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A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule

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This paper provides a comprehensive review of existing international labeling policies of genetically modified (GM) food and associated relevant international agreements in order to evaluate India's proposed mandatory labeling rule. Existing evidence from developed countries shows that mandatory labeling regulations have resulted in no additional consumer choice or information. Among the few developing countries with labeling policies, most have not effectively implemented their regulations. We show that India's proposed labeling rules for GM food would be among the most stringent globally and could potentially result in low consumer benefits at a high cost both domestically and internationally. India's proposed regulation also lacks a number of elements to be implemented. However, these conclusions are based on experiences from other countries and limited available information from India. More studies are needed to evaluate the potential economic effects of GM food labeling in India.

Key words: consumer choice, cross-country comparison, food policy, labeling, India, international trade.

Introduction

In recent years, an increasing number of countries have adopted labeling policies for genetically modified (GM) food. The first labeling policies were introduced by the European Union (EU) in 1997, but since then many other countries, including all developed countries, have adopted some type of labeling policy for GM food. However, these labeling policies differ widely in their nature, scope, coverage, exceptions, and their degree of enforcement. Consequently, the observed effects of these policies on consumer choice, consumer information, food marketing, and international trade also vary significantly.

India recently decided to consider introducing mandatory labeling requirements for GM food. On March 10, 2006, the Central Government of India, after consultation with the Central Committee for Food Standards, published two draft rules to amend the Prevention of Food Adulteration Rules (1955), introducing labeling and approval requirements for GM food and the products derived thereof. Draft rule *37- E Labeling of Genetically Modified Food* requires that all primary or processed foods, food ingredients, or food additives derived from a GM food be labeled accordingly, and that imported GM foods indicate the status of approval in the country of origin (see Appendix for the detailed rule).

Given that this draft labeling rule is being proposed, and at a time when many other developing countries are planning to introduce GM food labeling laws, it is informative to examine how other countries have addressed the issue and where this rule would place India compared to these other countries. In this paper, we provide an updated review of the different national labeling regulations of GM food; we discuss their economic effects and examine the implementation issues associated with these regulations. We also analyze the international harmonization efforts regarding the labeling of GM food and GM food shipments. Lastly, we place the Indian draft rule in this context, using lessons from international observations.

A Review of National Labeling Laws and Their Observed Effects

Current Rules in Developed and Developing Countries

During the last ten years, more than 40 countries have adopted labeling regulations, but the characteristics of the regulations and their degree of implementation vary greatly (Phillips & McNeill, 2000; Carter & Gruère, 2003; Haigh, 2004). While a large majority of countries belonging to the Organization for Economic Cooperation and Development (OECD) have implemented some type of labeling policy, only a few *developing* countries have introduced labeling laws, and even fewer have implemented them.

Among the countries with labeling laws, the only common feature is the quasi-generalized requirement to

Table 1. Type of labeling policies and degree of enforcement as of February 2007.

Type of labeling[a]	Countries with enforced labeling policies	Countries with partially enforced or non-enforced labeling policies	Countries with plans to introduce a labeling policy
Mandatory	Australia, China, European Union, New Zealand, Norway, Japan, Russia, Saudi Arabia, South Korea, Switzerland, Taiwan	Brazil, Chile, Croatia, Ecuador, El Salvador, Indonesia, Mauritius, Serbia, Sri Lanka (just introduced), Thailand (partial), Ukraine, Vietnam	Bolivia, Cameroon, Colombia, Egypt, Ethiopia, Georgia, India, Israel, Ivory Coast, Jamaica, Malaysia, Namibia, Nigeria, Paraguay, Peru, Philippines (voluntary), Singapore, Uganda, UAE, Uruguay, Zambia
Voluntary	Canada, Hong Kong, South Africa, USA		

[a]*For substantial equivalent products only.*
Source: Carter and Gruère (2003a), Cevallos (2006), Cloutier (2006), Haigh (2004), US Department of Agriculture (USDA, 2006), Wongruang (2006).

label products derived from GM crops that are *not substantially equivalent* to their conventional counterparts. This labeling requirement concerns GM products with novel traits, such as high-oleic-content canola, or the future nutritionally-enhanced rice (e.g., Golden Rice). Labeling is mandatory for these products in all countries with regulations because they recognize that consumers should be informed of the novel traits and properties of the food products in order to make informed decisions.

On the other hand, for products that are considered *substantially equivalent* to their conventional counterparts, which includes products derived from all transgenic crops with input-related traits (i.e., virtually all GM products today), there is a large international heterogeneity in labeling regulations. A first major dichotomy separates countries with *voluntary* labeling guidelines (e.g., Canada, Hong Kong, or South Africa) from those with *mandatory* labeling requirements (e.g., Australia, the EU, Japan, Brazil, or China). Voluntary labeling guidelines dictate rules that define what food can be called GM or non-GM, and let the food companies decide if they want to use such information signals on their products. In contrast, mandatory labeling requires food companies (processors, retailers, and sometimes food producers) to display whether the targeted product/ingredient contains or is derived from genetically engineered materials. A certain number of countries with mandatory labeling for GM ingredients also have voluntary guidelines for the labeling of non-GM food (e.g., Japan and the EU). This mixed mandatory/voluntary system is in place in countries with mandatory labeling for which consumers are willing to pay a premium to completely avoid GM ingredients, even at a residual level.

Secondly, the scope of the regulations widely differs among countries with mandatory labeling according to the following main characteristics:

1. Coverage: countries may require labeling for:
   - A list of particular food ingredients *or* all ingredients in packaged food products that include detectable transgenic protein or DNA;
   - Highly processed products *derived* from GM ingredients--even without quantifiable presence of GM ingredients;
   - Animal feed;
   - Additives and flavorings;
   - Meat and animal products fed with GM feed;
   - Food sold by caterers and restaurants;
   - Unpackaged food.

2. Threshold level for labeling of GM ingredients:
   - Applied to each ingredient or only to major three or five ingredients;
   - Level, ranging from 0.9% to 5%, except China with no threshold level.

In particular, one of the major differences in regulations among countries with mandatory labeling depends on whether the regulation targets the presence of GM in the *finished product* (like Australia, New Zealand, and Japan) or on GM technology as a *production process* (like the EU, Brazil, and China). In the former case, only products with detectable and quantifiable traces of GM materials or ingredients are required to carry a label. In contrast, in the latter case, any product derived from GM crops will have to be labeled, whether it contains any traces of GM material or not. This means that canola or soybean refined oils are required to be labeled even if current detection techniques cannot detect significant traces of transgenic DNA or proteins in the final product. This difference is crucial for enforcement: a product-based system can be enforced with testing equipment and can filter a cheater, whereas a process-based system requires viable and trustable documentation systems, which will lead to identity preservation or

Table 2. Characteristics of national labeling systems in major countries as of February 2007 divided into three groups according to the degree of stringency of their regulation.

Major Country	Labeling type[a]	Product/ process	Coverage	Major exemptions	Threshold level
European Union	Mandatory, & national voluntary guidelines	Process	Food, feed, additives, flavorings, products derived from GM, restaurants	Meat and animal products	0.9%
Brazil[b]	Mandatory	Process	Food, feed, products derived from GM, meat and animal products	Virtually none	1%
China	Mandatory	Process	List; products derived from GM, restaurants	Outside of list	None (0%)
Australia-New Zealand	Mandatory & voluntary	Product	All products based on content	Processed products	1%
Japan	Mandatory & voluntary	Product	List of food items	Processed products	5%[f]
Indonesia[b]	Mandatory	Product	List of food items	Outside of list	5%[f]
Russia	Mandatory	Product	All products based on content	Feed	0.9%
Saudi Arabia	Mandatory	Product	List of food items	Outside of list, restaurants	1%
South Korea	Mandatory & voluntary	Product	List of food items	Processed products	3%[g]
Taiwan	Mandatory & voluntary	Product	List of food items	Outside of list	5%
Thailand[c]	Mandatory	Product	List of food items	Outside of list	5%[f]
Argentina[d]	Voluntary	Product	-----Not specified- all products based on content-----		
South Africa	Voluntary	Product	-----Not specified- all products based on content-----		
Philippines[e]	Voluntary	Product	All products based on content		5%
Canada	Voluntary	Product	All products based on content		5%
United States	Voluntary	Product	All products based on content		n/a

[a] *For substantial equivalent products only.*
[b] *To our knowledge, the labeling regulation has not been fully implemented.*
[c] *Implemented with "voluntary" enforcement. Penalties are applied in case of reported fraud.*
[d] *No specific law.*
[e] *Proposed labeling regulation.*
[f] *On three main ingredients in each product.*
[g] *On top five major ingredients in each product.*
Source: Carter and Gruère (2003a), Cevallos (2006), Cloutier (2006), Foster & French (2007), Haigh (2004), USDA (2006), Wongruang (2006).

traceability requirements for the producers and importers, i.e., systems that track or identify GM food or GM free food from their origin to their final package and cannot guarantee the absence of cheaters.

Last but not least, national regulations differ by their degree of implementation and enforcement as shown in Table 1. Many developing countries have approved laws requiring the labeling of GM food, but have not implemented the laws, or have only partially enforced the laws. For instance, Brazil introduced labeling laws in 2003, but has yet to actually implement these laws (Cevallos, 2006). To a certain extent, other Asian countries, such as Indonesia, have only partially implemented their regulation. They may require importers to label their food as GM, but consumer products are not carrying GM labels. China has implemented labeling since 2004, and can be considered the only developing country with an effective labeling policy in place.

Table 2 shows international approaches to labeling according to these different criteria in major countries. We divide countries into three groups according to the relative degree of stringency of their regulations (Carter & Gruère, 2006; Cloutier, 2006). At one end of the spectrum, a first group of countries have introduced stringent

mandatory labeling regulations based on production process, with wide coverage, few exceptions, and a very low threshold, which follows the EU model of labeling regulation. This group includes all European countries (outside of the EU). At the other end of the spectrum, a third group, that includes Canada and the US, has voluntary labeling guidelines for GM or non-GM food. The second and intermediary group, which includes Japan and Australia, has mandatory labeling requirements based on differences in the finished products, with intermediate or higher threshold levels, and a number of exemptions. Most developing countries still have to implement or enforce the regulations. Among the ones in Table 2, we consider that regulations in Brazil and China belong to the EU group, Thailand and Indonesia follow the Japanese type of regulation, and South Africa and the Philippines follow the US/Canada type of regulation.

Observed Effects of Labeling Regulations

The overall objective of mandatory labeling requirements is to provide consumer information and consumer choice. In most countries, labeling is not primarily about food safety but about consumer information, as labeling policies are designed to follow safety approval clearance.[1] At the same time, the rationale behind the provision of consumer information differs according to the labeling regulation. Countries with labeling based on *production process* believe that at least some consumers base their purchasing decision not only on product related issues but also on environmental and/or religious, ethical, or other non-safety related reasons. Countries with *product* labeling base their regulation on consumer demand for product information. In addition, there is a philosophical debate as to whether labeling requirements support the principle of consumer autonomy or consumer right-to-know (Streiffer & Rubel, 2003; Hansen, 2004; McKay White & Veeman, 2007).

In the EU and Japan, the initial labeling requirements were introduced in response to consumer concerns. More specifically, they were intended to provide consumer choice and consumer information. However, the mandatory labeling policies in the EU and Japan have resulted in the virtual disappearance of any labeled GM product on the food shelves.[2] These policies encouraged food processors and retailers to avoid using GM ingredients (Kalaitzandonakes & Bijman, 2003; Carter & Gruère, 2003b). Some retailers voluntarily decided to shun GM ingredients, while others – such as food processors – avoided using GM ingredients due to the introduction of mandatory labeling in order to decrease their risk of loss in market shares due to the controversy over GM food in Europe. For food processors, the question of choosing whether or not to purchase GM ingredients is linked to the cost differences between GM or non-GM inputs and the expected loss in market shares due to the consumer aversion to eating GM food (Knight, Mather, & Holdsworth, 2005). Since most current GM food products are only used in small quantities as ingredients, the cost difference between GM and non-GM remains very low for most of these companies.

At the same time, the risk of losing in sales because of bad reputation is relatively high. Greenpeace and other anti-GM organizations quickly launched negative campaigns targeting GM-labeled products, and publicized supermarkets or food brands carrying GM labels. As a result, it is more profitable for EU or Japanese companies to avoid GM ingredients altogether. Furthermore, this situation may not change quickly because a large share of the public remains opposed to GM food, because no other food products have been released, and because there is a first-mover disadvantage: the first company to market GM products would face even tougher competition from its rivals (Carter & Gruère, 2003b).

As a result, the EU policy has driven GM ingredients outside of consumer market shelves (GMO Compass, 2007). A study of GM food labels on processed food products in France (Gruère, 2006) reveals that only a few products directly imported from the US and sold in specialty stores carry visible GM labels (such as popcorn and US salad dressing). Yet these products only represent very small niches, so virtually all processed products do not contain any GM ingredients over the 0.9% threshold level for adventitious presence. At the same time, meat and animal products processed from animals fed with GM are widely sold in the EU because

1. *Nevertheless, food safety concerns are indirectly related: certain consumers want to avoid GM food for fear of long-term unknown risks. Apart from that, certain countries now justify labeling for health, e.g., as a mean to respond to the accidental intrusion of unapproved GM crops in their marketing system.*

2. *This phenomenon has extended to other countries. To our knowledge, China is the only country with mandatory labeling where GM-labeled food products can be easily found in food markets.*

these products are exempt from the labeling legislation. Similarly, in Japan, all products targeted by labeling requirements are produced with non-GM ingredients. Yet, because of a higher threshold and the exclusion of highly processed products (such as soy oil), consumers *do* buy unlabeled products with GM derivatives, but that either do not contain GM materials or that only contain very limited GM material.

These outcomes show that in developed countries, thus far, mandatory labeling has failed to provide consumer information and consumer choice. Before the regulations, consumers did not know about GM content, while after implementation of the regulations they do not know more, but all products are basically non-GM (or only contain accidental GM traces under the threshold level). Markets have tuned to the new requirements, with an increase in the use of non-GM palm oil to replace GM soy oil in countries where these oils have to be labeled. European food companies have set up complete marketing channels within Brazil to assure their provision of non-GM soybeans for food purposes. Japanese companies have taken action to contract with US farmers to obtain identity-preserved non-GM soybeans for a price premium, and non-GM soybean is quoted on the Tokyo market (Bernauer, 2003).

Regarding the information content, all countries with mandatory labeling require products to display a very simple and rather uninformative message such as "contains genetically engineered soybeans" or "derived from genetically modified maize" or "Transgenic," which assumes that it would be useful information for all consumers, i.e., that all consumers are sufficiently educated to understand what it means. At the same time, no country mentions the fact that the GM ingredients in question have been approved by the food safety authority. All countries with mandatory labeling have food safety approval processes in place, and only authorize the use of the GM events that have been cleared by the authorities. The observed backlash by consumers against GM products might have been less important in these sensitive countries if this type of message was displayed. Consumers would have known that the presence of GM is considered safe by the authority.

Researchers in agricultural economics and food policy have also provided food for thought on the debate related to the use of mandatory labeling for GM food (McKay White & Veeman, 2007). Several agricultural economists from both sides of the Atlantic have long argued that mandatory labeling is not the best solution to provide consumer choice or consumer information, especially when it may affect trade (Phillips & Isaac, 1998; Valceschini, 1998; Runge & Jackson, 2003). Voluntary labeling provides the option for consumers that want non-GM or GM-free products to buy these products, whereas others will buy the regular products. In a sense, it reveals the demand for non-GM. As long as the market functions sufficiently well, the presence of non-GM products will reflect the share of consumers willing to buy it (Bansal & Ramaswami, 2007). In countries where most consumers are generally indifferent to the use of GM ingredients, such as Canada, non-GM products (in particular non-GM *organic* products) appear as a niche market responding to the demand of certain consumers (Gruère, 2006). In contrast mandatory labeling forces all food processors to take measures related to their sources of ingredients. This regulation tends to distort the market towards no GM at all in countries where agricultural biotechnology has a bad reputation, and where the food industry is concentrated and thus sensitive to actions by political pressure groups, such as anti-GM campaigns, despite the fact that a significant share of consumers would be willing to buy GM food (e.g., Noussair, Robin, & Ruffieux, 2004).

At the same time, several theoretical economic studies (e.g., Crespi & Marette, 2003; Fulton & Giannakas, 2004) showed that mandatory labeling could be beneficial in countries where the large majority of consumers are concerned with GM food as revealed by their willingness to pay for non-GM products, depending on the structure and amplitude of the costs of implementation. These studies provide interesting results, but the implication of their results in the current context may be limited due to their assumption that labeling translates into consumer choice, therefore excluding the current corner solution in developed countries with no labeled products available. Hobbs and Kerr (2006) demonstrated the relative superiority of mandatory labeling to import bans. But they also noted that their result is true except in cases where labeling acts as a hazard warning signal for consumers, thus resulting in no GM labeled products.

Because of the failure of GM labels to provide consumer choice, there is generally a lack of information on what effects these labels would have on consumers' actual decisions. A unique scanner data study in the Netherlands conducted at a time when some foods were labeled with GM ingredients before disappearing showed that there was no effect of labeling on consumer demand (Marks, Kalaitzandonakes, & Vickner, 2004). At the same time, many studies in developed countries used consumer surveys to measure the willingness to pay for labeling, but only a few compared these numbers to potential costs of labeling. Kaye-Blake, Bicknell,

and Lamb (2004) measured consumers' willingness to pay for mandatory labeling in New Zealand and showed that it exceeded the estimated costs of the regulation, whereas Loureiro and Hine (2004) showed that US consumer would not be willing to pay the estimated cost of mandatory labeling, and concluded that the US voluntary policy was economically justified.

Experimental economic studies showed that US consumers would likely perceive GM labeled products as inferior quality products (Tegene, Huffman, Rousu, & Shogren, 2003). A study in France revealed that consumers would likely not read GM food labels, were they available (Noussair, Robin, & Ruffieux, 2002). Their experiment demonstrated that groups of literate consumers were unable to see the message "gentically modified corn" written on ingredient lists of chocolate bars, even when they had time to observe the label for several minutes, but that they would alter their behavior after being shown the label. This raises the question of whether this information would be used by consumers as part of their purchasing decision. In another study, the same authors show that a significant share of French consumers would actually be willing to purchase products with GM ingredients for a discounted price (Noussair et. al, 2004). More recently, Lusk et al. (2005) combined a consumer experiment in the US and Europe with segregation cost estimates and show that on average US consumers would suffer welfare loss with mandatory labeling, while European consumers likely benefited from the labeling regulation because their willingness to avoid GM is larger than the cost of labeling.

In contrast, there is a general lack of information on the effects of mandatory labeling in developing countries. China is the only large developing country with a regulation effectively in place. International food companies have generally decided to avoid GM ingredients even in China, in order to avoid being targeted by the anti-GM groups in negative campaigns. At the same time, local food producers and national food companies have used GM soybeans and labeled their products as GM (soybean oil). Therefore China is the only country where some labeled GM products are available to consumers, but in this case it is difficult to find the non-GM counterparts. Chang (2007) used supermarket scanner data in the Nanjing region to show that the introduction of GM labels on soybean oil has resulted in a reduction of 2% of the share of soybean oil in total vegetable oil consumption. At the same time she acknowledges the fact that other factors may have driven consumers towards other vegetable oils. Her study also confirms that, where the regulation is enforced, virtually all soybean oil is labeled GM, therefore resulting in no more consumer choice.

More generally, research is lacking on the effect of GM labeling in developing countries in which many consumers could be more sensitive to prices than in the production process (Bansal & Ramaswami, 2007). The literacy rate among consumers should also be a concern for governments trying to provide information through labeling. The Chinese example may precede others — some targeted products could be all labeled GM without much change in consumer reaction. But at the same time, because Chinese consumers are relatively unaware and open to biotechnology, and there is much less civil society opposition to biotech in China, it would be wrong to simply generalize the Chinese example to other countries like India.

Cost of Labeling Requirements

On the cost side, a few national studies have been published for Canada, Australia, the United Kingdom, and the Philippines, and two regional studies were published for Oregon and Quebec. The cost of a labeling system obviously depends on several critical characteristics, such as the threshold level, the capacity of the industry to comply with requirements, and the public authority's capacity to enforce the labeling rules.

First, KPMG International (2000a) estimated the costs of implementing mandatory labeling in Canada and found that it would amount to US$35 to US$48 per person per year. According to Jaeger (2002), this estimate is high because the study was based on limited information and used upper bound aggregate estimates of costs (e.g., they assumed that 70 to 85% of processed foods would incur the full cost of segregation). The same year, KPMG (2000b) published a report on the introduction of mandatory labeling of GM food in Australia and New Zealand. That report estimated that the total costs of labeling would amount to US$9.75 and US$2.65 per person per year for Australia and New Zealand, respectively. This estimate included private costs of compliance and government costs of implementation. A third published report (National Economic Research Associate [NERA], 2001) studied the cost of five different labeling scenarios in the United Kingdom. The first scenario corresponds to the ongoing EU regulations in 2001, the second adds a voluntary labeling scheme for GM-free food, and the third includes products derived from GM ingredients but not meat or processing aids (as done in the extension of the EU rule in

2004). The fourth option adds a voluntary labeling scheme for GM-free food to the third scenario, and the fifth option includes all three (meat fed with GM, processing aids, and products derived from GM ingredients). The respective per-capita annual cost estimates are: US$0.23, $0.64, $1.77, $2.01, and $3.89.

Jaeger (2002) reviewed these different cost estimates available and used the results of those studies to discuss the costs of implementing the proposed mandatory labeling policy defined under Oregon's Ballot Measure 27. This proposed US state measure, which included very stringent labeling of GM food and non food products, was rejected by 70% of Oregon voters by referendum in November 2003. He concluded that the total annual costs of the Oregon labeling proposition would range from US$3 to US$10 per person per year. This approximation is based on the assumption that labeling is used by all processors with GM ingredients, and thus does not result in any change in product ingredients.

De Leon, Manalo, and Guilatco (2004) conducted a comprehensive economic study of the potential economic effects of labeling options in the Philippines, a country that produces GM maize and imports large volumes of potentially GM commodities. Their study shows that mandatory labeling would result in an increase of manufacturing costs by 11-12%, which would lead to increases of 10% in consumer prices for certain products. They conclude that, given the high cost of implementation and uncertainties in the international regulatory context, it would be better to avoid the immediate use of mandatory labeling. Instead they suggested a progressive policy alternative, initiated with the introduction of a voluntary labeling system, while waiting for a possible international standard on labeling.

Lastly, Cloutier (2006) provided a cost study of introducing a mandatory labeling policy for GM food in Quebec, separating fixed and variable costs for the different actors in the food chains.[3] The study reports that the total set up cost for a mandatory labeling system would amount to CAD 161.75 million (equivalent to US$20/person), and the variable cost for mandatory labeling after its implementation would amount to CAD 28.37 million annually (equivalent to US$3.5/person/year) for Quebec. These total estimates are relatively low, perhaps reflecting the very low use of targeted GM crops by regional farmers, and the lack of explicit threshold level in the analysis.

More generally, it is important to note that the economic effects of labeling are intrinsically linked to the presence or absence of domestically-produced GM crops, and imports or exports of GM food products. The three original producers and exporters of GM crops (i.e., the United States, Argentina, and Canada) have adopted voluntary labeling approaches, whereas the first countries to adopt mandatory labeling requirements are large importers that do not produce GM crops (or produce GM crops in very limited areas). China and Brazil are the only major countries in an intermediate position, as large producers and exporters of GM crops and with mandatory labeling. However, China officially only produces GM cotton, whose main products are not required to be labeled anywhere, and Brazil only produces GM soybeans, which tend to be mostly exported and used as animal feed in countries that do not label meat fed with GM. This situation raises the question of whether labeling can be considered a non-tariff barrier to trade. We will now turn to international considerations.

International Agreement and International Trade

The Codex Alimentarius, the Biosafety Protocol, and the World Trade Organization (WTO) are the three international institutions directly involved in discussions over labeling of GM food. India is a member of the WTO, a ratifying member of the Biosafety Protocol, and an active member of the Codex Alimentarius negotiations. As a consequence, it is important to consider the legal international context to evaluate whether the draft rule would be consistent with India's international obligations.

First, the Codex Committee on Food Labeling (CCFL) under the Codex Alimentarius Commission has been working on finding a common position on the labeling of GM food since the beginning of the 1990s. Until 2006, there was no agreement within the Codex on the labeling of GM food. No formal standard has been adopted on labeling, but draft guidelines were published and provided the basis for discussion. The "Proposed Draft Guidelines for the Labeling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modifications/Genetic Engineering" (section 3) includes the following recommendations (BRIDGES, 2005): 3.1. Labeling should be required for GM food that is not substantially equivalent; 3.2. Labeling should be required for GM food that contains allergens; 3.3.

3. *The assessed labeling policy is product-based and it excludes animal feed, animal products, and food sold at restaurants.*

Labeling should be required for substances with physiological or metabolic impacts; 3.4. Where label indicates the presence of production process, GM food (food containing GM and food with ingredients derived from GM food) should be labeled; 3.5. For GM food products for which there are religious or dietary concerns, labeling should be required.

The first three provisions (3.1, 3.2, and 3.3) were supported by virtually all active members of the Codex Commission. They recommended labeling requirements for GM food with significant changes in product characteristics. In contrast, article 3.4 was the object of a large disagreement among Codex members. This article recommends the use of labeling based on differences in production methods; under this article, all GM food should be labeled, whether or not there is any GM ingredient in the final product. The draft guidelines also included additional sections on threshold levels for adventitious presence of GM food, possible labeling exemptions, text declaration, rules of implementation, and enforcement.

During the May 2006 annual session of the CCFL in Ottawa, Canada, no agreement was found on GM food labeling and the issue was almost dropped from the agenda. But after discussions, the CCFL agreed to have a new working group on this issue. Presently, in view of national differences, it is unlikely that a Codex consensus will be found on the guidelines (Fletcher, 2006), except possibly on the first three provisions.

Secondly, the Cartagena Protocol on Biosafety provides rules related to identification for any transboundary movement of living modified organisms intended for direct use as food, feed, or processing (i.e., unprocessed GM commodities, noted as LMO-FFPs). It is important to note that these rules *are not directly related* to domestic labeling regulations—they only concern traded shipments of LMO-FFPs. In other words the Protocol supports the use of GM labels for imported and exported commodity shipments, not consumer products. Yet, many countries believe that a comprehensive requirement for traded GM commodities would support the legitimate use of mandatory labeling requirements in the trade arena because it would justify importer requirements of a similar nature to mandatory labeling on consumer products. But this would only be the case if the WTO officially recognizes the Protocol as a binding international agreement, and in any case, it would not justify labeling requirements for processed GM food products (that are not LMO-FFPs).

Under Article 18.2.a, parties to the Protocol should request information from exporters regarding the presence and the identification of LMO-FFPs in any shipment before importation. Until March 2006, the Protocol only required exporters to notify of the potential presence of LMO-FFPs in traded shipments by writing that the shipment "May Contain" LMO-FFPs. During the third meeting of parties in March 2006 in Brazil, Protocol members agreed to have a two-option rule on information requirements (BRIDGES, 2006). Shipments containing LMO-FFPs identified "*through means such as identity preservation systems*" must show that the shipment "Does Contain" LMO-FFPs and provide identifiers of each GM event. Shipments of LMO-FFPs which are not well-identified would only have to label their shipment as "May Contain" LMO-FFPs (Redick, 2007). At the same time, parties decided to reconsider the rule at the 2008 meeting of parties with the possibility of extending the requirements with "Contains" to all shipments of LMO-FFPs in 2012.

Even if the "contains" requirement will likely not apply to a large trade volume in the short run, it could become mandatory for Protocol members and then drive the GM producers and exporters to comply with it after 2012. Recent economic studies have evaluated the potential costs of stringent information requirements with "contains" in US, Canada, Argentina, Australia, or China (Kalaitzandonakes, 2004; JRG Consulting Group, 2004; Foster & Galeano, 2006; Huang, Deliang, Yang, Rozelle, & Kalaitzandonakes, 2006). These studies report that even with the most efficient trade commodity system, because particular GM events are currently commingled in trade shipments, stringent information requirements for GM commodity shipments would be highly costly for both exporters and importers of the main current GM commodities and potentially other grains.

Thirdly, labeling remains a sensitive issue in the context of the WTO. In addition to the General Agreement on Tariff and Trade (GATT), the Agreement on the Applications of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barrier to Trade (TBT Agreement) are at the heart of the question of the legality of GM food regulations (Sheldon, 2002). First, the SPS agreement provides rules related to safety regulations, but its application to labeling could be limited since most countries justify labeling as a consumer regulation rather than a safety regulation.[4] Secondly, the TBT agreement concerns domestic regulations that may be involved for other societal goals (Josling, Roberts, & Orden, 2004). The TBT agreement would likely rule if the importer raises technical standards or regulations (such as labeling) that

are not directly related to safety or whose purpose is not related to safety, but that still may be trade distorting (Morgan & Goh, 2004).

The TBT agreement includes two main clauses relevant to the case of mandatory labeling of GM food (Heumueller & Josling, 2004). First, Article 2.1 restates the main principles of the GATT agreement with regard to 'national preference' treatment and 'most favored nation' treatment. Imported products "*shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.*" The main point of contention on this article relates to the definition of 'like products,' which could be based on end product differences or on consumer preferences. Secondly, Article 2.2 of the TBT provides conditions under which a technical regulation is allowed for WTO members; it mainly requires two conditions: a broadly defined legitimate objective and the absence of any other less trade-distorting measures that could achieve the same objectives. For the case of labeling requirements, the interpretation would depend on the legitimacy of a specific labeling requirement, on its importance, and visual effects to achieve the objective as compared to other measures (such as voluntary labeling for the objective of information provision). Heumueller and Josling (2004) argue that the TBT may rule for or against the labeling requirements, depending on the interpretation of this agreement.

In the absence of Codex standards on GM food labeling that would be recognized as a reference by the WTO, each national labeling regulation would have to be evaluated individually to assess whether or not it is consistent with WTO obligations. Yet, existing studies and past evidence suggest the following two points. First, process-based labeling requirements, i.e., mandatory labeling regulations that apply to highly processed products without significant traces of GM, are more likely to be at risk of being found inconsistent with the WTO. The US government has announced several times that it was considering launching a WTO dispute against the labeling and traceability regulation of the EU. A ruling on such a dispute would create a precedent on the question of the legality of mandatory labeling requirements based on production process and methods, and could apply to other countries with process-based labeling requirements. Secondly, the Cartagena Protocol's potential future requirements with "Contains" and lists of particular GM events may also be found inconsistent with the WTO. In particular, non-members of the Protocol, that are exporters of GM commodities could launch a dispute against a Protocol and WTO member with stringent information requirements for traded commodities.

Lessons Learned: the Indian Draft Rules in the International Context

Established in March 2006, the Indian Draft rule 37- E includes a definition of genetically engineered or modified foods and the following provisions: (a) that mandatory labeling will be required for all primary or processed foods, food ingredients, or food additives derived from a GM food; (b) labels must indicate that the food has been subject to genetic modification, and; (c) labels for imported GM foods must indicate that the food has been approved for marketing in the country of origin (see Appendix). We will examine each of these provisions in light of our international analysis.

Provision (a): Labeling of all GM Food Products

First, draft rule 37-E proposes labeling requirements with a very comprehensive product coverage. The proposed standard would rank India's regulation among the most stringent GM food labeling policies in the world. Provision (a) of the rules requires labeling for "GM food, derived there from, whether it is primary or processed or any ingredient of food, food additives, or any food products that may contain GM material…without any exceptions." In addition, the definition of genetically modified food (provision (i)) states that "food and food ingredients composed of or containing genetically modified or engineered organisms…or food and food ingredients produced from but not contained genetically modified or engineered organisms." In view of these two quotes, the requirements would include ingredients derived from GM and/or that may contain GM material.

Thus, the requirements would apply to all highly processed products such as crude or refined soybean oil or cottonseed oil. Oil produced with GM soybeans may contain very minimal shares of GM material, which can in some cases be detected, but not quantified at a level of statistical significance. More specifically, crude oil may contain proteins with traces of transgenic DNA while refined oil does not (Chandrashekhar, 2006). The

4. *When introducing labeling, many WTO members only notified the TBT, while several countries notified both the SPS and TBT, and China only notified the SPS (WTO, 2006). Therefore, even if we do not provide details here, mandatory labeling policies in certain countries could also be challenged under the SPS Agreement.*

question then becomes whether meat and animal products (e.g., milk from animals fed with GM cottonseeds) would also be required to be labeled. Even if they do not include animal products, the draft rules, by including products derived from GM ingredients, are similar in nature to the EU rules. Hence, they are much stricter than the Australian, Japanese, or South Korean labeling requirements, and thus will likely be more expensive and more difficult to implement than the ones of these developed countries.

Provision (b): Labeling Information Content

Secondly, like in all other labeling countries, the labeling specification (clause (b)) only refers to the displaying of the words 'genetically modified,' not to the fact that the GM material has been approved by the governing body. This is arguably regrettable, because the information content remains limited and might act as a hazard warning signal to uninformed or partially informed consumers. In developed countries, consumers' negative perception of GM food, reinforced by this imprecise information, triggered a rapid reaction by the main market actors, who preferred to avoid GM ingredients in order to escape the negative publicity associated with GM labeling requirements. Such a situation might occur for India's packaged food products, thus resulting in a 'no GM' versus 'non-GM' choice for consumers, imprecise information, and likely higher food prices.

Provision (a) and (c): Labeling Imported GM Commodities

Thirdly, the draft rules require labeling for all GM food imported (as part of requirements under provision (a)), and that in addition (provision (c)) those imported food should say that the GM foods have been approved for marketing and use in the country of origin. To our knowledge, no other country explicitly asks for that second requirement, but it may not be as much a burden for the exporter as the requirement to label GM products. In fact, except during cases of gene escapes (Ledford, 2007), all GM food products exported have already been approved in the exporting country, and it is highly unlikely that a country would permit the production of a GM crop not approved for domestic consumption but only designed for export markets. Hence, we raise issues and concerns regarding the application of provision (a) to imported commodities, not the additional requirement under provision (c).

Provision (a) applies to both domestic and imported commodities, consistent with the General Agreement of the WTO. But the draft rules, like the regulations of the EU, could potentially be disputed at the WTO under the TBT agreement. In the current trade context, India is reportedly mostly importing soybean oil derived from GM soybeans, and all these imports will be subject to the labeling. At the same time, at the domestic level, there are no GM soybeans, and only cottonseeds derived from Bt cotton and oil derived thereof, whether packaged or not, would have to be labeled. Cotton does not represent a large share of total food budget. As a consequence, these labeling rules could be seen by the exporter as an effective non-tariff barrier to trade. Recent press articles from industry observers (Low, 2006; Chandrashekhar, 2006) explained that India was trying to find ways to increase the domestic price of oilseeds, and one observer even reported that GM labeling was advanced as an indirect way to protect the domestic market for edible oils in the long run. Furthermore recent discussions on GM labeling in India focused on imported soybean oil, not domestic cottonseed products (Sharma, 2007). This type of argument suggests that if an exporting nation's oilseed industry was significantly affected by the loss in trade, it could launch a WTO dispute with a convincing claim against India. Furthermore, unlike in the EU, there is no compelling evidence to date that the introduction of GM food labeling requirement in India responds to any type of overwhelming consumer demand.

Moreover, recent developments do not lead one to believe that an international standard will be agreed upon for GM food labeling anytime soon. The Codex Committee on Food Labeling is not making progress after 14 years of debate on GM food labeling, and almost decided to drop the issue altogether. As a result, there is no standard at the international level. The Biosafety Protocol, which includes a clause on information requirements for traded LMO-FFPs, is also facing difficulties to approve a single harmonized rule, because of international differences. The latest compromise of a two option rule, while being unstable, might be the most advanced possible rule, balancing the demand for strict requirements by some Protocol members with the reality of potential costs of implementation for exporters and importers. Besides, even if the Protocol adopted strict labeling requirements, they would not justify the use of stringent labeling rules for consumer products, and would definitely not justify labeling for imported processed products (that are not living modified organisms), particularly those that do not contain GM material such as soybean oil.

General Comments: Economic Effects and Missing Elements

Fourth, there is no explicit threshold level for labeling in the draft rules. This can be interpreted in two ways. First, from a strict interpretation of the provision "any GM material," the regulation would apply at the 0% level. Secondly, the threshold level might be the subject of an amendment to the draft rules to be formulated in the near future. The level of detection (i.e., a 0% level) is the official, but likely unapplied, standard of China. This level means that any trace element, even if not detectable, in any food product should trigger a labeling requirement. Practically, assuming perfect enforcement, in a global market with commingled trade commodities, a 0% level would result in the fact that *all products derived from traded commodities* (maize, soybeans, canola, cottonseed, and other main grains such as wheat, barley, or even rice) would have to carry a GM label. In countries with GM crops and well integrated marketing systems for commodities, such as the US and Canada, perfect separation at the 0% level is considered impossible. Even the EU, which has the most stringently implemented standard, is at 0.9%. Thus, the Indian rules should clearly indicate a threshold level, taking into account the practical consequences of a zero-percent threshold level.

More generally, we acknowledge that it is difficult to predict the precise economic effects of the proposed GM labeling regulations simply based on our comparison of regulations. But our review demonstrated that the benefits of labeling, both in terms of consumer information and consumer choice, can be elusive because of the economic incentive structure for food industry participants, the role of anti-GM campaign, and consumer perceptions. Nonetheless, Indian consumers may be indifferent to GM, the industry may not be reactive, and the labeling might end up as a commonality for all packaged products. More research is needed to evaluate the expected effects of labeling on packaged and unpackaged food in India.

In terms of costs, previous studies in developed countries with industrialized food sectors suggest very significant costs, from US$1 to US$10 per capita per year, or more than 10% of manufacturing costs, which could amount to billions of dollars for India. However, it is clear that the industry structure and consumer response to price could be different in India. Three factors will drive the cost of implementation: first, the applied threshold level (a lower level raises costs); second, the degree of enforcement due to the need of testing facilities, experienced personnel, and whether or not the requirement applies to highly processed products, requiring a traceability system that goes back to the production farm; and third, the number of GM food varieties produced domestically. This last factor will likely be critical. Most countries that are producing GM food or feed have rejected mandatory labeling because of the costs of implementation and because of the market disadvantage it gives to products derived from transgenic crops. While Brazil both commercially produces a GM food or feed crop (GM soybeans) and has mandatory labeling, the labeling regulation has yet to be implemented. Spain produces GM maize only for animal feed, which has to be labeled, but labeling does not apply to animal products in the EU.

With such rules, if India intends to commercialize GM food crops in the near future, such as rice or brinjals (eggplants), all products from these crops would have to be labeled, and would potentially suffer from a discounted market price if consumers perceive the information as a hazard warning, or if labels are used by anti-GM groups. As a result, either GM producers would try to market their products without a label (illegally), or they might prefer to switch back to conventional non-GM food. Such an evolution would greatly reduce the returns from research and development for future GM food crops in the private and public sectors.

Concluding Comments

Existing evidence from *developed* countries shows that while mandatory labeling regulations have failed thus far to demonstrate any visible benefit in terms of consumer choice and consumer information, they have contributed to the disappearance of GM food ingredients in targeted products. At the same time, there is a general lack of evidence on the effects of GM food labeling requirements in *developing* countries, as most of these countries have not fully implemented their national regulations. Existing cost studies on labeling requirements in countries with industrialized food sectors suggest very significant market costs of implementation.

India's proposed labeling rule for GM food is among the most stringent globally due to its extensive coverage. More specifically, it includes all highly processed products derived from GM crops, even without detectable traces of transgenic material. The proposed labeling content only refers to genetic modification, not to the fact that the GM material has been approved by the governing body or any other useful information. Furthermore, no other countries require the display of

information regarding the approval status for marketing and use in the country of origin. The requirement to label all imported products derived from GM may result in significant international legal challenges.

In our review of international agreements, we note that not one of the relevant international agreements explicitly authorizes or supports labeling requirements for imported food products containing, or derived from, GM crops, as included in the Indian draft rule. Instead, there is a risk that such process-based labeling of GM food would be found inconsistent with WTO obligations. Lastly, there is no explicit threshold level for labeling in the draft rules. In the current world trade system, a 0% threshold level would result in labeling of all food produced from potentially GM commodities.

On the basis of this analysis and in view of existing evidence, we would like to make the following two assertions. First, India's proposed regulation could lead to increased price for consumers, potentially lower revenues for small producers, and large implementation costs. Other developing countries, often with more concentrated and industrialized food marketing systems, have had difficulties enforcing less stringent labeling regulations. This suggests that the proposed rule risks being unenforceable in India. Secondly, international experience with GM food labeling also suggests that political pressure groups may capture labeling regulation, thus resulting in no consumer choice or information.

Still, it is noted that these conclusions on the potential effects of GM labeling are based on observations from other countries, not from India. Consequently, our main recommendation is to conduct more applied research and analysis on the potential effect of this and other labeling options for GM food in India before making any decision on this complex issue. More studies are needed in order to choose the best rule responding to India's political objectives. Such effort could lead to a discussion of the issues at stake in the presence of all relevant stakeholders that will be directly affected by the potential regulations.

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Appendix: Indian Draft Rule

Excerpt from the Draft Rules to Amend Prevention of Food Adulteration Rules, 1955.

1. These rules may be called the Prevention of Food Adulteration (……. Amendment) Rules, 2006.
2. They shall come into force on the date of their final publication in the Official Gazette.
3. In the Prevention of Food Adulteration Rules, 1955 (hereinafter referred to as the said rules) after rule 37D, the following shall be inserted, namely,

i. **"37- E Labeling of Genetically Modified Food** – Genetically engineered or modified foods means food 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; In addition to the labeling provisions as prescribed under these rules, the genetically modified food shall also conform to the following labeling requirements:

a) a GM food, derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall be compulsorily labeled, without any exceptions;

b) the label of all package (s) of GM food(s) or foods containing ingredients, derived from biotechnology or bioengineering or food additives or any food product that may contain GM material shall indicate that they have been subject to genetic modification. These provisions will be applicable to all such products both imported or domestically produced; and

c) the label of imported GM food or derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall also indicate that the product has been cleared for marketing and use in the country of origin so that the verification, if needed can be taken up with that country without having to resort to testing."