an opaque and fast-track channel designed precisely to allow what must be prohibited.

(c)
In Chap 1, Sec 4: here we find how "prior approval" works:
"Procedure for grant of prior approval (1) In case a Genetically Modified or Engineered Food contains any Living Modified Organisms (LMOs), after taking prior approval from GEAC for Environmental safety, the application for the approval of the Food Authority may be submitted ..."

Here the GEAC is invoked, which experience of the last decade has shown is a body completely controlled by the ag-biotech industry.

(d)
"(2) In case a Genetically Modified or Engineered Food does not contain any LMOs, the application for the approval of the Food Authority may be submitted directly in Form-II ..."

Another stratagem that uses "approval" as an in-built means of bringing in foods based on genetically modified/engineered seed and crop.

(e)
"(6) The food business operator shall, after grant of approval apply for license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011."

As "food business operator" is not defined in Chap 1 Sec 2 on definitions, it presumably relates to its definition under the Food Safety and Standards Act 2006. This text is

premature. There is no scope for any such licensing when rules expressly forbid GMOs/GEOs/LMOs as food or as material for processed food.

(f)
"(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."

The term "reason to believe" means voluntary disclosure by the "food business operator". This cannot be a safety standard.

(g)
"(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 FSSAI wants to implement clearance given by the OECD to GM/GE foods. Such clearance will be blanket for a food product category. This is an attempt to make justification for the import of genetically modified/engineered foods rest upon regulations by a multi-lateral organisation and not in Indian law. Bad in law.

(h)
"(12) Genetically Modified Organisms or Genetically Engineered Organisms or Living Modified Organisms shall not be used as an ingredient in any infant food."

This is the only actual safeguard in the draft legislation.

(i)
In Chap 1, Sec 7
"7. GM Food Labelling- All food products having individual Genetically Engineered (GE) ingredient 1% or more shall be labelled. The labelling shall be as: "Contains GMO/Ingredients derived from GMO" "

FSSAI is already making provision for labelling, not prohibiting. When a category of foods (genetically modified/engineered) must be prohibited, labelling does not arise. Furthermore, the assigning of "1% or more" is a direct breach of safety.

I find these more than enough to show conclusively that the intention of the FSSAI behind the drafting of this proposed legislation are mala fide. it is clear to me that the regulator has refused to assess risk in any serious way. How could the regulator do so, when in the first place it circulated the draft legislation first to industry for its comments before presenting it to the citizens of India? This alone is enough to reject the draft legislation, for completely subverting the meaning of 'public consultation'. This being the very obvious bias, it follows that the citizens of India have no way of ascertaining how many sections and clauses of the proposed legislation have been drafted by FSSAI at the instance of industry.

Moreover, this draft legislation is redolent with fatal flaws in the procedure of food safety assessment from the start. It is entirely possible that one of the models for this draft legislation is the Joint FAO/WHO Biotechnology and Food Safety Report of 1996, a report that was rejected and criticised for:
* Making contentious claims for the benefits of GM technology.
* Failing to assume responsibility for, or to address major aspects of food safety, such as the use of food crops for producing pharmaceuticals and industrial chemicals, as well as issues of labelling and monitoring.
* Restricting the scope of safety considerations to exclude known hazards, such as the toxicity of broad-spectrum herbicides.
* Claiming erroneously that genetic engineering does not differ from conventional breeding.
* Using a 'principle of substantial equivalence' for risk assessment that is both arbitrary and unscientific.
* Failing to address long-term impacts on health and food security.
* Ignoring existing scientific findings on identifiable hazards, especially those resulting from the horizontal transfer and recombination of transgenic DNA.

The same failures and flaws are fully visible in the draft regulation called the Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021. It makes only for a template designed to expedite product approval at the expense of safety considerations. This draft legislation must be scrapped entirely.

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