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Consumer's Prerogative Analysis of the Genetically Modified Food Labelling Regulation in India, in Comparison with the U.S.A. and Europe

VIDISHA JOSHI[1]

ABSTRACT

Modern technology brought with itself, the ability to feed increasing number of mouths, with the help of genetic engineering. Genetically modified food has specific characteristics, the ability to be pest-resistant, to sustain in severe environmental conditions, to provide specific nutrition, to name a few. However, the fear of the unknown has always made people question the risk associated with the use of this modern technology. The fact that genetic engineering involves altering the DNA of the crop, has made many consumers sceptical about its usage. This, together with the ethical concerns relating to people's right to know what they consume, has led to the debate over labelling of genetically modified food. The labelling policy of the United States of America addresses this debate from the point where providing this information was considered unnecessary, solely based on the fact that the consumers want to know what they consume, to the point, where they have a functional policy dealing with various aspects of labelling. On the other hand, labelling policy of the European Union sets an example of what constitutes a stringent and effective labelling policy relating to genetically modified food. India, too, is considerable of the growing concerns relating to people's autonomy in deciding what they should consume, which can be achieved by providing them the information, which would enable them to make an informed choice of whether they should consume a food which is genetically modified or not. As India is on its way to have a regulation for the same, this paper addresses the issues pertaining to the draft policy in India, and what can be incorporated, with reference to the policy followed in the United States and the European Union.

Keywords: *Genetically modified food, Consumer's right to know, Bioengineering*

[1] Author is a LLM Student at Hidayatullah National Law University, Raipur, India.

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I. INTRODUCTION

Rapid population growth causes major implications for today's society. It implies more mouths to feed, leading to an ever-increasing need for higher food production. The need for increased food production cannot be satisfied without requiring more land to cultivate, more availability of water and causing unpredictable consequences to the environment. In such a situation, bioengineered food comes to the rescue as it helps boost the food production to meet the ever-increasing food demands of the planet. However, there also exists another side to the story; the effects it has on the health of the consumer as there are chances that consumption of such food poses significant risks like gene drift, production of new allergens or toxins and transfer of genetically modified proteins to the human cells. Labelling of such GM food, thus, can be considered as a balance between the two sides of the coin, increased production on the one hand, and the balance of informing the consumers that a particular food item is genetically modified, thus, giving them an opportunity to make an informed choice, on the other.

As genetically engineered food gained popularity owing to its capability to increase food production, its negative impacts on human health, lack of consumer choice and informed consent were often neglected. However, a study conducted by the Centre for Science and Environment on the presence of genetically modified (GM) ingredients in food products available in the country, for the first time, brought the vacuums in governing GM foods in India into limelight. It noted that 21 of the randomly picked 65 food products, including that for new-borns, from different retail outlets in the country were found GM positive in the lab tests. This led to the formulation of draft FSS (Labelling and Display) Regulations, 2018 which seek to make labelling of genetically modified food mandatory if they have total genetically engineered ingredients of 5% or more. This threshold of 5% was further reduced to 1%.

However, these regulations have not been notified yet and continue to remain a draft. The lack of proper legal framework to deal with genetically modified food in India is a serious concern, considering the health concerns as well as the lack of consumer choice attached to it. This can also be considered as a set-back to India, as most of the nations like the United States of America, countries in the European Union, Japan, Australia, Brazil, South Africa etc. have a policy that regulates the labelling of genetically modified food. Therefore, having a functional policy for the same will enable India to come at par with such nations with respect to the regulation of genetically modified food.

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Further, a comparison is being drawn between the GM food labelling policies of the E.U. and the U.S.A with India because the U.S.A. took time to ascertain whether providing such information to the consumers is a part of their right to know, and even after having a policy at place, the debate still continues and deliberations are being made to take back the policy. The case of the U.S.A. addresses the issue whether the risks involved in the consumption of GM food is high, even higher than the risks involved in consuming the food prepared by natural plant breeding techniques. Also, the framework being followed in the E.U. is well established, stringent and is being implemented effectively. It can act as a model policy for India as India's draft policy can be considered vague as it just mentions about the threshold to be applied for labelling (1%). It fails to address the concerns relating to size and colour of the label, placement of label, enforcement measures, among other things.

The current study thus focuses on analyzing the current legal framework in India relating to labelling of genetically modified food, with reference to what can be further incorporated, taking lessons from the regulations of the U.S.A. and the E.U.

II. THE BASIS FOR LABELLING OF GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL SHIFT IN THE U.S.A.'S STAND ON LABELLING OF GM FOOD

(A) Use of genetically modified food in the United States

Before we address the issue of labelling of genetically modified (GM) food in the U.S., we need to first understand the process used to develop such food, i.e. how GM food differs from the food obtained from conventional breeding and, the reason behind the use of GM food and its labelling. The process which is used to make GM food and the subsequent output (the GM food) forms the basis of the major argument that the U.S. Food and Drug Administration (FDA)[2] puts forth for not providing the information related to labelling of such foods[3].

1. The process

When we talk about manipulating the genome of an organism, it can be achieved by basically two techniques- conventional plant breeding and biotechnology (genetic engineering or genetic modification). Conventional breeding is achieved when the scientists select particular plant specimen with desirable traits from a great variety of naturally occurring types of plants and reproduce them by pollinating other plants with the pollen carrying desirable traits. Genetic Engineering or Genetic Modification, on the other hand, involves artificial

[2] U.S. Food and Drug Administration, https://www.fda.gov/home accessed 29 March 2020.
[3] The substantial equivalence principle which is discussed in the later part of the chapter.

manipulation, modification and recombination of DNA[4] or other nucleic acid[5] molecules in order to modify an organism or population of organisms. It involves isolating a gene from one organism and inserting it into the genome of another unrelated organism. Because genetic engineering involves direct modification of an organism's genome, it generates more opposition than conventional plant breeding.

2. Why genetic modification concerns the U.S.A.?

The United States of America was the first country to use genetically modified food as genetically modified microbial enzymes were the first application of genetically modified organisms in food production which were approved in 1988 by the US Food and Drug Administration[6]. Further, till date, the US has been the largest producer of GM food. By 2018, it was reported that about 75 million hectares of land in US was used to produce GM food.[7] The introduction of a pesticidal gene from a soil bacterium, Bacillus thuringiensis ("Bt"), into corn and cotton[8] and the introduction of an Agrobacterium gene producing a degradative enzyme[9], that confers tolerance to the herbicide glyphosate, into soybeans have been the most monetarily significant and widespread applications of genetic engineering in the United States.

3. The advantages of genetically modified food

As the population around the world rose with a limited area of land to cultivate, a need was felt to utilize the available land to the maximum extent and produce as much as possible. In such a situation, biotechnology, with the introduction of genetic engineering, came to the rescue as it sought to produce crops with improved shelf-life, processing characteristics, flavour, nutritional properties,[10] and agronomic characteristics, potential to lower pesticide use, combat the epidemic hunger crisis in developing countries and strengthen the economies

[4] Deoxyiibonucleic acid is a compound consisting of a large number of nucleotides attached together in single file to form along strand.
[5] Long chain molecule formed from a large number of nucleotides (polynucleotide) universally found in living thin.
[6] M Buiatti, P Christou and G pastore, 'The application of GMOs in agriculture and in food production for a better nutrition: two different scientific points of view' (NCBI, 18 October 2012) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639326/ accessed 29 March 2020.
[7] M Shahbandeh, 'Global genetically modified crops by countries 2018, based on acerage' (*Statista*, 1 October 2019) https://www.statista.com/statistics/271897/leading-countries-by-acreage-of-genetically-modified-crops/ accessed 26 March 2020.
[8] Mohamed Samir Tawfik Abbas, 'Genetically engineered (modified) crops (*Bacillus thuringiensis* crops) and the world controversy on their safety' (*Springer Open*, 2018) https://ejbpc.springeropen.com/articles/10.1186/s41938-018-0051-2 accessed 26 March 2020
[9] Loredano Pollegioni, Ernst Schonbrunn and Daniel Siehl, 'Molecular basis of glyphosate resistance: Different approaches through protein engineering' (*NCBI*, 1 August 2012) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3145815/ accessed 22 March 2020.
[10] GM rice (Iron rice).

of industrialized countries.[11]

The development of GM technology can be expressed in a three-fold manner-

i. *Agricultural benefits*- which includes insect resistance and herbicide tolerance. This also led to the decrease in the use of herbicides and pesticides, thus reducing environmental degradation and spread of toxins in the human food chain.

ii. *Enhancing nutritional content*- the Gold rice strain is a classic example of one such GM crop that fights night blindness due to the deficiency of vitamin A. Also, GM rice (known as Iron rice) helps to counter iron deficiency.

iii. *Strengthening the ability of the crop to grow in different environments and grow faster*- this directly impacted the production chain by ensuring that the crop survived worst conditions of the weather (such as drought, high winds, and acidic or excessively salty soil) and grew faster.

4. The risks posed by the consumption of GM food vis-à-vis the effects of GM food on human body

The first and foremost argument which the advocates of labelling of genetically modified food put forth is its effects on human health. Although not the only argument which supports labelling of such food, this argument forms the basis of how harmful the consumption of GM food is.

The risk posed by the consumption of GM food on human health is due to the process of genetic engineering itself. It creates unpredicted alterations irrespective of which gene is transferred. This is found to create mutations in and around the insertion site and elsewhere.[12] The very first crop submitted to the Food and Drug Administration's voluntary consultation process, the FlavrSavr tomato, showed evidence of toxins. Out of 20 female rats fed the GM tomato, 7 developed stomach lesions.[13]

Many children in the United States and Europe have developed life-threatening allergies to peanuts and other foods. Introduction of a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals[14]. A proposal pertaining to incorporation

[11] Anton E Wohlers, 'Labeling of genetically modified food: Close to reality in the United States?' (2013) 32 Politics and the Life Sciences 73.
[12] Wilson A, Latham JR and Steinbrecher RA. 'Transformation- induced mutations in transgenic plants: Analysis and biosafety implications' (2006) 23 Biotechnol Genet Eng 109.
[13] Department of Veterinary Medicine, FDA, 16 June 1993 http://www.Biointegrity.org/FDA does/17/view 1.html accessed on 10 May 2020.
[14] Charu Verma and others, 'Review on impacts of Genetically Modified food on human health' (2011) 4 The Open Nutraceuticals Journal 5.

of a gene from Brazil nuts into soybeans was abandoned out of the fear of causing unexpected allergic reactions.[15]

However, the direct effects of the consumption of genetically modified food on human body have not been established due to the lack of evidence. Tests have been conducted, but mostly on animals. Nevertheless, the effects such food had on the animals cannot be overlooked. As the health effects on human body are unknown, many people prefer to stay away from these foods.[16] After all, it is the very fear of unknown which highlights the need of labelling of such food so as to provide the consumers, the right to make an informed choice, about a danger which is not yet discovered, but might be a possibility in the future.

(B) Addressing the debate over labelling of GM food in the United States of America

1. The stand of the FDA on labelling of GM food

The Food and Drug Administration first approved the commercialization of a GM food, the Flavr-Savr tomato[17]. The regulatory agency deemed this biotechnology food beneficial to the consumer and safe for both human consumption and the environment.[18]Since then, the US has remained the strongest advocate of GM crop dissemination owing to the constant lobbying pressure by multinational agricultural biotechnology corporations, which were primarily based in the US. This coupled with the fact that the US has always been the largest producer of GM crops, resulted in strengthening the FDA's belief in minimal regulatory interference, especially with respect to labelling.

The Food and Drug Administration (FDA), under its 1992 policy[19], required labelling of food that has a nutritional or food safety property which is significantly different from what consumers would expect of that food i.e. if the food-

a. has nutritional characteristics that differ from comparable non-genetically engineered foods,

b. contains transferred proteins from known allergenic sources (such as a peanut protein expressed in a soybean), or

c. has elevated levels of toxic compounds.

It is pertinent to note that the FDA required labelling of such differences in the food and not

[15] Nordlee JA and others, 'Identification of a Brazil-nut allergen in transgenic soybeans' (1996) 334 N Engl J Med 690.
[16] A.S. Bawa, 'GM food: safety, risks and public concerns- a review', (*NCBI*, 19 December 2012) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3791249/ accessed on 10 May 2020.
[17] Ruse M and Castle D, 'Genetically modified foods: debating biotechnology' (2002) Prometheus Books.
[18] FDA on Biotechnology of Food (FDA Backgrounder, 18 May 1994).
[19] Statement of policy: foods derived from new plant varieties 1992, part VI.

per se "labelling" of GM food. The method of development of genetically engineered food which caused such differences was not considered material information required to be disclosed in the labelling of foods under the U.S. food safety laws. The FDA believed that "*the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. 321 (n) and would not usually be required to be disclosed in labelling for the food*"[20]. FDA believed that the new techniques of genetic engineering were extensions at the molecular level of traditional methods which are used to achieve the same goals as pursued with traditional plant breeding.[21]

The policy which the FDA used was based on the *principle of substantial equivalence*[22] wherein, it is believed that because genetic engineering technology does not result in an end product that is materially different from similar products produced by conventional agricultural methods, i.e. the product of conventional breeding techniques is substantially equivalent to the product of genetic engineering, neither the fact that the food is GM nor the fact that it was produced using biotechnology needs to be disclosed on the label. This principle was further based on the lack of material evidence to prove that GM food posed any risk to the health of consumer, which could not have otherwise occurred, if the consumer consumed food obtained from conventional breeding.

Efforts were however made from the public seeking their right to know the fact that the food is genetically engineered. In 1998, Alliance for Bio-Integrity, a non-profit, non-political organization filed a lawsuit before the US district court in Washington DC against the FDA's Policy on GM foods[23]. The Court however reiterated the FDA's stand on food labelling based on consumer demand. The court held that the FDA does not have the regulatory authority to require such labelling as special labelling for GE foods is not required under section 201(n) of the Federal Food, Drug and Cosmetic Act, if the sole justification for such requirement is consumer demand.[24] Also, the court concluded that GM food does not substantially differ from conventional food products. Hence, mere consumer demand cannot suffice for labelling of GM food.[25]

[20] FDA, 'Statement of Policy- Foods derived from new plant varieties' (*FDA Federal Register,* 29 May 1992) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties accessed 30 March 2020.
[21] Ibid.
[22]'Substantial Equivalence' (FDA) https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence#overview accessed 30 March 2020.
[23] *Alliance for Bio-Integrity v Shalala* [2000] 116 F. Supp. 2d 166.
[24] Ibid.
[25] Alliance (n 22).

Early in 2001, the FDA proposed voluntary guidelines[26] for companies who choose to label foods as to whether they do or do not contain GM ingredients, basing on the reasoning that some consumers are interested in knowing whether a food was produced using genetic engineering and some manufacturers want to respond to this consumer interest.[27] However, it was reiterated in the guidelines that the FDA still believes that GE food is no different from its conventional breeding counterpart, and hence, mere consumer will cannot form basis of mandatory food labelling for GM food. The guidelines provided the use of both positive (GMO-free) and negative (contains GMO) labels[28].

Furthermore, in 2012, about a million people had signed the petition seeking food labelling. The FDA was of the opinion that though it recognizes and appreciates the strong interest that many consumers may have in knowing whether a food was produced using GE, it supports voluntary labelling for food derived from GE.[29]

Therefore, the attitude of the US, or rather the approach it took on genetically engineered food labelling highlights the *risk-benefit analysis*[30]. As long as there is no evidence that GM food is posing any risk which would not have occurred by any conventional breeding counterpart, there is no need to require labelling of such food. Time and again, public made efforts to showcase their interest in knowing, or rather their right to know whether the food they are consuming is genetically engineered or not, but the efforts went in vain as the FDA's stand was strong as ever.

2. The philosophical shift vis-à-vis the need for labelling

Over a period of time, the public was continuously making efforts to assert their right to know what they eat, and hence, quoting reasons as to why they need to know whether the food is GM or not. The general public argued that they have a right to know whether their food is genetically modified or not because the DNA in GM food is different from the DNA in conventionally grown food; that labelling of food is not always dependent on nutrition or food safety; that mandatory labelling would allow scientists to track the effects of GM food consumption; and that labelling of genetic modification would not be any more expensive than other mandatory labelling (the opponents of mandator GM food labelling always quoted

[26]'Draft guidance for Industry: Voluntary labeling indicating whether foods have or have not been developed using Bioengineering: Availability' (FDA, 18 January 2001) https://www.federalregister.gov/documents/2001/01/18/01-1047/draft-guidance-for-industry-voluntary-labeling-indicating-whether-foods-have-or-have-not-been accessed 29 March 2020.
[27] Ibid.
[28] Draft guidance for Industry (n 25).
[29] 'Foods derived from genetically engineered plants' (*FDA*, 8 April 2013) http://www.fda.gov/Food/FoodScienceResearch/ Biotechnology/ucm346858.htm accessed 22 March 2020.
[30] Anton (n 10).

this as an excuse).

This gave rise to the Consumer's Right to Know Policy[31], which is "*the notion that the public has a basic right to know any fact it deems important about a food or a commodity before being forced to make a purchasing decision*."[32] The justification for food labelling is based on the Consumer's Right to Know Policy which focusses on health and safety concerns, religious or ethical dietary restrictions, environmental concerns, and production method objections.

It should also be noted that back then, the USA lacked a federal law on labelling of GM food. However, a number of states[33] had their own labelling laws, and the FDA had issued federal guidelines relating to voluntary GM food labelling. However, the laws were not federal, and the state laws were non-uniform, thus hampering the trade and food supply chain. Taking into consideration the raising public outrage and the concern about a patchwork of conflicting state and local GMO labelling laws[34], the Congress proposed to enact a uniform federal GMO labelling standard.

(C) National Bioengineered Food Disclosure Standard, 2018

The National Bioengineered Food Disclosure Standard, 2018 [referred to as NBFDS hereafter] is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the status of foods being biologically engineered. It entails who is responsible for making disclosures, what the disclosure should look like, and when they are and are not required. Instead of the commonly used but somewhat stigmatized terms "G.M.O.'' and "genetically engineered," the NBFDS requires labels to be represented by "bioengineered" or "BE."

1. The definition of BE food

The food is bioengineered if it contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature. Crops that contain changes, which could theoretically be achieved through conventional breeding or occur through a natural mutation are excluded from the definition under the expression

[31] The concept of a "Right to Know" is traceable to a message that President Kennedy sent to Congress in 1962 regarding the protection of the consumer interest, which focused on the right to safety, the right to be informed, the right to choose, and the right to be heard.
[32] David Alan Nauheim, 'Food labeling and the Consumer's right to know: Give the people what they want' (2015) 4 Liberty University Law Review 99.
[33] States like Vermont, Connecticut and Maine.
[34] One objective of the labeling bill was to prevent the creation of what would be the unworkable patchwork of state-by-state mandatory GM labeling.

"*could not otherwise be obtained through conventional breeding or found in nature*".

The Standard further excludes animal feed (which is not considered food because it is not intended for human consumption); foods in which modified DNA is not detectable (e.g., refined oils and sugars); and incidental additives[35].

2. Exemptions

The following food is exempted from the labelling requirements-

a. Food served in a restaurant or similar retail food establishment[36]

b. Food produced by very small manufacturer[37]

c. Food containing BE substance under the required threshold[38]

d. Foods derived from animals who consumed BE food[39]

e. Foods certified under NOP[40] [41]

3. Threshold

Food in which any single ingredient contains more than 5% of a bioengineered substance, regardless of whether its presence is inadvertent or unintentional, is subject to disclosure.[42]

4. Disclosure options

Food makers are given a choice of 4 disclosure methods: text[43], symbol[44], electronic or digital link[45] and text message[46] disclosure.

Disclosure may be made on:

- The information panel adjacent to the manufacturer/distributor information
- The principal display panel
- If there is insufficient space on either of those panels, then on any other panel likely to be seen by a consumer under ordinary shopping conditions

[35] 7 C.F.R. s. 66.1.
[36] 7 C.F.R. s. 66.5(a).
[37] The Standard defines this term as "any food manufacturer with annual receipts of less than $2,500,000", 7 C.F.R. s. 66.1.
[38] 7 U.S.C. s. 1639b(b)(2)(B).
[39] 7 U.S.C. s. 1639b(b)(2)(A).
[40] 7 U.S.C. s. 6524.
[41] NOP certifies that the food is organic.
[42] 7 C.F.R. s. 66.5(c).
[43] 7 C.F.R. s. 66.102.
[44] 7 C.F.R. s. 66.104.
[45] 7 C.F.R. s. 66.106.
[46] 7 C.F.R. s. 66.108.

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The disclosure is required to be of sufficient size and clarity to appear prominently and conspicuously on the label[47] making it likely to be read and understood by the consumer under ordinary shopping conditions.

5. Enforcement

Failure to make a required disclosure is prohibited[48]. Complaints of possible violations may be made to the US Department of Agriculture's Agricultural Marketing Service (AMS). The AMS may investigate and conduct a records audit. Results of the audit or investigation will be shared with the regulated entity and are appealable. Following any appeal, the AMS will make a final determination and will post the summary of the results on its website.

6. Criticism

The NBFDS was primarily criticized for exempting highly refined sugars and oils, like those made from genetically modified sugar beets and corn, which typically contain no genetic material after being processed. It was argued that this exemption could significantly curtail the number of foods that carry the label, and would violate people's right to know going by the reasoning that it's not just what we ingest that matters but how food is produced. This exemption signifies that the US's approach towards labelling of GM food is based on the final product rather than the product as well as the process.

Furthermore, the standard was criticized for using the terminology 'BE' for moving away from the alleged stigmatizing term 'GM'. BE is a medical term and most of the population is unaware of what it meant. Terms like GM or GMOs is recognizable by people as being something which is modified using biotechnology. Thus, the term BE does not suffice the purpose of informing the public at large. Also, the mode of disclosure through text message and electronic code [QR code] was criticized as this requires a smartphone and broadband connection.

However, the development of the US's stand on labelling of GM food highlights the debate over the requirement of food labelling and signifies how the consumer's prerogative to be informed of the constitution of the food they consume has developed over a period of time and is being given importance in the present day.

[47] 7 C.F.R. s. 66.100(c).
[48] 7 U.S.C. s. 1639b(g)(1).

III. THE MODEL POLICY: EUROPEAN UNION'S STAND ON LABELLING OF GENETICALLY ENGINEERED FOOD

(A) The regulation of GMO in the European Union

The European Union (referred to as EU hereafter) has in place a comprehensive and strict legal regime on genetically modified organisms (GMOs), food and feed made from GMOs, and food/feed consisting or containing GMOs, also including labelling of such food[49]. The EU's legislation and policy on GMOs and the subsequent labelling is based on the *precautionary principle* enshrined in the EU[50], is designed to prevent any adverse effects on the environment and the health and safety of humans and animals, and reflects concerns expressed by sceptical consumers, farmers, and environmentalists.[51] GMOs, or food and feed consisting of or containing GMOs, are assigned a unique identifier and the food containing GMOs are labelled as such to ensure traceability and enable consumers to make informed choices. The right of consumers to information[52] is recognized in the EU, and hence the EU is obliged to promote this right in legislation affecting the consumers.

(B) The key features of the GM food labelling policy of EU which makes it a Model Policy

Regulation (EC) No. 1829/2003 and Regulation No. 1830/2003 put in place rules to ensure products containing GMOs and food derived from them can be traced at all stages of the production and distribution chain[53]. This is done to ensure clear labelling of GMOs placed on the market and to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.

1. Defining Genetically Modified Organisms (GMOs)

A genetically modified organism (GMO) as "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*."[54]

2. The Threshold limit

[49] Regulation (EC) No. 1830/2003 and Regulation 1829/2003.
[50] Treaty on Functioning of European Union 1957, art. 191 (it refers to the precautionary principle without defining it, aims to safeguard the environment. The principle also applies to areas related to food, human and animal health, and consumer interests).
[51] Preamble (n 43).
[52] Treaty on Functioning of European Union 1957, art. 169.
[53] Traceability.
[54] Directive 2001/18/EC of the European Parliamenthttp://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF accessed 29 March 2020.

A food is required to be labelled if it contains, consists of or is produced from GMO in the proportion of 0.9% threshold[55] per food ingredient.

3. Exemptions

The following products are exempted from being labelled-

a. A product which contains traces of GMOs less than 0.9 %, if it is technically unavoidable[56]

b. Medicinal products[57]

4. Traceability

Traceability is the ability to track GMOs and products produced from GMOs at all stages of the production and distribution chain. It is instrumental in providing consumers and the food trade with the information and safeguards about food derived from GMOs. It allows them to make informed choices based on accurate labelling.

There are 3 main requirements for sellers when placing product containing GMO in the market[58]-

a. Indication of each food ingredient produced from GMOs

b. If no list ingredient exist, indication that the product is produced from GMOs

c. Communicate the unique identifiers assigned to each GMO under the regulation

5. Labelling Requirements[59]

Final consumer packaging or pre-packaged products containing GMOs should be labelled: '*This product contains genetically modified organisms [or the names of the organisms]*'.[60] When there is more than one ingredient, the label must appear in the ingredient list,[61] and it shall be printed in the font of at least same size as the list of ingredients[62]. When there is no list of ingredients, the same phrase must appear on the label.[63]

In addition to the labelling requirements, labelling shall also mention any characteristic or

[55] Regulation 1829/2003, art. 12(2).
[56] Ibid.
[57] Regulation 1829/2003, Preamble clause (16).
[58] Regulation 1830/2003, art. 5.
[59] Regulation 1830/2003, art. 13.
[60] Regulation 1830/2003, art. 13(1)(b).
[61] Regulation 1830/2003, art. 13(1)(a).
[62] Regulation 1830/2003, art. 13(1)(d).
[63] Regulation 1830/2003, art. 13(1)(c).

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property, as[64]-

a. where a food is different from its conventional counterpart as regards the following characteristics or properties:
    i. composition;
    ii. nutritional value or nutritional effects;
    iii. intended use of the food;
    iv. implications for the health of certain sections of the population;
b. where a food may give rise to ethical or religious concerns.

6. Inspection and checks[65]

The EU member states must carry out inspections, sample checks and tests, to ensure that the GMO labelling rules are followed. Each country must also impose effective penalties for infringements. Products can be withdrawn if they have unforeseen adverse effects on health or the environment.

6. The Model Policy

The elaborate as well as stringent measures ensure that the GM labelling policy is adhered to, to the maximum extent. The EU policy covers minute details, on the one hand, and provides stringent measures in case of contravention, on the other. Further, the EU policy is time tested. This makes the EU policy a Model Policy for labelling of GM food.

IV. DRAFT FSS (LABELLING AND DISPLAY) REGULATIONS, 2018: AN ANALYSIS OF THE INDIAN STAND ON LABELLING OF GENETICALLY MODIFIED FOOD

(A) Regulation of GM food in India: An overview

The first step towards labelling of genetically modified food in India was taken in the year 2012, when the Department of Consumer Affairs, updated the Legal Metrology (Packaged Commodities) Rules, 2011 with the 2012 amended Rules. Rule 6(7) of the 2012 amended rules is of specific significance with regard to the labelling of GM food. It required "*every package containing genetically modified food shall bear at the top of its principal display panel, the words, 'GM'*."[66] It is pertinent to note that many groups engaging closely with the GM issue were also caught somewhat unaware when this development took place. This signifies the lack of publicity and implementation of the provision. Furthermore, the Food

[64] Regulation 1830/2003, art.13(2).
[65] Regulation 1830/2003, art. 9.
[66] Legal Metrology (Packaged Commodities) Amendment Rules 2012, Rule 6(7).

Safety and Standards (Packaging and Labelling) Regulation, 2011 also did not talk about labelling of genetically modified food at all.

The unawareness of the 2012 rules, its ambiguity, coupled with the inadequacy of the FSS Regulation of 2011 to deal with labelling of GM food led to the Draft FSS (Labelling and Display) Regulations, 2018.

(B) Labelling of Genetically Engineered or Modified Foods under the Draft FSS Regulations, 2018[67]

1. The draft provision

The entire draft regulation of 2018 contains just a single provision pertaining to the labelling of GM food, which is as follows[68]-

All food products having total Genetically Engineered (GE) ingredients 1% or more shall be labelled. The total GE ingredients shall be of top three ingredients in terms of their percentage in the product. The labelling shall be as: "Contains GMO/Ingredients derived from GMO".

It highlights-

i. The threshold [i.e. 1%]

ii. All food being genetically engineered [The definition of GE under the FSS Act, 2006 highlights how it covers both the product as well as the process]

iii. How to calculate the threshold? [top 3 ingredients based on their percentage in the product]

iv. The manner of representation [i.e. Contains GMO/Ingredients derived from GMO]

2. Definition

The 2018 draft Regulations define the term "labelling".[69] The term "genetically engineered" or "genetically modified" has not been defined under the Regulations. For this purpose, another provision of the Regulations seeks to direct us to the Food Safety and Standards Act, 2006 [referred to as the FSS Act hereafter] for the required definition-

"*All other words and expressions used herein and not defined, but defined in the Act, rules or regulations made thereunder, shall have the meanings assigned to them in the Act, rules or*

[67] Draft Food Safety and Standards (Labelling and Display) Regulations 2018, 2.7.
[68] ibid.
[69] Draft Food Safety and Standards (Labelling and Display) Regulations 2018, 2(1)(11).

regulations, respectively."[70]

The FSS Act defines "genetically engineered or modified food" as-

"F*ood 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*."[71]

3. Contravention

For failure to comply with the provisions of draft FSS regulations, one has to refer to the FSS Act, 2006 under the provision of penalty for selling food not of the nature or substance or quality demanded[72], penalty for misbranded food[73] (as providing misleading claims upon the label of packaging, if the label is not true to the nature of ingredients, for e.g., if the ingredient is derived from GE beyond threshold, but is labelled "as GMO free", so that the consumers buy it), penalty for false advertising[74] and offences by companies[75] (as labelling of GM food beyond threshold is the responsibility of the company manufacturing such food). It is pertinent to note that there is no specific provision which exclusively deals with the contravention of mandatory labelling requirements of GM food.

(B) Lacunas in the draft legislation

The draft FSS regulations of 2018, read with the FSS Act of 2006, though provides definition of GM food (wherein both product as well as process has been considered), the threshold limit, the process to calculate and the manner of representation, it fails to cover other essential criteria like the size and the colour of the text, the placement of the label and specific enforcement measures.

Furthermore, a parallel has, time and again, being drawn between the regulation mandating labelling of GM food beyond threshold and the regulation relating to the certification of organic food under the Food Safety and Standards (Organic Foods) Regulations, 2017 which says that it will have to be mandatorily "certified" that it does not contain residues of insecticides. Under the Organic Foods Regulation, a farmer has to approach a third-party certification agency, and wait to obtain an organic certificate. Those who cannot afford to pay for the third-party certification, will have to form a group under the Union government's

[70] Draft Food Safety and Standards (Labelling and Display) Regulations 2018, 2(2).
[71] Food Safety and Standards Act 2006, s. 22(2).
[72] Food Safety and Standards Act 2006, s. 50.
[73] Food Safety and Standards Act 2006, s. 52.
[74] Food Safety and Standards Act 2006, s. 53.
[75] Food Safety and Standards Act 2006, s. 66.

Participatory Guarantee System of organic certification. On the contrary, the proposed regulations for genetically modified food are so lax that authorities will have to depend on the self-declaration by the industry. Thus, can it be concluded that[76] for the government, what is good, needs to be certified that it is safe, and what is bad, gets a clean chit of health, which is self-certified by the industry?

Also, the draft FSS regulations of 2018 propose to use the terminology "Contains GMO/Ingredients derived from GMO". However, it should be kept in mind that most of the population in India is illiterate and is not well versed with English. This could create an issue as the main purpose of labelling of GM food is to provide the consumers, the right to make informed choice relating to the food they consume. If they are not able to understand what a specific label means, how are they expected to achieve the essence of making an "informed choice"?

Furthermore, the mode of measuring the threshold of GM limit of 1% can be brought into question. The total GE ingredient is calculated taking into account the top three ingredients in terms of their percentage in the product i.e. their weight. Firstly, the technology used to detect presence of GMO is qPCR[77], which is quite expensive. Secondly, qPCR can quantify the percentage of genetically modified gene in a food product. But to convert the percentage of genetically modified gene into percentage of weight requires standard reference material for every genetically modified gene. Even developed countries are finding it difficult to procure standard reference material for all possible genes. Due to this reason, the E.U. has set its regulation on the percentage of the genetically modified gene in the product and not the percentage of the weight of genetically modified ingredients in a product.[78]

Therefore, to conclude with, the draft FSS Regulations of 2018 can be considered as a decent start for the labelling of GM food in India. However, for effective implementation of the same, the regulations need to incorporate certain essential provisions, without which, the 2018 regulation would be as futile as the 2012 amended rules.

V. CONCLUSION AND SUGGESTIONS

The fact that the population of India is increasing more than ever, coupled with the fact that there is limited cultivable land due to increased urbanization, creates an issue as there are more mouths of feed and limited supply of food, the availability of the same again being

[76] Food Safety and Standards (Organic Foods) Regulations 2017, Rule 4.
[77] quantitative Polymerase Chain Reaction (qCPR).
[78] Amit Khurana and others, 'Vacuum in governance on genetically modified foods in India' (*DowntoEarth*, 26 July 2018) https://www.downtoearth.org.in/blog/food/vacuum-in-governance-on-genetically-modified-foods-in-india-61230 accessed 21 March 2020.

subject to the weather conditions. The genetic modification of food tends to solve this issue. However, there are concerns relating to the consumption of GM food as well.

India has already considered the right to health to be a part and parcel of the right to life under Article 21 of the Constitution of India[79]. One of the primary concerns relating to GM food is that we are still unaware whether genetically modified food poses any risk to health, a risk which would otherwise not occur by the consumption of a product of conventional breeding. However, such concern is not the only issue faced in India. India being a home to various cultures and ethics, Indians are of the belief that we are what we eat. The divergent culture also signifies the divergent ethical concerns relating to what we consume.

Thus, labelling strikes a balance by allowing producers to grow GMOs and send them into national and international commerce, feeding mouths utilizing the minimal resources, while simultaneously educating consumers about the large array of genetic modifications and altered attributes of GMOs so that they may make informed choices and may avoid GMOs if they wish.

However, the current draft policy does not do justice to the concept of providing "informed choice" to the consumers and requires modifications, taking lessons from the policies followed in the United States and the European Union.

India needs to redraft its Draft FSS Regulations, 2018 to incorporate the following details-

a. Size and colour of text of label[80] [Efforts should be made to represent the label in the size which is conspicuous to general public while purchasing the same]
b. Placement of label[81] [GM labelling should be on the front-of-the pack]
c. Specific enforcement measures[82] [Measures relating to regular checks and the method for the same, as identifying the presence of GM gene in a food is not an easy technique]

Further, India should rethink on the following measures-

a. The mode of representation used i.e. "Contains GMO/Ingredients derived from GMO". Rather, a symbol[83] should be used which is publicized and everyone is made aware of the fact what that symbol means, like the green dot in a square for vegetarian food, making it more consumer-friendly

[79] *CESC Ltd. v Subash Chandra Bose* [1992] SC 573.
[80] Taking example from the E.U. and U.S.A. policy.
[81] ibid.
[82] ibid.
[83] Taking the example of U.S.A.

b. The method of calculating the threshold[84] i.e. the weight measure. Taking examples from USA and EU, the calculation should rather be based on percentage of GM gene, as it is much feasible to calculate

c. Specific penalties[85] should be incorporated in the FSS Act, 2006 pertaining of violation of labelling policy for GM food, rather than the general provisions.

Evidently, the specific requirements which Indian labelling policy lacks, are a part of the policies followed in the European Union and the U.S.A.

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[84] E.U. and U.S.A. (n 73).
[85] Ibid.