Original Article

Global consensus – Need of the hour for genetically modified organisms (GMO) labeling

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ABSTRACT **The controversies surrounding genetically modified organism (GMO) labeling motivated to assess the legitimate concerns of different stakeholders. This article provides a brief overview on GM labeling regulations and conceptual differences in labeling policies adapted by different countries. Mandatory labeling perspectives of consumers and producers were carefully evaluated. On the basis of the evaluation, it is argued that mandatory labeling does not provide any meaningful information to the consumers. The shortfalls of detection techniques and conflicting roles of governing authorities to approve the GM products after rigorous trials and experimentation on one hand and imposing stringent regulation on the other complicates the issue further, resulting in technological hurdle. In conclusion, the regulatory authorities should at least consider avoiding mandatory labeling on approved GMOs while a unified traceability system should be considered at regional level to monitor risk management of GM products on health and environment. Policy regulations imposed on GMO on unwarranted grounds would be an obstacle for further development of the technology. Therefore, consensus among different stakeholders is crucial for benefiting technologies.**
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BACKGROUND AND MOTIVATION

The advent and application of genetically modified organisms (GMO) have undoubtedly revolutionized the agronomic and animal husbandry practices over the past 10 years. Genetic modification refers to 'any change to the heritable traits of an organism achieved by intentional manipulation'. Although GM foods pertain primarily to transgenic modification through micromanipulation of genetic material in laboratories, traditional cross-breeding techniques also falls under this category.[1] Genetic modifications are usually performed for the enhancement of desired traits such as increased resistance to non-selective herbicides, improved nutritional contents and pest-resistant varieties using genetic engineering techniques.

The first GMOs were introduced in the second half of 1980s for industrial production of medicinal products.[2] Since then, there has been a considerable debate and discussion on

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the real and/or perceived risks involved in the deliberate release of GM crops. Scientists, lawmakers and people welfare activists were divided on the unprecedented utilization of GMO in food and feed production. The supporters of GMO states that ensuring adequate food supply for rapidly growing population will be a challenge that is expected to be doubled in the next 40 years. Therefore, to meet the growing demand, GM foods appear to be the option to increase food production. According to the report from United Nations Population Fund,[3] more than 800 million people remain malnourished in developing countries. Thus biotechnological progress on better yields in shorter time and increased nutrition may provide solution for food crisis and other associated problems. On the other hand, GMO critics have raised environmental and health concerns of GM food. They believe that safety and environmental concerns are more important and overweigh the improved food taste and increased food production.

While the conflict between the two sections continues to grow, consumer concerns about GMO crops prompted government's intervention to develop regulations mandating food products containing GMOs to be labeled. However, lack of consensus on mandatory labeling among government authorities of different countries makes the approach unsuccessful. For instance, the debate surrounding the labeling of GMOs is largely framed as how much information should be supplied to consumers, and whether the information provides adequate knowledge on the content that will enhance the consumer's choice on decision making.

Given this background, this study attempts to provide legitimate concerns of different stakeholders to assess the pros and cons of mandatory labeling policy. The article is structured as follows. First, it gives a brief history and role of food labeling followed by the genesis of GMO labeling. Second, it explores the two major conceptual differences in GMO labeling. Consumer perspectives and producer concerns occupy the third and fourth sections, respectively. Fifth, the article focuses on the potential role of regulatory authorities with concluding remarks.

HISTORY, TYPE AND ROLE OF FOOD LABELING

As early as the thirteenth century, the King of England proclaimed the first food regulatory law that prohibited bakers from mixing peas and beans into bread dough. In America, it was in 1906 that the first national regulation on food labeling was drafted by Pure Food and Drugs Act to prevent misleading statements on food labels.[4]

Labeling is the primary means of communication between producers and consumers. The main objective of labeling is to help consumers identify the products that best match their preferences. In other words, labeling helps consumers to identify the product of interest and its contents, allowing the consumer to exercise freedom of choice. The Codex Alimentarius has published the general standard for the labeling of different food commodities, which is expected to be followed by the food industries globally.[5] The labeling policies differ widely in their nature, scope, coverage and degree of enforcement leading to varying degrees of information to consumers. In general, information such as statement of identity, name and address of the responsible party, quantity declaration, ingredients list, nutritional facts, date of production and expiry, meaningful coding system for batch identification and allergen information are expected to be part of the standard labeling practice.

In the case of GM foods, initial labeling legislation was framed by the European Union (EU) in 1997.[6] Further refinements on legislation covering GMO derivatives were formulated later.[7] The International Codex Alimentarius commission attempted to develop guidelines for labeling biotech products in 2007.[8] Lack of consensus among stakeholders of different countries prevented Codex commission to make guidelines on

GM labeling. Nevertheless, increasing number of countries have become involved in labeling with different regulation characteristics.[9] It becomes imperative to consider the two most common aspects (mandatory and voluntary) of labeling, which is the subject of debate between the EU and the United States. In the case of mandatory labeling, the regulatory authority requires all GMO-based products to be labeled, and monitors whether such compliances are met by the food industries by means of documentation and laboratory testing. On the other hand, voluntary labeling requires truthful and non-misleading information to be provided by the industries on the food. Although both the labeling schemes have their own merits and drawbacks, the present study focuses on mandatory labeling as more and more countries are attempting to adapt mandatory labeling policy.

CONCEPTUAL DIFFERENCES IN GMO LABELING

According to Food, drug and cosmetic act of the United States, products having material fact to consumers should be labeled. The term 'material fact' means different things to different people. For instance, FDA considers organoleptic changes as material fact and enforces labeling on such products. Furthermore, the US stance on GM labeling is based on 'substantial equivalence' (SE) principle. It embodies the concept that a novel food (genetically modified) should be considered the same as, and as safe as, conventional food if it demonstrates the same characteristics and composition as the conventional food.[10] It was first introduced in 1993 and subsequently endorsed by FAO and WHO. The proponents of the SE principle argue that there is no need to adapt mandatory labeling as consumers' concerns are about health, safety aspects, functionality and use of food rather than the process of manufacturing. Moreover, mandatory labeling of GMO foods creates an impression and even acts as warning that it is different from or less safer than non-GMO counterparts. For instance, no requirements exist for labeling to indicate the breeding technique applied to produce them. In addition, they contend about the inconsistency with the Codex General standard for the labeling of prepackaged foods, that foods shall not be described or presented in a manner that is false, misleading and deceptive, or is likely to create an erroneous impression regarding its character in any respect.

Conversely, the opponents argue that SE is a pseudoscientific concept and even anti-scientific as it was created primarily to provide an excuse for not requiring biochemical and toxicological tests.[11]

On the other hand, the EU has adapted 'precautionary approach' in GM food. The real or perceived risk of GMO on long-term exposures is unknown, and hence for traceability purposes GM labeling is required in addition to consumer's 'right to know policy'. One of the main concerns raised by the EU is the long-term effects of GMO. As the population has not been exposed for enough time, it is difficult to consider and measure the impacts of such foods. In this case, Bovine spongiform encephalopathy (BSE) has been chosen as a typical example in which the impact of beef infected with BSE was not evident for years.[12] Therefore, absence of evidence does not mean evidence of absence,[13] as there is a possibility of time lag between exposure to health or environmental risks and their effects.

Moreover, it is also important to consider religious and ethical preferences[14] so that consumer rights are fulfilled. For instance, Muslim population following the doctrines of Quran forbids scavenger animals (that is Pork), whereas the Hindu population predominantly shun all animal and fish products based on the doctrines of Hinduism. In this situation, the consumers are unable to detect the presence of GM ingredients unless they are disclosed through labeling. With the help of labeling information, consumers are able to make choices and act according to

their beliefs and desires, thereby enhancing the consumer sovereignty.

Consumer sovereignty relies on three general principles when it comes to ethical marketing. It includes, target consumer having the capability to understand the product and the risks, the choice of foods provided by competition and sufficient information to judge whether expectations of the goods are satisfied.[15] Without labeling information, the consumer is said to lack sovereignty, leading to irrational decisions. Such gap between the producer and consumer categorizes GMO products as credence good[16] as the consumer cannot assess the long-term attributes of GMO. Thus, labeling the credence attributes can alleviate asymmetric information to consumers.

CONSUMER PERSPECTIVES

It has been estimated that 60–70 per cent of processed foods in North America contain at least some ingredients derived from genetic modifications.[17] However, consumers are not aware of consuming such foods.[18] The mandatory labeling seems to be a policy proposal having marked consensus among consumers in the United States. The survey conducted in Canada also suggests that 88 per cent of the consumers want GM labeling.[19]

The representative survey conducted by the European commission on biotechnology revealed that medical and industrial biotech-nologies are broadly supported by the general public while strong opposition for agricultural biotechnologies exists.[20]

The result of the survey from Taiwan showed that 83 per cent of the surveyed Taiwanese population is in favor of mandatory labeling.[21] In the case of India, an overwhelming proportion of the consumers would like to see mandatory labeling if GM foods are introduced into the market.[22] Similarly, more than 90 per cent of Australian consumers were in favor of labeling GM foods.[23] Consumers from the industrialized countries express desire to avoid GM foods.[24,25] Furthermore, 60 per cent of the consumers in Germany want process labeling to ensure that GMO has not come into contact with non-GMO at any stage of the production process.[26]

It is argued that whether or not there are risks or benefits associated with GM, whether or not there are substantial differences between GM and non-GM foods, consumers have the right to make informed decisions.

PRODUCER PERSPECTIVES

The initiatives to establish food laws on GM labeling have incurred many criticisms from the producers. They argue that a GM crop can be grown only after extensive testing and approval as safe for human, animal and the environment by vigorous approval process. Hence, it is not a safety issue, and claims that activists groups exaggerate the risk claims involved in new technologies[27] to promote their own interests. Moreover, they claim that genetic modification benefits both the industry and the consumers. For instance, GM foods are currently less expensive than the non-GM foods. Thus, mandatory labeling would incur an additional cost of up to 30 per cent,[28] owing to segregation and identity preservation requirements.[29] To ensure labeling threshold, expensive genetic testing has to be included resulting in higher costs.[30] Moreover, the DNA detection methods currently available have their own limitations on highly processed materials, and do not detect the transgene in final product.[31] With regard to seed production, it is even more complicated. Adventitious presence of GM may occur during any stage of production. As plant breeding and seed productions are conducted in the same open farming environment, it is almost impossible to obtain 100 per cent purity in any seed. The French seed producers argue that the low threshold of 0.5 per cent is not practical, and estimate that 42 per cent of the French production would fail to meet the threshold.[32] Although low level of detection may be

achievable using PCR-based techniques, such detection does not correspond to impurities in conventional seed production. Further, the cost of the seed production for 0.5 per cent threshold is expected to be increased by more than 40 per cent.[33] Despite the uncertainties surrounding various analytical procedures to test GMO, they are being used on a day-to-day basis in a variety of situations to segregate GM and non-GM foods. The market demands leave them no choice but to test, despite their limitations irrespective of flaws described on the approaches.

ROLE OF REGULATORY AUTHORITIES

The GMO issue has put forth a major concern about the legitimacy of governing authorities. The regulatory bodies from different countries are attempting to draft/implement regulatory frameworks for GMO crops and its products. More than 40 countries have adapted labeling regulations[9] However, the policies and their degree of implementation vary from country to country.[33,34] One of the main challenges for harmonized labeling approach in GMO products seems to be associated with coordinated action in the regulation of biotechnology. At the international level, legal regulatory frameworks are associated with three key bodies: The Codex Alimentarius commission that was created in 1963 by FAO and WHO to develop food standards. The main aim of the commission is to protect the health of consumers in addition to ensuring fair trade practices internationally. The World Trade Organization (WTO), which is an International organization whose primary objective is to open trade for the benefit of all, also helps to maintain trade barriers to protect consumers, prevent the spread of disease and protect the environment. The third one is the convention on biological diversity governing the movement of living modified organisms from one country to another. The Cartagena protocol on biosafety seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. Nevertheless, Codex Alimentarius commission is recognized as the International organization responsible for standard setting relating to food safety. Therefore, WTO members shall base their measures related to human and plant health on codex standards, guidelines or recommendations.[35]

The Codex committee on food labeling has been considering the labeling issues for the past 2 years. The costs associated with the implementation and enforcement of labeling and its potential benefits are being considered by the committee. For instance, issues relating to test requirements, traceability through agricultural production, processing and distribution, verification of documents, feasibility of analytical methods and their detection limits, and consumer education are among the key issues to be addressed. But it seems unlikely that global consensus would be reached in the near future as the United States expressed strong objections to process labeling.[36]

In the developing countries, consumers do not have any knowledge on GM foods. Thus, if they buy GM food, it does not necessarily mean that they have to face the consequences in case of any adverse reaction.

In any case, government authorities approve GM foods only after rigorous trials and experimentation. The safety concerns are carefully assessed to satisfy the government norms before it appears in the market. Therefore, conflicting stance on approving GM food and imposing stringent misguiding regulations complicates the issue further, resulting in technological hurdle. Moreover, the history of technology clearly shows that many innovations after strong initial rejection are subsequently widely diffused, but with considerable improvements, especially with regard to risk reduction, improved convenience of use and usefulness.[37] One of the main reasons for GMO hostility in European countries seems to be risk/benefit balance, which is perceived unfavorable besides lack of confidence among general

public in the regulatory process and the promoters.[37] Therefore, the government should proactively attempt to educate their citizens by means of awareness programs so that consumer confidence will improve on GMO. Once this is achieved, it would be easy to establish consensus at global level.

The world summit on food security is aiming at new global goal of eliminating hunger by 2025. To accomplish the task, technological innovations should be duly considered and implemented at each level so that the benefit reaches the deprived mankind.

CONCLUDING REMARKS

It has been estimated that farmers have earned 27 billion US dollars from GM technology, and in addition application of pesticides have also reduced considerably.[38] To this end, rapid depletion of arable land owing to growing industrialization and encroachment of human habitats on farming areas poses serious threats to sustainability of available resources. Considering the present global resources, it is imperative to let the technological progress in the area where modern biotechnology can potentially serve to address the abovementioned concerns in a way that overweighs the risks associated with the technology itself. Although consumer's acceptance of GM food is linked to perceived risks and benefits,[39,40] where consumer skepticism attributing to unknown health and environmental consequences exist, nothing is persuasive. The biotechnological progress on better yields in shorter time and increased nutrition would mitigate growing public opinion on GMO[41] without depleting the natural resources.

It is widely accepted that product information is important to consumers as they have the right to choose what they want to eat. In the case of GM foods, survey evidence supports the claim that consumers are interested in knowing about the issue of labeling while many of them have an interest in knowing whether their foods are in fact genetically modified. Thus, being interested in something does not give the right to information about it.[1] Moreover, putting some words on the package does not ensure that the information is transmitted for decision making as consumers knowledge level on science vary considerably.[12] Most of the studies indicate that consumers prefer GM-free food as long as they do not have to pay premium for such foods. Therefore, it is arguable that mandatory labeling does not provide valuable information to consumers. In addition, GM foods are currently less expensive than non-GM foods, and labeling would incur an additional cost of up to 30 per cent[29] in addition to providing redundant information. Furthermore, the detection methods have their own limitations, particularly with processed food. Analytical flaws have been reported on food components such as calcium, iron, carbohydrates, which inhibits the PCR preventing reliable detection of GM ingredients.[42] In addition, it would be difficult to statistically signify the level of GMO in case of larger mass in which each unit represents a sample. The Certified reference material (CRM) used in the molecular analysis is not representative for the sample under analysis besides varying molecular dosage of GM sequences in a test sample or CRM.[43] Thus, without proper standards, testing, verification services and enforcement, GM labeling may be more harmful than helpful, creating confusion and uncertainty as reported[44] in previous studies.

Most of the GM varieties available in the market today are either herbicide-tolerant or pest-resistant traits. In other words, the purpose of inserting the desirable gene is to control the pest or weed, which is a process similar to application of pesticide or herbicide. In the latter case, mandatory labeling is not practiced anywhere so as to inform the consumers and is not considered as 'right to know'. However, regular inspection and monitoring process by regulatory authorities are being carried out to check whether the level of pesticides exceeds the permissible limit as it can cause potential health problems

on consumption. In such cases, the product would be considered unfit for consumption and rejected. In the case of GM foods, claims on adverse effects can neither be confirmed nor contested by scientific evidence. In terms of long-term effects on consumers or environment, a precise tracking system with unique identity for GMO products could resolve these problems. In addition, transparency and traceability will ascertain public confidence in new technologies to lift *de facto* moratorium on GM approvals. The recent recall of Coca-Cola's bottled water product containing higher levels of bromate illustrates the efficacy of the tracking system to recall over half a million bottles in the United Kingdom in less than 24 hours.[45]

Hunger alleviation in African and Asian countries can be achieved if the GM debate is depolarized and long-term impacts on health and environment are addressed with transparency and forthrightness from proponents and opponents to gain public confidence.

In conclusion, the regulatory authorities should at least consider avoiding mandatory labeling on approved GMOs with an exception of products derived from organisms that affects the religious sentiments of the people. Second, unified traceability system should be considered at regional level to monitor risk management of GM products on health and environment. Policy regulations imposed on GMO on unwarranted grounds would be an obstacle for further development of the technology. Therefore, consensus among different stakeholders is crucial for benefiting technologies.

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