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GMO Labeling: Regulatory Review of the Divided World

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Abstract

Genetically Modified Organisms, a product of modern biotechnology, took the world food market by surprise. A scurry of GM food products entered our food chain. The production, development, and commercial release of these products was highly divergent in space and time. Resultantly, traceability and labeling of GMOs become an arduous as well as a requisite task. GMOs and products derived from them have been marred in controversies over their biosafety, ecological, economic, and ethical impacts. Thus, labeling and identity preservation of these products become even more important as well as contentious. The paper aims to dissect and establish that the actual labeling practice is far more complicated requiring planning and regulation at every step. The analyses of universally applicable ecological principles, country-wise legal structure, and existing international legislation depicted divergent approaches on GMO labeling which emerges due to varying social, economic, cultural, and political status of the countries. The need is to develop and implement a globally coherent labeling policy for the benefit of humankind.

Keywords: GMO, labeling, regulation, international, legislation

INTRODUCTION

Advances in biotechnology often present both opportunities and challenges to the regulatory authorities. There are many issues that regulatory authorities must contend with, like the complexity of technology, fiscal restraints, and globalization as was in the case of Genetically Modified Organisms (GMOs). Genetic Engineering (GE) has emerged as a significant tool, modifying living organisms across natural barriers. It is a relatively new field of science in the nascent stage of its development. Our current understanding of this technology is modest because of the vastness of the gene pool and diverse unexplored genomes. However, this breakthrough science, based on recombinant DNA technology has been applied to various fields including pharmacy, medicine, forensics, and agriculture. Its application in agriculture to modify major crop plants has been criticized on various grounds.

The release of any Genetically Modified Organism (GMO) in the environment is fraught with lots of perils. Their effect on ecology, environment, health, ethics, economy, and society as a whole has led to perplexing debate. Research and development of GMOs involve high precision science. These organisms are tagged with ecological problems like the development of super-weeds, secondary pests, effects on non-target pests, and increased chemical usage (Benbrook, 2012) [1]. The issue of bio-safety of these GMOs or GMO-derived food products has been debated the world over by scientists. Research studies are supporting both the proponents and opponents of GMOs which further increases the confusion. Such corroborating evidence, repeated patterns of illness, and health reactions have increased consistently in the past few years and superimposed the known potential risks of GM foods (Smith, 2009) [3]. Some of the adverse effects attributed to GMOs include new allergens in the food supply, antibiotic resistance,

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production of new toxins, concentration of toxic metals, enhancement of the environment for toxic fungi to grow, increased cancer risks, degradation of the nutritional food value, and other unknown risks that may arise later (Acosta, 2000) [2]. Thus, entry of these GM foods into the food chain is fraught with health, ecological and economic repercussions. Consequently, there is a complex interplay of ecological, health, and economic factors of GMOs which makes decision-making a difficult task. The existing regulatory framework is highly fragmented at the national and international level especially about labeling laws. Such contrasting regulation along with weak and fragmented international policy needs to be highlighted and addressed. This paper aims to bring forth the existing lacunae in GMO labeling and regulation at all levels of governance. The current analysis wishes to give direction to the development of a comprehensive regulatory framework on GMOs which will, in turn, give impetus to need-based growth of technology and harmonious trade.

METHODOLOGY

World over, the evolution of the GMC legislation started simultaneously but quickly took different paths. The contrasting and divergent legislations between countries originate from their respective varying economic, political and social setup. The current study was conducted in two phases of legal analysis. In the first phase, a comprehensive analysis of GMO legislation with special reference to labeling thresholds was drawn continent-wise. Five countries with maximum GMO use from every continent were selected and a detailed analysis of GMO legislation was done through official legal documents as well as Global Agricultural Information Network (GAIN) reports. A tabulated summary was prepared to demarcate the differences in regulation within and among countries and continents.

As GMCs appears to be a great business opportunity for many countries, their trade between the countries is also prevalent. Such trade becomes arduous because of a lack of regulatory concordance at a global scale. In the second phase of the review, two prominent international legislation on GMOs given by Cartagena Biosafety Protocol and Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Barriers to Trade (TBT Agreement), 1995 By World Trade Organization (WTO) were studied and analyzed for concordance [4].

RESULTS

Phase I: Labeling Laws

Regulation of GMOs plays an important role in its research, development, and societal acceptance. GMO regulation itself is highly varied and unharmonious globally. The Precautionary Principle as adopted by European Union and Substantial Equivalence as a driving force for American nations are two distinct approaches to GMO regulation (Kaur et al, 2012) [6]. Based on these two approaches GMO labeling follows two distinct labeling methodologies; mandatory labeling and voluntary labeling. Under the first technique, the government makes it compulsory for all the GMO food manufacturers to label their products as GMO while in the second approach government leaves it on the food manufacturers if they wish to label their products as GMOs or not. Further, under mandatory labeling, a country has to set a threshold level on the GMO content in the food product before labeling it. Based on these two approaches a dissection of Global GMO labeling is drawn in the current study.

European Union (EU), as a leading agricultural producer, importer, and exporter, plays a key role in food security. European governments, societies, and industries remain conflicted about the use of Genetically Modified (GM) plants in agriculture and food production. Public perceptions, commercial use, research, and even regulatory approaches vary among the European Union's (EU) 27 countries. Within the EU, member states could be put into three categories according to their domestic policy, farmer and industrial approaches, and public opinion on biotechnology.

- Group A Open to biotechnology- Spain, Portugal, Czech Republic, Slovakia
- Group-B Considering benefits of biotechnology- Bulgaria, France, Germany, United Kingdom
- Group-C Opposed to biotechnology- Austria, Hungary, Greece, Italy

The only GM crop authorized for cultivation in the European Union (EU) is MON810 (GM corn) which is commercially grown (Henard et al, 2012) [7]. Consequently, the 2015 Novel Foods Regulation of the EU requires all food and feed produced from or containing GM products to be labeled as such. Conventional food and feed that contains over 0.9 percent of biotech events adventitiously must be similarly labeled (EFSA, 2015) [8]. Even after varied views on these products entire EU has harmonious GMO labeling at 0.9% threshold.

Table 1. Comparative analysis of country wise GMO labeling regulation.

Continent	**Countries**				
Europe	***UK***	***Spain***	***Russia***	***Germany***	***Austria***
	Regulated under Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 at 0.9% threshold.	No separate labeling laws follows EU Regulation (EC) no 1830/2003 and Regulation (EC) no 1829/2003 on mandatory labeling at 0.9 % threshold level	Federal Law No. 2300-1 of February 7, 1992, Amended 2005, On the Protection of Consumers Rights sets 0.9 % threshold regulated by Rospotrebnadzor	No separate labeling laws follows EU Regulation (EC) no 1830/2003 and Regulation (EC) no 1829/2003 on mandatory labeling at 0.9 % threshold level	Mandatory labeling under Ordinance on Labeling of products that contain LMOs and Ordinance on thresholds of certain Genetically Modified Organisms in Feed at 0.9% threshold
America	USA	Argentina	Canada	Brazil	Mexico
	No mandatory labeling laws	No specific labeling requirement	Regulated by Health Canada and CIFA under Food and Drug Act, and Consumer Packaging and Labeling Act at 5% threshold	Regulated under Directive 2,658/03 on labeling of products containing biotech events above the 1% limit	No labeling policy
Asia	China	Indonesia	Philippines	Japan	India
	Regulated under MOA Decree 10, and Measures on Agricultural GMO Labeling Administration with no threshold limit	Regulated under BPOM Regulation on food labeling 2012 by National Agency of Drug and Food Control (BPOM) at 5 % threshold.	No labeling policy, Halal certification to GE foods under the Philippine National Standard or PNS 2067/2008 Amd 01:2011	Mandatory labeling regulated under Food Sanitation Law, 1947 and Japanese Agricultural Standards (JAS) by MAFF at 5% threshold	No labeling laws
Africa	South Africa	Kenya	Senegal	Nigeria	Ghana
	Mandatory labeling under the Consumer Protection Act (68/2008) at 5% threshold	No labeling laws	Mandatory labeling under Biosafety Law, by National Biosafety Committee , Ministry of Environment	Mandatory labeling under National Biosafety Act by National Biosafety Committee, Federal Ministry of Environment	No clause on labeling under the Ghana Biosafety act, 2011

Source: https://gain.fas.usda.gov/

80% of GMOs especially GM Crops are produced in American countries only (Lusk et al, 2018) [9]. The USA with its open policy on GMOs has a large legislative network. It follows the principle of substantial equivalence where GM food is considered equivalent to conventional food and the same legal statutes apply to it. It gives more discretion to the states who are in support of GMOs. Three primary agencies involved in US GMO regulation are the Environmental Protection Agency (EPA) which regulates biotechnology products including microbial/plant pesticides, new uses of existing

pesticides, and novel microorganisms; US Department of Agriculture (USDA) which regulates biotechnology products including plant pests, plants, and veterinary biologics; and US Food and Drug Administration (FDA) regulating biotechnology products including food, feed, food additives, veterinary drugs, human drugs and medical devices (Yeh et al, 2019) [10]. Currently, the USA has no policy on labeling, co-existence, risk assessment, and post cultivation monitoring of GM Crops. Recently, National Bioengineered Food Disclosure Standard formulated under FDA establishes requirements for labeling foods that humans eat that are or may be bioengineered to be made mandatory by 2022 (USDA, 2019) [11]. While, Health Canada and the Canadian Food Inspection Agency (CFIA) are responsible for all federal food labeling policies under the Food and Drugs Act, in Canada. The standard for voluntary labeling and advertising of foods that are and are not products of GE is set at 5% threshold. Similarly, in Brazil, labeling of GMOs is regulated under Directive 2658/03 on labeling of products containing biotech events above the 1% limit. Most of the other countries including Argentina and Mexico have no legislation on GMO labeling (Silvia, 2012) [12].

The Asian continent presents the most varied approach on this issue. Most of the Asian countries have accepted these products but with lots of apprehensions and without any basic regulating legislation (Corpuz, 2005) [13]. These countries represent the transition phase in the adoption of GMOs. The current Indian policy framework on GMOs depicted many lacunae. Multi-departmental control lacking any stringent bio-safety and socio-economic evaluation was well evident. In the present form, there is no labeling, traceability, and post cultivation monitoring regime in India. China's labeling regulations, governed by the Ministry of Agriculture Decree 10, require the labeling of approved agricultural biotech products with no threshold limit and prohibit the importation and sale of any unlabeled or mislabeled products. In Indonesia, the packaged food that contains at least 5 percent of the transgenic product must be labeled as "Food Containing Genetically Modified Material" on the label. The Philippines currently does not have any rules relative to labeling or traceability of biotech products but these GE products are now subject to halal certification, according to the amended Philippine National Standard or PNS 2067/2008 Amd 01:2011. Labeling of GMOs in Japan is regulated by MAFF under Food Sanitation Law, 1947, and Japanese Agricultural Standards (JAS) at 5% threshold level. Three labels are seen on food; Non-GMO, GMO, and Non-Segregated, where the threshold of 5% by volume is fixed to label a food as Non-GMO. Currently, Singapore also does not have labeling regulations as the authorities recognize that it is a very complex issue that requires careful consideration of several factors, e.g. threshold levels, types of foods to be labeled, and the scientific basis to be used for labeling (Kong, 2012) [14].

The African continent is at the nascent stage concerning the development, production, and regulation of GMOs is concerned. Only a few of the African nations have a regulatory framework to control GMOs (David, 2012) [15]. Like, South African legislation makes the labeling of all GMO at 5% threshold mandatory under the Consumer Protection Act but there are no co-existence guidelines in the country.

(Esterhuizen, 2012) [16]. Senegal also directs the state to label GMOs but no threshold limits have been given under current guidelines. Australia and New Zealand the Asian pacific nations have coherent GMO regulation and labeling regulated by Food Standards Australia New Zealand (FSANZ) under, Food Standards Australia New Zealand (FSANZ), Act at 0.1% threshold as per regulations of Food Standards Code (Crothers, 2012) [17]. Clear inter-continental and intra-continental divide among the countries is seen over their respective GMO labeling. These labeling policies are primarily driven by their respective economic and political condition and less by scientific rigor. Although, ecological principles apply to all the countries equally still a stark divergence in acceptance and regulation of GMOs was observed in this country-wise study.

Phase II: International Legislation

There is a complex interplay of ecological, biosafety, social, and economic factors of GMOs which makes decision-making a difficult task for every nation. Therefore, it necessitates the evaluation of existing international legislation governing GMO regulation transnationally. A review of two major international legislation governing the produce, use, trade, and labeling of GMOs is drawn out in this section. The Cartagena Protocol on Biosafety provides rules for the safe transfer, handling, and use of living modified organisms (LMOs). It aims to address the threats posed by LMOs to biological diversity, also taking into account risks to human health. The precautionary approach is one of the main features of the Protocol. Articles 10.6 and 11.8, deal respectively with LMOs for intentional introduction into the environment and LMOs for direct use as food, as feed, or for processing (CBD, 2018). These have provisions regarding lack of scientific certainty regarding the extent of the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the Party of import due to insufficient relevant scientific information and knowledge. The protocol provides for compulsory risk assessment of LMOs to identify and evaluate their possible adverse effects of LMOs on the conservation and sustainable use of biological diversity (Eggers and Mackenzie, 2000) [19].

On the other hand, World Trade Organization (WTO) agreements have direct implications on international trade in GMOs. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), 1995 plays an important role to prevent domestic sanitary or phytosanitary measures from having unnecessary negative effects on international trade and being misused for protectionist purposes. It allows countries to give these objectives priority over trade, provided there is a demonstrable scientific basis for their food safety and health requirements (WTO, 1995). The agreement does not refer to GMOs explicitly, but the measures aimed at regulating such trade could reasonably come within the scope of the agreement, provided that their objectives are consistent with it. The agreement permits the adoption of SPS measures on a provisional basis as a precautionary step where relevant scientific evidence is insufficient. However, article 5.7 states that members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period where bears the cost of risk assessment.

Labeling and documentation requirements related to food, nutrition claims, and concerns, quality, and packaging regulations are normally subject to the Agreement on Technical Barriers to Trade (TBT Agreement), 1995(5). Governments may introduce TBT regulations when necessary to meet several legitimate objectives, including the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health, or the environment. Under this agreement, technical regulations should not be more trade-restrictive than is necessary to fulfill a legitimate objective. In complete contrast to the Cartagena protocol, according to this agreement, measures should not discriminate between imported products and “like” products of domestic or foreign origin (WTO, 1995). If GMOs and GM products are considered “like” products in relation to conventional products, then there are no grounds for applying any special treatment to them, including mandatory labeling schemes.

International trade in GMOs and products thereof takes place midst the rules agreed by WTO Members and statutes of Cartagena Protocol on Biosafety. Interestingly, the rules included in these different legal instruments are not consistent with each other and give rise to conflicts between GMO-exporting countries and potential importers. Both the SPS Agreement and TBT Agreement, encourage the international harmonization of food standards. Importantly, the SPS Agreement cites Codex standards, guidelines, and recommendations as to the preferred international measures for facilitating international food trade (WTO, 1995). It formulates standards on pest risk analysis, requirements for the establishment of pest-free areas, and specific guidance on topics related to the SPS Agreement of WTO (Weirich, 2008) [20]. But there is limited scope to apply the precautionary principle under the SPS Agreement, contrary to the Cartagena Biosafety Protocol which is an instrument primarily

concerned with the conservation and sustainable use of biological diversity, more than with international trade.

Conflicting positions of WTO and Cartagena Protocol on GMO safety and trade makes the trade negotiations difficult. Under the protocol, importing countries can ban imports because of a lack of scientific certainty whereas on the contrary, the SPS Agreement allows countries to provisionally adopt sanitary or phytosanitary measures when relevant scientific evidence is insufficient but obliges them to seek the additional information necessary for a more objective assessment of risk and to review the SPS measure within a reasonable time (Petetin, 2017) [21]. While the Protocol and the SPS Agreement contain very similar obligations concerning the Party of import ensuring that its decision is based on a risk assessment, under the Protocol the importing country does not have to finance the underlying scientific studies to demonstrate that the product to be imported meets the level of risk that it has chosen whereas, in the case of the SPS Agreement, it is the importing country that usually bears the costs of the risk assessment (Bodiguel and Cardwell, 2010) [22]. Under the Biosafety Protocol, Parties may consider socio-economic complications arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially about the value of biological diversity to indigenous and local communities. Within the SPS framework, socio-economic considerations include potential damage in terms of loss of production or sales in the event of the entry, establishment, or spread of a pest or disease; the costs of control or eradication in the territory of the importing member; and the relative cost-effectiveness of alternative approaches to limiting risks. The Biosafety Protocol sets forth rules related to handling, transport, packaging, and identification requirements of GMO imports.

This is in direct contradiction to Article 2.1 of the TBT based on the principle of non-discrimination outlined in Article I and Article III of the GATT 1994, as far as imported products and "like" products or domestic origin or originating in any other country is concerned (Lee, 2010) [23]. If GMOs and GM products are considered “like” products in relation to conventional products, then there are no grounds for applying any special treatment to them, including mandatory documentation and identification schemes.

The lack of scientific validation on GMO biosafety and use is accentuated when countries producing these have a contrasting regulatory framework as well as a fragmented approach to the international treaties in effect. Table 2 summarizes the status of all GMO-producing countries on these two international legislations discussed. Major GM Crops growing countries like the USA, Brazil, Argentina, Canada, Chile, and Australia never ratified to the Cartagena Protocol on Biosafety to the Convention on Biodiversity. For countries actively involved in the trade of these crops, the protocol is seen as a big hindrance that makes the trade an arduous task. Interestingly some countries that have ratified the protocol are still actively growing and promoting GMOs. Mexico which is the center of origin of Maize has been growing GM maize in its territory for over a decade, in direct conflict with the guidelines set under the Cartagena Protocol to which it is a party (Eggers and Mackenzie, 2000). But a major part of the globe especially the developing countries are dubious of the real benefits of the technology in a local setting. For this reason, countries like, China and India have different positions on the international treaties and are treading on this path with great caution. The countries of the European continent strongly opposed to this technology have ratified to international biosafety protocol as well as are WTO members.

Under such a scenario, trade problems arise when countries have different regulations regarding the testing and approval procedures necessary to place GMOs and their products on the market, or when they disagree about labeling and identification requirements. EU member countries ban imports and sales of GMOs and their products altogether. In countries like the USA and Brazil, a large part of the production of some crops, such as maize or soybeans, is from genetically modified seeds and is mixed with non-modified varieties during storage, transport, and processing. These countries argue it would be unnecessary and very costly to keep GMOs separate and consider that labeling requirements or

import bans are unnecessary trade barriers. Therefore, the two international GMO legislation assessed here further deepen the discord among countries on GMO regulation instead of harmonizing it.

Table 2. International Status of major GMO promoting countries.

S. No.	Country	Cartagena Protocol	WTO
1	Argentina (soybean, maize, cotton)	No	M
2.	Australia (cotton, canola)	No	M
3	Bangladesh(brinjal)	Rtf	M
4	Bolivia (Soybean)	Rtf	M
5	Brazil (soybean, maize, cotton)	Acs	M
6	Canada (canola, maize, soybean, sugar beet)	No	M
7	Chile (maize, soybean, canola)	No	M
8	China (cotton, tomato, poplar, papaya, sweet pepper)	Apv	M
9	Colombia (cotton)	Rtf	M
10	Costa Rica (cotton)	Rtf	M
11	Egypt (maize)	Rtf	M
12	Eswatini (cotton)	Acs	M
13	Ethiopia (cotton)	Rtf	No
14	Honduras (maize)	Rtf	M
15	India (cotton)	Rtf	M
16	Indonesia(sugarcane)	Rtf	M
17	Malawi (cotton)	Rtf	M
18	Mexico (cotton, soybean)	Rtf	M
19	Myanmar (cotton)	Rtf	M
20	Pakistan (cotton)	Rtf	M
21	Paraguay (soybean, maize, cotton)	Rtf	M
22	Philippines (maize)	Rtf	M
23	Portugal (maize)	Acp	M
24	South Africa (maize, soybean, cotton)	Acs	M
25	Spain (maize)	Rtf	M
26	Sudan (cotton)	Acs	O
27	U.S.A (canola, maize, soybean, sugar beet, cotton, squash, papaya, alfalfa)	No	M
28	Uruguay (soybean, maize)	No	M
29	Vietnam (maize)	Acs	M

Source: Executive Summary Global Status of Commercialized Biotech-GM Crops 2019 -ISAAA; list of parties to Cartagena Protocol where rtf = Ratification, acs = Accession, acp = Acceptance, apv = Approval, No= not a member; list of WTO members where M= member, O=observer, No= not a member.

DISCUSSION

The world today projects a strong inter and intracontinental divide on the issue reaffirming the research findings of Davison (2010) [24]. The development and use of GMOs is not an isolated scientific technique. Right from research and development to its release in the environment multitude of social, ethical, and economic concerns come into play. Multi-departmental control of GMOs lacking any stringent biosafety and socio-economic evaluation is well evident at all stages and in various nations (Kaur et al, 2013) [25]. In the present form, there is no labeling, traceability, and post cultivation monitoring regime. This divergent regulation of countries dwelled more on the socio-economic and political status of the country and less on science and ecological principles. It relies heavily on the country's economic policy. The USA being a major producer of GMOs supports it vehemently. Their existing regulations promote GMOs and food derived from them as equivalent to conventional food which in turn boosts its production and trade. While EU, which is a major importer of food and feed, has a cautious approach applying precautionary principle which is well evident in its

regulatory regime. Asian countries projected a varied approach as they are open to GMOs but have serious concerns over its biosafety.

This global disharmony is aggravated in the absence of any stringent international legislation. The present international legislation on GMOs is weak and fragmented. Cartagena Protocol on Biosafety to Convention on Biodiversity, 2000 [18] was the most important of these legislations studied. It regulated the trade of GMOs between countries but ironically major GMO-producing countries like the USA, Argentina, Brazil, and Australia have not ratified it, demeaning its existence (Gupta, 2000) [26]. With ratifications from only 173 countries, it has proven to be a weak regulator. Moreover, the statutes of the protocol are in complete contrast to the SPS and TBT agreement of WTO, which are major drivers of transnational trade. Lack of legally binding international legislation and inharmonious national policies has affected the trade of GMOs, organic food products as well as conventional food due to fear of pollution of non-GM products with GM material (McFadden and Malone, 2018) [27]. The discordant policy at the national and global level augments perplexity. The growing networks and contesting frames make the formation of a harmonious global policy framework an arduous task.

CONCLUSION

The current research study aimed at reviewing the regulatory coherence of GMOs in tune with the ecological basis under the existing legal framework. The technology, scientists, farmers, and consumers suffer due to these divergent policies at the national and international levels. The need is to evaluate these crops on long-term ecological and bio-safety aspects and then develop an effective regulatory framework. The need-based approach to the technology involving long-term analysis on health, economic, biosafety and social concerns over GMOs need to be developed before formulating a policy for posterity. As in the words of Albert Einstein (1956) [28]

"Science can only ascertain what is, but not what should be, and outside its domain value judgments of all kinds remain necessary".

So is the case with GMOs. With this review, we hope to give direction to research to assess and ascertain the real purpose, impacts, efficacy, and benefits of GMOs to all segments of society, before adopting them.

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Conflict of Interest

The authors declare no conflict of interest.

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