NISHIMURA & ASAHI

西村あさひ法律事務所

Food Safety Regulations in India: Genetic engineering, manufacturing, packaging, labelling and advertising

Asia / Agri-food Newsletter

February 6, 2023

Author:
E-mail Taeko Suzuki
E-mail Varsha Bhattacharya

1. Introduction

India has several laws that regulate food safety. In the previous issue of this newsletter, we identified the key laws governing food safety in India, and also discussed the regulation of food additives, insecticides and novel foods. In this issue, we will focus on the regulation of genetic engineering of food, along with the regulation of manufacturing, packaging, labelling and advertisement of food in India.

2. Regulation of genetic engineering of food

Genetic engineering, or genetic modification of food, is regulated under the Environment (Protection) Act, 1986 ("**EPA**"). Under the EPA, the Government of India issued the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms Genetically Engineered Organisms or Cells Rules, 1989 ("**GM Rules**"), which came into force in 1993.[1] Under the GM Rules, further guidelines have been issued on conducting of field trials, food safety assessment, environmental risk assessment, etc.[2]

The GM Rules were issued in order to protect the environment, nature and health, in connection with the application of gene technology and microorganisms,[3] and are implemented by the Ministry of Environment, Forest and Climate Change ("**MoEF**") of the Central Government, and by the state governments, through six competent committees discussed below.

(1) Scope of the GM Rules

The GM Rules apply to:[4]

- "Microorganisms" - defined to include *"all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protodones and nematotes"* listed in the Schedule to the Rules, and *"those that have not been presently known to exist in the country or not have been discovered so far"*.[5]
- "Gene technology" - defined as "*the application of the gene technique called genetic engineering, include*

1 Notification S.O.677(E), dated 13.9.1993

2 Such as the Recombinant DNA Safety Guidelines, 1990; Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008; Guidelines for Environmental Risk Assessment of Genetically Engineered Plants, 2016; Guidelines for the Safety Assessment of Genome Edited Plants, 2022; etc.

3 Preamble, GM Rules

4 Rule 2(1), GM Rules

5 Rule 3(v), GM Rules

self-cloning and deletion as well as cell hybridisation".[6]

- "Genetic engineering" is further defined to mean "*the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. 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*".[7]
- New gene technologies apart from those referred to above, and to organisms and cells generated through such other technologies, and to products of which such organisms and cells form a part.[8]

The subject matter of the GM Rules is also specifically identified to include "*genetically engineered organisms, micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc. of which such cells, organisms or tissues hereof form part*",[9] making the GM Rules applicable to any genetic engineering or modification of any food. This subject matter is referred to hereinafter as "**GMO**".

In relation to the above subjects, the GM Rules apply in the following cases:[10]

- sale, offers for sale, storage for the purpose of sale, offers and any kind of handling over with or without consideration;
- export and import of GMO;
- production, manufacturing, processing, storage, import, drawing-off, packaging and repacking of GMO; and
- production, manufacture, etc., of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc., which make use of GMO in one way or another.

(2) Regulatory authorities created under the GM Rules

Notably, the GM Rules created the following six committees as "competent authorities", each with a designated set of functions:[11]

1. *Genetic Engineering Appraisal Committee ("**GEAC**")* - its role, under the aegis of the MoEF, is to approve (a) activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production; and (b) proposals for release of GMO and products into the environment. It is the apex body among the six authorities established under the GM Rules.

2. *Recombinant DNA Advisory Committee ("**RDAC**")* - its role is to review developments in biotechnology at national and international levels, and recommend safety regulations for India in the research, use and applications of recombinant DNA.

3. *Review Committee on Genetic Manipulation ("**RCGM**")* - its role is to monitor the safety of ongoing research

6 Rule 3(iii), GM Rules

7 Rule 3(iv), GM Rules

8 Rule 2(3), GM Rules

9 Rule 2(2), GM Rules

10 Rule 2(4), GM Rules

11 Rule 4, GM Rules

projects and activities involving GMO. It is also required to review all ongoing projects involving high-risk categories and controlled field experiments.

The RCGM is also tasked with publishing manuals that specify the regulatory procedure for activities involving the use of GMO in research and in industry applications, to ensure environmental safety. It is also required to prescribe procedures for restricting or prohibiting the sale, import and use of GMO listed in the Schedule to the GM Rules.

4. *Institutional Biosafety Committee ("**IBSC**")* - its role is to assist an occupier or any person, including research institutions, to prepare an on-site emergency plan in accordance with the guidelines published by the RCGM.

5. *State Biotechnology Coordination Committee ("**SBCC**")* - This committee is empowered to inspect, investigate and take punitive action in case of violation of statutory provisions. It is required to periodically review the safety measures in different industries for handling GMO.

6. *District Level Committee ("**DLC**")* - This committee is set up to monitor safety regulations in installations that use GMO. It is also tasked with creating an off-site emergency plan in relation to installations it monitors.

(3) Prescriptions under the Rules

The import, export, transport, manufacture, processing, use or sale of any GMO without the approval of the GEAC is prohibited.[12] Production, sale, use or import of any substances or food stuff containing GMO is not permitted without prior approval of GEAC.[13] Production processes using or generating GMO require prior approval from the GEAC for release of GMO into the environment, before such production can commence.[14] Intentional or unintentional release of GMO into the environment is not permissible, except in special cases where the GEAC approves such release.[15]

Further, license from the GEAC is required to be obtained by any person operating or using GMO listed in the Schedule to the GM Rules for scale up or pilot operations.[16] The GEAC is also required to give directions to an occupier regarding measures to be taken to prevent discharges of microorganisms and other items listed in the Schedule from laboratories, hospitals, etc.[17]

All GEAC approvals shall be granted for a fixed period not exceeding four (4) years, which can then be renewed. However, GEAC approval can be revoked if:[18]

- New information on harmful effects of the GMO emerges;
- The GMO causes environmental damage that could not be envisaged at the time of grant of approval; or

12 Rule 7(1), GM Rules

13 Rules 10 and 11, GM Rules

14 Rule 8, GM Rules

15 Rule 9, GM Rules

16 Rule 7(4), GM Rules

17 Rule 7(3), GM Rules

18 Rule 13(2), GM Rules

- There is non-compliance with any condition imposed by the GEAC in the approval.

Apart from GEAC approvals and licenses, the GM Rules also mandate that the use of GMO for research should be limited to laboratories notified by the MoEF under the EPA, for this purpose.[19] Experiments outside such notified laboratories for the purpose of education may be permitted in some cases, and shall be monitored by the IBSC.[20]

(4) Consequences of non-compliance

The SBCC and the DLC are charged with monitoring and oversight. In case of non-compliance with any statutory provisions, the committees are empowered to take measures at the expense of the person responsible, including emergency measures to prevent damage to the environment, even without any order or notice. The committees also are empowered to take samples for more detailed examinations, and to ask any other government authority for assistance.[21]

The GM Rules also provide for an appeal against a decision of the GEAC or the SBCC to an authority appointed by the MoEF.[22]

3. Regulation of food manufacturing

The manufacturing process of food is regulated by the Food Safety and Standards Act, 2006 ("**FSSA**"), discussed in detail in the previous issue of our newsletter. The FSSA renders liability on a manufacturer or a packer for an article of food if it is not manufactured or packaged in accordance with the provisions of the FSSA.[23]

It also obligates any business owner or operator whose business is related to food in any manner to obtain a license to operate the food business, among other obligations.[24] Relevant aspects of such licensing are provided for in the Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011 ("**Licensing Regulations**"). Under these regulations, no person is permitted to commence any food business unless such person possesses a valid license; and every licensee is required to file annual returns listing the food products handled during the previous year.[25]

Some of the other approvals and licenses that a food operator may be required to obtain from various authorities under other laws include: health and trade licenses from the municipal corporation of the relevant area, environmental clearance, no-objection certificate for fire prevention and safety, registration under the police act of the relevant city/state, verification certificate under the Standards of Weights and Measures Act, 1976 for each of the outlets issued by the Department of Legal Metrology of the relevant areas, registration under the shops and establishments act of the relevant state, and eating house and liquor licenses.

---

19 Rule 7(2), GM Rules

20 Rule 7(5), GM Rules

21 Rule 15, GM Rules

22 Rule 19, GM Rules

23 Section 27(1), the FSSA.

24 Sections 23, 26, 28, and 31, the FSSA

25 Regulation 2.1, Licensing Regulations

4. Regulation of food packaging

Section 23 of the FSSA mandates that no person shall manufacture, distribute, sell or deliver any packaged product that is not packaged or labelled in accordance with the prescribed regulations.

The Food Safety and Standards (Packaging) Regulations, 2018 ("**Packaging Regulations**"), issued under the FSSA, impose an obligation on all food business operators ("**FBOs**") to ensure that the packaging materials used comply with the Packaging Regulations.[26] Every FBO must obtain a certificate of conformity from a laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories ("**NABL**").[27]

The Packaging Regulations provide for a positive list system by imposing certain general requirements, such as requiring that the packaging material coming in direct contact with food must be of food grade quality; that it must be suitable for the type of product and the manner of handling; and that it should be hygienic and tamper-proof, etc.[28] The Packaging Regulations provide for further specific requirements for primary food packaging, depending on the type of material.[29]

5. Regulation of food labelling

(1) General prescriptions on labelling

Labelling of food is regulated by the Food Safety and Standards (Labelling and Display) Regulations, 2020 ("**Labelling Regulations**") issued under the FSSA, which prescribe labelling requirements for packaged foods and display of essential information on premises where food is manufactured, processed, served or stored.[30]

The Labelling Regulations, among other prescriptions, mandate that the descriptions on labels should not be false or misleading in any manner,[31] and should be clear, unambiguous and legible.[32]

They also list all the information points that need to be reflected on the labels, such as:[33]

- the name of the food indicating the true nature of the contents;
- the ingredients to be listed in descending order by volume or weight;

26 Regulation 3(1), Packaging Regulations

27 Regulation 3(14), Packaging Regulations

28 Regulation 3, Packaging Regulations

29 Regulation 4, Packaging Regulations

30 Regulation 1(2), Labelling Regulations

31 Regulation 4(3), Labelling Regulations

32 Regulation 4(7), Labelling Regulations

33 Regulation 5, Labelling Regulations

- nutritional information, except for certain exempt items;[34]
- declaration of vegetarian or non-vegetarian contents using a prescribed symbol;
- name and address of brand owner;
- FSSAI logo and license number;
- net quantity, retail sale price and customer care information;
- lot or batch identification;
- dates marking manufacture, packaging and expiry;[35]
- country of origin for imported foods (labelling of imported foods is also subject to the Food Safety and Standards (Import) Regulations, 2017);
- instructions for use;
- food allergen declarations; and
- prescribed symbol for food material sold in retail but not meant for human consumption.

The Labelling Regulations also prescribe requirements for display of information in food service establishments. Among other things, they require such establishments to mention the calorific value of food items, details regarding food allergens, logo indicating vegetarian or non-vegetarian contents, nutritional information, etc.[36] E-commerce FBOs are required to procure the information from the FBO and make it available on their website, if applicable.

The Labelling Regulations also provide similar prescriptions for non-retail containers.[37]

(2) Labelling of novel foods

Novel foods are subject to the same labelling requirements as provided in the Labelling Regulations. In addition, they also may be subject to prescriptions in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 ("**Novel Food Regulations**") which create room for the FSSAI to incorporate special requirements.[38]

(3) Labelling of genetically modified foods

Rule 6(7) of the Legal Metrology (Packaged Commodities) Rules, 2011 requires that packages containing genetically modified foods are to be labelled with the term "GM".

---

34 Exempted items include unprocessed products comprising a single ingredient, processed foods comprising a single ingredient where the only process is maturing, water intended for human consumption, herb or spice mixtures, salt and salt substitutes, table-top sweeteners, coffee beans or grounds or chicory mixtures, tea and infusions, vinegar and vinegar substitutes, additives like flavouring, chewing gum, alcoholic beverages, and foods for special dietary uses or for special medical purposes. Regulation 5(3)(c), Labelling Regulations

35 Expiry date is not required for fresh fruits and vegetables, wine, beverages with more than 10% alcohol by volume, vinegar, sugar boiled confectionary, food grade salt for industrial use, solid sugars and chewing gum. Regulation 5(10)(d), Labelling Regulations

36 Regulation 9, Labelling Regulations

37 Regulation 10, Labelling Regulations

38 Regulation 13(2), Novel Food Regulations

6. Regulation of food advertisement

The FSSA prohibits any food advertisement which is misleading, deceiving or contravenes the provisions of the FSSA or the rules made under it.[39] In addition to the FSSA, provisions governing advertisement of food are provided in the Food Safety and Standards (Advertising and Claims) Regulation, 2018 ("**Advertising Regulations**").

The Advertising Regulations prescribe some general principles, that include:[40]

- claims must be truthful, unambiguous and not misleading;
- claims must not encourage or condone excessive consumption of a particular food;
- claims relating to nutritional or health attributes must be scientifically substantiated;
- all disclaimers are to be conspicuous and legible;
- advertisements shall not be portrayed as meal replacements unless specifically permitted under the FSSA;
- advertisements cannot undermine the importance of healthy lifestyles; etc.

The Advertising Regulations also prescribe the specifications in which a nutrition claim may be made.[41] "Nutrition claim" is defined as "*any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins, minerals and other permitted listed nutrients*", and include (i) "nutrient content claims" which would be a claim that ascribes the level of nutrients in a food, and (ii) "nutrient comparative claim" which is a claim that compares nutrient levels in two or more foods.[42]

The Advertising Regulations also regulate the making of health claims. "Health claim" is defined as "*any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health*", and it includes (i) a "nutrient function claim" that describes the physiological role of the nutrient in the functions of the body, (ii) an "other function claim" that describes the beneficial effects of the food which relate to a positive contribution to health, and (iii) a "reduction of disease claim".[43] While it is permissible to make health claims, there are many restrictions on the manner in which such claims may be made and require to be supported by contemporaneous scientific substantiation.[44] For certain health claims involving reduction of disease risks (other than those for which criteria are already prescribed), the FBO must obtain prior approval from the FSSAI.[45]

---

39 Section 24, FSSA

40 Regulation 4, Advertising Regulations

41 Regulation 5, Advertising Regulations

42 Regulation 2(1)(l), Advertising Regulations

43 Regulation 2(1)(h), Advertising Regulations

44 Regulation 7, Advertising Regulations

45 Regulation 11, Advertising Regulations

In order to respond to the business needs of our clients, we publish newsletters on a variety of timely topics. Back numbers can be found here. If you would like to subscribe to the N&A Newsletter, please fill out the N&A Newsletter subscription form.

Public Relations Section, Nishimura & Asahi E-mail✉