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An Analysis of Trade Related International Regulations of Genetically Modified Food and their Effects on Developing Countries

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ABSTRACT

This paper reviews current trade-related regulations of genetically modified (GM) food and discusses their effects on developing countries. There is a large heterogeneity in current import approval and marketing policies of GM food worldwide. At the international level, the harmonization efforts are led by the Codex Alimentarius Commission, the Cartagena Protocol on Biosafety and the World Trade Organization. While internationally harmonized guidelines for safety approval have been finalized, we show that there is no clear consensus on labeling regulations for GM food, and there is an increasing risk of conflicts among international agreements. We analyze the GM food regulations of two large rich importers, Japan and the European Union (EU) and discuss their differences and their potential impact on international trade. We also show that the effects of international and domestic trade related regulations critically depend on the type of traded products and their intended use: food and unprocessed products are subject to more stringent regulations than animal feed and processed products. Finally, we identify the main spillover effects of national and international regulations on developing countries' policy making, and suggest four policy arrangements on GM food to enable developing countries to satisfy production, consumption, international trade, and risk management objectives simultaneously while complying with their international obligations.

Key words: Genetically modified food, Labeling, Biosafety, Non-tariff barriers to trade, Developing countries.

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An Analysis of Trade Related International Regulations of Genetically Modified Food and their Effects on Developing Countries

Guillaume P. Gruère

1. INTRODUCTION

Ten years after its first products, agricultural biotechnology has allowed significant agronomic improvements of some of the major field crops traded internationally (soybeans, cotton, maize and canola). In 2005, transgenic crops, also called genetically modified (GM) crops, were grown in seventeen countries by an estimated 8.5 million farmers on a total acreage of 90 million hectares (James 2005). The fact that so many farmers are now planting GM crops and that the total area in these crops is increasing annually (e.g. 11 percent increase in area between 2004 and 2005) is an evidence of the commercial success of this production technology.

However, there are only four GM crops widely produced, and these four crops are mostly used for animal feed or non-food uses,¹ whereas no major transgenic “food” crop has been released yet.² If the number of GM “food” crops in the regulatory pipeline of many countries has been steadily increasing in the last five years, ranging from fruits and vegetables to major field crops such as wheat and rice, only a few transgenic “food” crops were officially approved and produced at a small scale (GM papaya and sweet corn in the United States, GM white maize in South Africa, and GM rice in Iran).³ In addition, only five large countries represent the overwhelming majority of GM crop acreage (Argentina, Brazil, Canada, China and the United

¹ Approximately 65 percent of maize and 71 percent of soybean supply is used for animal feed; cotton is mostly used for textile and cottonseed is mostly used for animals.

² The quotes for “food” put the emphasis on the fact that these crops are mostly used for human consumption. In contrast, in the article, we will use the generic term GM food without quotes for raw and processed products derived from GM crops and used for food and/or animal feed.

³ Iran has reportedly released transgenic rice and it has been planted at a small scale in 2004 (Aglay 2005).

States represent over 96 percent of GM crop acreage). These limitations reflect the other side of the economics of GM crops; the demand side and the effects of GM food regulations.

Due to consumer, environmental, ethical or political reasons, many countries have adopted stringent regulation regarding the approval and the marketing of food and feed products derived from GM crops. Some of these regulations (such as labeling requirements or import approval), associated with the relative lack of demand in rich importing countries for GM products have offset the economic productivity gains of GM food crops to the point of making them potentially unprofitable for developers, large producers and exporters of these crops. In particular, GM wheat was developed in the United States, but was shelved by the Monsanto in 2004 before commercialization, partially because it lacked the full approval of producer associations from U.S. and Canada who reportedly feared to lose export markets (Berwald, Carter, and Gruere forthcoming).

In fact, international regulations of GM food vary widely among developed countries. In particular, the European Union and the United States have adopted different approaches on the marketing of genetically modified food. The EU regulations follow an approach based on the “precautionary principle” and consumers’ “right to know,” with stringent approval, labeling and traceability standards on any food produced from or derived from GM ingredients. In contrast, the U.S. regulation approach is based on differences in the end product, and includes a voluntary safety consultation and voluntary labeling guidelines for GM food.⁴ Most other developed countries, including Japan, Canada, or Australia have introduced intermediary regulations between these two (Carter and Gruère forthcoming).

⁴ However, the voluntary safety consultation de facto Acts as a mandatory safety approval because all four comply with it (See Section 2).

⁵ Regarding labelling, non-substantially equivalent GM foods have to display the difference with conventional products, but there is no labeling requirement related to the fact that they were produced with genetic engineering.

In the developing world, some of the large agricultural traders (such as Brazil) have developed biosafety and marketing regulations on GM food, but at the same time many other developing countries have not adopted any specific regulation of GM food because they lack the capacity to do so, or perhaps they have adopted a position of wait and see. One of the reasons advanced by these latter countries is that the introduction of any GM crop and the implementation of any particular regulations may have a direct effect on their current and future agricultural exports to countries with stringent regulations (Zarrilli 2005). With the increasing globalization of agriculture, some of them prefer to observe policies implemented in other countries and the development of international harmonized regulations before deciding what set of regulation they should adopt.

At the international level, two main institutions have worked in an effort to provide harmonized regulations on agricultural biotechnology: the Cartagena Protocol on Biosafety, which is part of the United Nations (UN) Convention on Biodiversity, and the Codex Alimentarius Commission, under the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO). In addition, discussions over the regulation of agricultural biotechnology has arisen at the World Trade Organization (WTO) as the United States, Argentina and Canada launched a trade dispute against the alleged EU moratorium on approval of new GM crops in 2003. U.S. observers believe that another trade dispute may follow on the strict traceability and labeling requirements replacing the moratorium in the EU since April 2004.

The objectives of this paper are first to analyze current trade related national and international approval and marketing regulations of GM food, and second to identify the effects of these regulations on developing countries' policymaking. Our review of policy is limited to

trade related regulations of GM food. We deliberately exclude biosafety regulations concerning the planting and environmental release of GM crops except if they are likely to affect international trade. We define GM food as raw and processed products derived from GM crops and used for food and/or animal feed. These products represent an average trade value of \$42 billion/year.⁶ Since there is no trade related regulations on non-food or non-feed products from GM crops (e.g, cotton fibers derived from GM cotton, or ornamental GM plants), regulations considered in this article do not apply to them.

The paper is organized as follows. In the next section, we offer a general overview of current approval and food labeling policies worldwide. In the third section, we present current and pending regulations of the Codex Alimentarius Commission, the Cartagena Protocol on Biosafety and at the WTO. In the fourth section, we review the regulations of two large importing regions (the European Union and Japan) and we discuss the effects of these regulations on international trade. In the fifth section, we classify all the reviewed trade related regulations according to the type of products they affect: raw versus processed GM products and those affecting products used for food versus animal feed. In the sixth section, we identify the main effects of international regulations on developing countries, and draw lessons from our review of regulations to analyze what should be done to find adequate policy response for developing countries under these constraints. We conclude this paper by drawing policy lessons and identifying future areas of research.

⁶ Measured as import value; for details and source of data, see Table 3 in Section 3.

2. OVERVIEW OF NATIONAL TRADE RELATED REGULATIONS OF GM FOOD

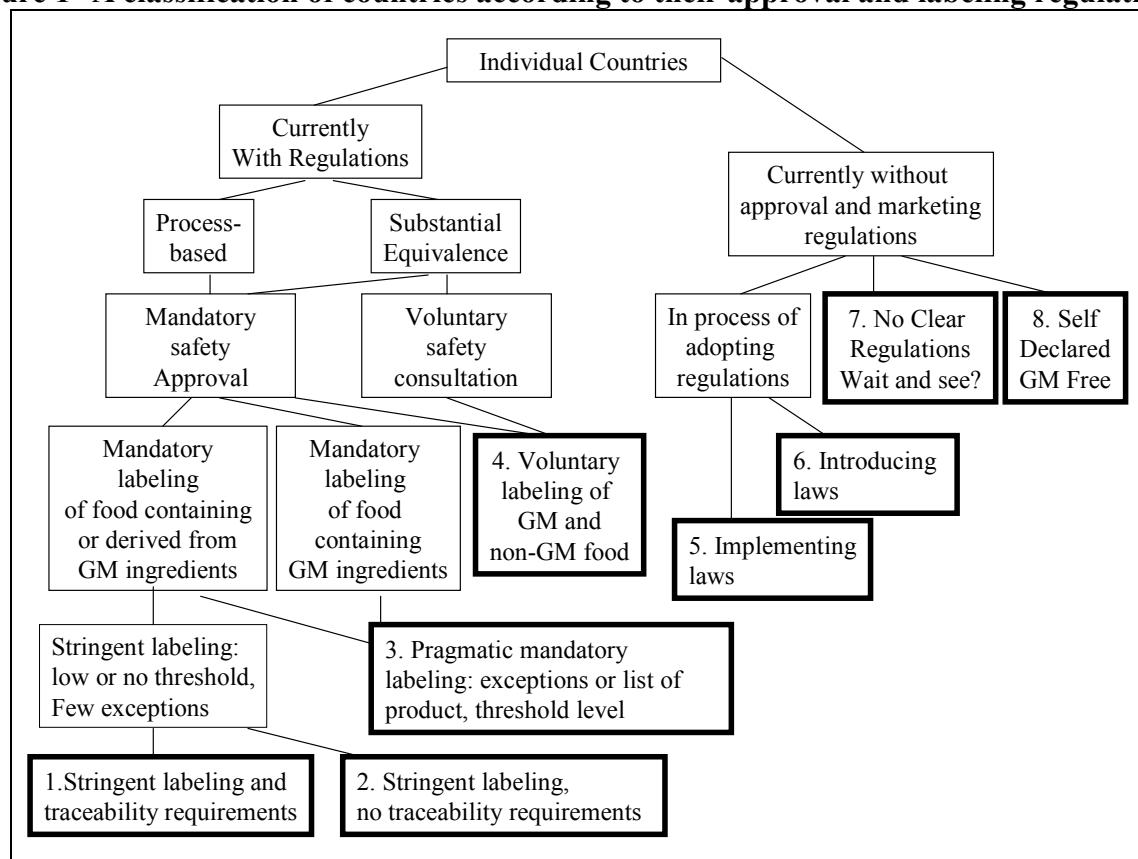
Trade related regulations of GM food include import approval measures and marketing regulations. More specifically, unlike in the case of conventional commodities, exported GM food is subject to specific import approval procedures or complete bans in many countries, labeling requirements in an increasing number of countries, and traceability requirements in a few countries. Import approval is a direct measure affecting market access, whereas labeling and traceability indirectly affects trade through the imposition of the cost of implementation for exporters of GM crops. In addition, marketing regulations can affect the demand for GM versus non-GM crops; for example, GM food labels can act as perceived hazard warnings and reduce demand for these crops despite their approval from food safety authorities.

In 2005, ten years after the introduction of the first GM crop, there is large heterogeneity across nations in the regulations of GM food. At a macro level, countries can be divided into three groups according to the status or type of their regulations (Zarrilli 2005): first, countries with a comprehensive and stringent regulatory framework applied to GM food, including mandatory safety approval and mandatory labeling; secondly, countries that have adopted a more pragmatic regulatory approach based on the notion of substantial equivalence with voluntary labeling instead of mandatory labeling for GM food; and third a large number of countries either without regulations or pending towards adopting certain regulations on GM food approval and marketing. Currently, developed countries are in the first and second group, while most developing countries are in the third group, with a few notable exceptions. The distinction between voluntary and mandatory labeling is important, because it drives a number of necessary regulatory requirements. Mandatory labeling requirement affects the whole agro-food channel from the retailers to the producers requiring them to acquire and transmit information about the

presence or origin for each food product, whereas voluntary labeling is driven by private incentives and the presence of market niches for non-GM food.⁷

Even within these groups, the regulatory process from approval to commercialization varies widely across individual countries. Figure 1 presents a schematic decision tree of countries according to their approval and marketing regulations.

Figure 1--A classification of countries according to their approval and labeling regulations



At the first level of division, countries may or may not have adopted any type of approval or marketing regulation on GM food. Then among the ones with regulations, there are two main groups of countries, the ones that rely on a test of substantial equivalence (substantial equivalent products are exempt from specific requirements) and the other who generally do not and whose

⁷ For more information on an economic comparison between voluntary and mandatory labeling, see Runge and Jackson (2003) and Carter and Gruere (2003).

regulatory procedure depends on the production process (which means that any food produced with or derived from transgenic crop is subject to GM food regulations). Each country has also adopted its set of safety approval and labeling policies with specific characteristics. As shown in Section 4, the specificities of the labeling regulation largely determine the observable effects of regulations on international trade. More stringent regulations will generally require more costly procedures on behalf of exporters and more comprehensive policies may have a more important trade effect. On the other hand, countries with no specific regulations include those that are about to adopt approval or marketing regulations, the ones with no clear regulations, and the ones that have declared themselves GM free. A subdivision in Figure 1 separates countries that are in the process of introducing regulations from the ones about to implement regulations of GM food.

At the end of the division tree in Figure 1, countries can be divided into eight categories or groups (defined by their eight terminal boxes) according to their regulatory framework. Table 1 presents example of countries in each of these eight groups. OECD countries are represented in the first four categories (except Mexico and Turkey), and several countries with transition economies (such as Brazil or China) are also located in these four categories.

Table 1--Characteristics of group and examples of countries in each group

	Food safety approval regulations	Labeling regulations	Specificity	Countries
Group 1	Process based mandatory	Stringent mandatory Includes derived products	Traceability requirements, 0.9% threshold	EU, East Europe
Group 2	Process based mandatory	Stringent, mandatory, includes derived products	No traceability, low threshold	Brazil, China, Russia, Switzerland, Norway
Group 3	Process based mandatory	“Pragmatic” mandatory	Many labeling exceptions	Australia, Japan, Korea, Saudi Arabia, Thailand
Group 4	Substantial equivalence, mandatory (US: voluntary consultation)	Voluntary for substantial equivalent food	5% threshold level for labeling	US, Canada, Argentina, South Africa, Taiwan
Group 5	Mandatory (in place or pending)	Mandatory, introduced but not implemented	“Pragmatic” labeling requirements	Indonesia, Malaysia, Mexico, Philippines, Vietnam,
Group 6	Mandatory (in place or pending)	Intention to require labeling	Slow regulatory process	India, Kenya
Group 7	Considering mandatory	No clear position	Wait and see approach	Bangladesh, most African countries
Group 8	No	No	GM free	A few African countries (Zimbabwe, Zambia)

All these countries have adopted specific regulatory framework for GM food and other products derived from GM crops. In contrast, most developing countries are currently in groups 5 to 8, because they are either without or in the process of adopting specific trade related regulations of GM food.

The large producers and exporters of GM crops have well defined regulations, but most of them are in Group 4 (Canada, United States, Argentina, South Africa), with pragmatic regulations of GM food, while the last two are in Group 2 (Brazil and China), with stringent regulations. In contrast large importers of these crops are in Groups 1 and 3 with relatively more

stringent regulations. More specifically, Table 1 shows the level of stringency differentiating national regulations or approaches. Most groups of countries have adopted, are about to adopt or intend to adopt mandatory safety approval regulations of GM food. The United States is a particular case; it has a voluntary safety consultation that is de facto considered a mandatory requirement, because all companies comply with it for liability reasons. But different groups have distinctive approaches on labeling of GM food. As argued in the following section, this reflects the level of success of international harmonization efforts: international convergence on specific requirements for safety approval and important divergences among countries with regulations on labeling and traceability of GM food.

To sum up, this overview of national regulations reveals that there is a large heterogeneity in regulations among countries, first in terms of development stages of regulatory framework, and second between countries with well defined regulations. Developed countries differ in their general approach of regulations, with most GM producers and exporters in groups of pragmatic regulations while importers tend to have more stringent marketing regulations for GM food and GM derived products. Developing countries tend to have fewer regulations in place. We will now review the major international efforts to harmonize policies on approval and labeling regulations of GM food.

3. INTERNATIONAL HARMONIZATION EFFORTS

There are six international organizations directly or indirectly involved in setting up harmonized rules, standards and recommendation related to international trade in GM crops (Smyth et al. 2004). Table 2 reviews these institutions coverage, membership and orientation.

Table 2--International institutions involved in the regulation of international trade of GM crops and GM food

Institution	Coverage	Member States (5/2005)	Dispute Settlement Mechanism	Role
International Office of Epizootics (1924)	Infectious animal disease	167	Non-binding; sets WTO	Harmonizes trade regulations for animal and animal products
			standards	
GATT/WTO (1947/1994)	Trade in goods and most services	148	Binding	Sets rules for transparency and dispute settlement
International Plant Protection Convention (1952)	Pests and pathogens of plants and plant products	136	Non-binding; sets WTO standards	Sets international standards for plant
OECD (1961)	Harmonization of international regulations, standards and policies	30	None	Writes consensus documents and international data
Codex Alimentarius Commission (1972)	Food labeling and food safety standards	170	Non-binding; sets WTO standards	Sets international standards and recommendations
Biosafety Protocol (2003)	Transboundary movements of GM organisms	120	None	Information sharing and biosafety measures

Source: Smyth et al. (2004) page 80, and institutions' websites.

Among these six institutions, three only have an indirect role in the regulation of the products of agricultural biotechnology. The International Office of Epizootics and the International Plant Protection Convention are based on multilateral treaties that provide standards on the movement of animal and plant pathogens, respectively. Even if they have standards that may apply to living modified organisms,⁸ they do not have specific rules on GM food. These institutions may affect international trade because their standards are recognized as reference standards by the Sanitary

⁸ In particular the IPPC has a particular standard (ISPM 11) providing guidance on risk assessment for living modified organisms.

and Phytosanitary (SPS) Agreement of the WTO. If a country follows an IPPC or IOE standard it is presumed to be in compliance and not adopt other standards. Countries can use other standards but under SPS rules they have to make a case for their standard on the basis of risk. The third organization is the Organization for Economic Cooperation and Development (OECD). The OECD develops documents, guidelines and recommendations on harmonized rules, policies and standards on agricultural biotechnology for its members. Because the EU and the United States are members of the OECD, any recommendation on how to regulate biotechnology approved in this forum may influence future international decisions in other institutions.

The three other institutions, namely the Codex Alimentarius, the Biosafety Protocol and the WTO are directly involved in trade related issues and the regulations of the products of agricultural biotechnology. We will present their specific harmonization efforts in the next three sections.

UN FAO/WHO CODEX ALIMENTARIUS

The Codex Alimentarius is an inter-governmental organization managed jointly by the United Nations Food and Agriculture Organization and the World Health Organization. The Codex has two main purposes 1) to protect the health of consumers and 2) to promote fair practices in international trade (Kimbrell 2000). The Codex provides international recommendations and standards based on a consensus among members. The Codex standards and recommendations are important for international traders, because they are recognized as reference standards of food safety in the Sanitary and Phytosanitary Agreement of the World Trade Organization.

The Codex Commission has been working on finding a common terminology, a common food safety approval procedure, and a common position on the labeling of GM food since the

beginning of the 1990s. The Codex Commission has published guidelines for the safety assessment of GM food, but it failed thus far to reach any agreement on the issue of GM food labeling.

On questions related to food safety, the Codex Commission reached an official agreement, which resulted in the publication of the following three documents in 2003:⁹

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology: This document lays up a framework of analysis, with the following steps:
 - **Risk assessment:** it should be based on a comparison of the new food with the conventional food;
 - **Risk management:** it should take into account the level of risk and the uncertainty associated with it, and may include labeling and post-market monitoring;
 - **Risk communication:** it is necessary to assure the transparency in the system;
 - **Consistency:** the risk analysis for these particular products should be consistent with other risk analysis;
 - **Capacity Building and Information Exchange:** this part underlines the necessity for the parties to help developing countries to build a regulatory capacity, and should be encourages to share information
 - **Review Process:** the risk analysis should be reviewed after a certain period to account for new scientific knowledge and technologies.

⁹ See Codex Alimentarius (2003a;2003b;2003c).

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: This document proposes a framework for food safety assessment, largely based on the principle of establishing substantial equivalence between the GM product and its conventional counterpart. It recommends to proceed with the following steps:
 - Description of the recombinant-DNA plant;
 - Description of the host plant and its use as food;
 - Description of the donor organism(s);
 - Description of the genetic modification(s);
 - Characterization of the genetic modification(s);
 - Safety assessment:
 - expressed substances (non-nucleic acid substances);
 - compositional analyses of key components;
 - evaluation of metabolites;
 - food processing;
 - nutritional modifications; and
 - other considerations.
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms: This document proposes a framework for the safety assessment of GM organisms following the same general scheme as the guideline for GM food. It adds two steps to the safety assessment: first an assessment of viability and residence of microorganisms in the human gastrointestinal tract, and secondly an assessment of antibiotic resistance and gene transfer.

The international consensus on risk assessment of safety of GM food reflects the similarities between existing approval procedures across major trading countries. In particular, the mandatory safety assessment in the European Union, Japan, Korea, Canada, Australia and New Zealand and the voluntary safety assessment guidelines of the U.S. Food and Drug Administration all prescribe to follow a framework based on these different steps. The main differences of approval procedures among these developed countries appear at the risk management level.¹⁰

In contrast, on the labeling of GM food, there is no agreement within the Codex and the effort of the Session on Food Labeling seems to be stopped. No formal standard has been adopted on labeling. There are 8 steps to follow in the setting of Codex standards (MacKenzie 2000), from the decision to elaborate a standard (Step 1) to the point where the draft standard is adopted by the Codex Alimentarius Commission and sent to governments for final acceptance (Step 8). After eleven years of discussions within the Codex Committee on Food Labeling, the draft guideline on the labeling of GM food remains at Step 3: the proposed draft standard is sent again to international organization and governments for comments.

In 2004, at the 32nd Session of the Codex Committee on Food Labeling, only the amendment *Definition of Terms* of the General Standard for the Labeling of Prepackaged Foods, which is directly related to the labeling guidelines, was advanced to Step 7 of the Procedure. But the actual “*Proposed Draft Guidelines for the Labeling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modifications/Genetic Engineering*” remained at Step 3 of the Procedure in 2005.

¹⁰ We detail the specific steps for the EU and Japan in Section 4. For more detail on the other countries’ procedure, see Carter and Gruère (Forthcoming).

The labeling provisions of the draft guidelines (section 3) include the following recommendations:

- 3.1. Labeling should be required to GM food that is not substantially equivalent;
- 3.2. Labeling should be required for GM food that contain allergens;
- 3.3. Labeling should be required for substances with physiological or metabolic impacts;
- 3.4. Where label indicate 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 three first provisions (3.1, 3.2 and 3.3) are supported by virtually all active members of the Codex Commission. They recommend labeling requirements for GM food with significant changes in product characteristics. In contrast, article 3.4. is 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 detectable GM ingredient in the final product.

The United States, Canada, and others are opposed to this latter recommendation, because they consider that it has no information related to food safety (since all commercialized GM food would have passed the safety assessment), which means that it has no place in the Codex Alimentarius, and that such labeling products under this rule may act as a warning effect on consumers. While others, including, the EU, Switzerland, Brazil, India, and Cameroon support this clause, because they see it as a response to a strong demand for information from consumers. They agree that this labeling clause is not related to food safety but to consumer

information, and they refer to other work of the Codex Committee on Food Labeling on the issues of country-of-origin labeling and organic food labeling.

The draft guidelines also include a provisional section on the necessity to set up a threshold level for adventitious presence of GM food, and a section on exemptions for labeling provisions 3.4 and 3.5, letting countries decide whether or not to require labeling on certain specific GM food products (such as oils and other highly processed products). The sixth section provides recommendations on text declarations for labeling based on product characteristics (i.e., under provisions 3.1, 3.2, and 3.3) and labeling based on the method of production (under provisions 3.4 and 3.5). The last section proposes to consider rules of implementation and enforcement (such as testing standards and traceability).

During the 32nd Session of the Codex Committee on Food Labeling in 2004, countries did not reach any type of agreement, and failed to make progress on the labeling guidelines. Some countries (such as Canada) said they would like to split the text of the guidelines into two parts, one with labeling provisions related to changes in the product and health and safety related labeling (sections 3.1, 3.2, and 3.3) and the other with labeling based on methods of production (sections 3.4 and 3.5). They argue that the first part would quickly advance in the Codex approval Procedure, because there appears to be a consensus on this issue. But other countries (such as the EU and the United States) would prefer to keep the text together. In addition, there was no consensus on setting up a new taskforce to help advance in the labeling issues.

During the 33rd Session, in May 2005 in Malaysia, the Codex Committee on Food Labeling discussed GM food labeling during a whole day. Once again, there was no simple consensus, but this time two clear groups of countries were identified. A group of thirty countries (including the EU, Japan, Brazil, Malaysia, India, Kenya, Indonesia, Switzerland, Norway, New

Zealand, Tunisia, Senegal, Swaziland, Panama, Turkey and Ghana) showed support for a standard including extensive labeling requirements for GM food and based on the adoption of sections 3.4, and 3.5 of the proposed guidelines. In a second group, seven countries (the United States, Mexico, Argentina, Thailand, Australia, and the Philippines) were in favor of the adoption of sections 3.1, 3.2 and 3.3 – related to GM products with substantial differences- and clearly opposed to the other two sections of the proposed guidelines. Given the significant difference between these two groups, the Chair of the Committee decided to form a Working Group whose task will be to “reconstitute” the proposed guidelines. In the current state of debate, this effort should help to separate clauses that gather support from the overwhelming majority of countries –those that require labeling on products that are not substantially equivalent- and that could be adopted easily, from clauses that remain contested- those that require the labeling of GM food products and products derived from GM ingredients- and that could be first accepted on a voluntary basis (BRIDGES 2005).

UN CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety was introduced in January 2000 as part of the United Nation Convention on Biodiversity in an effort to set up a harmonized framework of risk assessment, risk management and information sharing on the transboundary movements of Living Modified Organisms (LMOs). The Protocol entered into force on 11 September 2003, ninety days after receipt of the 50th instrument of ratification, but the Parties still have to decide a number of specific rules to implement it. GM organisms, GM seeds, and raw products from GM crops (used for food or feed) are considered LMOs. As shown in Table 3, unprocessed food (i.e., LMOs) represents over 60 percent of the total trade value of GM commodities (measured as

import value), at a total of about \$26 billion/year, in comparison with \$16 billion for processed products.

Table 3--Five-year average (2000-2004) world import value of raw versus processed products for major GM commodities

Total import value (\$ million)	Maize	Soybeans	Rapeseed	Cottonseed	Total four crops
Unprocessed (raw)	9,932	13,091	2,516	235	25,789
Processed	1,290	12,879	1,989	131	16,358
Share of unprocessed	87.9%	50.4%	55.8%	55.9%	61.2%

Source: Author's derivations, derived from UN Comtrader data base (HS 1996 classification).

In detail, the share of total trade value varies by crop; a very large share of maize is exported unprocessed, whereas roughly half of the soybean trade value comes from processed products (mainly soybean oil and soybean oil cake). In addition, the overall share of unprocessed food for these crops remained approximately constant between 2000 and 2004 (between 60.7 and 63 percent).

The key elements of the Biosafety Protocol (BSP) are the following (Secretariat of the Convention on Biological Diversity 2000). First, the BSP introduces an Advanced Informed Agreement (AIA) procedure between exporters and the importers of LMOs for intentional introduction into the environment (Art. 7). This procedure requires the exporter to provide an application with a comprehensive risk assessment and risk management file before the *first* entry of any particular LMO. In addition the BSP initiates a harmonized information sharing mechanism, the Biosafety Clearing-House, where all risk assessments and information should be reported. The BSP provides rules related to the bundling, transport, packaging and identification for any transboundary movement of LMOs (Article 18). The BSP also institutes a financial mechanism to provide support for the parties that cannot afford its implementation (Art. 22). Finally the BSP introduces liability rules in the case of illegal transboundary movements of LMOs.

In the context of international trade, Article 18 of the BSP allows importers of LMOs intended to be released in the environment to request information regarding specific GM content and varieties to the exporters, and obliges the exporters to conduct a risk assessment on any new GM crop. In addition, BSP parties may decide to ban imports of one or more GM crop variety as a precautionary measure. The BSP follows a precautionary approach, consistently with the Convention on Biodiversity, and was supported by the EU and other countries as what they consider a necessary procedure to protect human health and the environment from GM crops with unknown or non-quantified long term risks.

There are specific rules for LMOs intended for direct uses as feed, food or processing (noted LMO-FFPs). This group of LMOs represents about 90 percent of all movements of LMOs (Kalaitzandonakes 2004). Article 11 and Article 18.2.a. of the BSP provide the main set of rules for LMO-FFPs. These particular LMOs are not subject to the full biosafety assessment of Article 18 because they are not intended to be released in the environment. Article 11 suggests that importers use domestic regulations that are consistent with the objective of the Protocol. In the absence of domestic regulatory framework, Article 11 suggest as an option that developing countries ask exporters to provide a simplified risk assessment analysis before the first introduction, and decide whether or not to import it based on this assessment within a predictable timeframe, not to exceed 270 days. Many importing countries already have approval regulations for GM food, but if applied this article could extend the requirements for exporters of GM food to developing countries with no specific regulations. More importantly, under Article 18.2.a, parties to the BSP should request information from exporters regarding the presence and the identification of LMO-FFPs in any shipment before importation. At present, the BSP only requires exporters to notify the potential presence of LMO-FFPs in traded shipments by writing

that the shipment “may contain” LMO-FFPs. However, the definitive nature of the information requirements was not agreed, and a decision was expected in the Second Meeting of the Parties in Montreal, in June 2005.

However, no agreement was reached on the specific implementation of Article 18.2.a. during the Second Meeting of the Parties (May 30 to June 3 2005 in Montreal, Canada), and the issue was reported to the next annual meeting of the Parties to be held in Brazil in March 2006. In particular, BSP members could not agree on the degree of detail required to exporters and on the presence of a threshold level for the adventitious presence of GM crops without notification in non-GM shipments.

Despite the divisions and conflicts, the negotiations resulted in the writing of a draft decision by the Swiss Chair of the so called Working Group 1, which gathered support by all members except Brazil and New-Zealand. Under this proposed draft rules, there are three main propositions on documentation requirements:

1. If a country exports a shipment of non-GM with the possible (but unknown) presence of several GM varieties, the exporter would have to state clearly that the shipment “*may contain LMO-FFPs that have been approved in the Party of Import*,” to provide the list of possible GM crops with unique identifiers for each GM event possibly present in the shipment, and to check that it actually has the authorization to export all possible varieties.
2. If a country exports an explicitly known GM shipment (mix or single GM crop), the exporter would have to declare that the shipment “*Contains the following GM crops*” and provide a detailed list with unique identifiers for each GM event present in the shipment, and to check that it actually has the authorization to export all possible varieties.
3. If a country exports a non-GM shipment, the exporter would not be required to mention anything as long as there is no GM content over the possible threshold level decided by the importer.

Although the draft decision listed these three measures, the distinction between when to apply Options 1 and 2 is not well defined- it is based on intentional knowledge of the presence of

GM. It is more likely that BSP members will choose to apply either Option 1 or 2 to all shipments. For example, a second version of the draft decision was letting the importing country choose whether the exporter should be required to comply with Option 1 or Option 2 for any GM shipment. The main debate is whether the BSP should require Option 1 or Option 2 for all GM shipments, and whether there should be any mention of threshold level (Option 3).

Despite the potential cost they would likely bear with III or IV, importers without domestic regulations on GM (African countries, led by Ethiopia) are strongly opposed to scenario I and in favor of III or IV.

A recent study conducted for the International Food & Agricultural Trade Policy Council (Kalaitzandonakes 2004) showed that depending on the implementation rules, these regulations could impose a substantial cost on exporters and importers of the main GM and non-GM crops. Depending on the type of identification (may contain GMO, type of LMO, quantitative evaluation of each type of LMO), the report estimates annual testing cost between \$1 and 87 million per year for the U.S. and Argentina maize exporting industry, in countries where different types of GM and non-GM corn are commingled. Many other types of costs would be added to that. The report also argues that to enforce the agreement, the same level of expenses would be required for importers, and that developing countries would probably have to pay more to access the necessary technology and manage a team of expert measurement of LMOs. An earlier report done for the Canadian government (JRG Consulting Group 2004) estimates that information requirement costs for all crops would range between CAD 33 and 155 million per year (between \$28 and 124 million per year) for Canada, depending on the necessity to test non-GM traded crops (wheat and barley, adding CAD 67 million) and on Canada's decision to ratify the Cartagena Protocol on Biosafety (adding an estimated CAD 55 million).

WORLD TRADE ORGANIZATION

Unlike the two other international bodies presented in this section, the World Trade Organization (WTO) does not have any mandate on GM food regulations. The WTO's role in the context of international trade and agriculture biotechnology is directly related to trade distorting regulations. There is no specific article of the WTO Agreement related to agricultural biotechnology; however the general rules of the trade agreement are in question when biosafety and marketing regulations potentially act as barriers to trade. Many WTO country members have adopted different domestic regulations on the approval and the marketing of GM food and in the absence of international consensus and standards, the Dispute Settlement Body of the WTO can act as an arbitrator to resolve trade disputes among members.¹¹

Two WTO agreements are at the heart of the question of the legality of GM food regulations. First the Agreement on the Applications of Sanitary and Phytosanitary Measures (SPS Agreement) provides rules related to safety regulations. Secondly, the Agreement on Technical Barrier to Trade (TBT Agreement) concerns domestic regulations that may be involved for other societal goals. In the case of GM food, the SPS agreement would rule in a dispute related to the validity of GM food safety regulations (including bans) based on unproved risks of GM food. The TBT agreement would 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.

The case of agricultural biotechnology presents new challenges to the application of the WTO trade agreement. First, the current WTO trade agreement does not provide a clear guidance

¹¹ Recent cases (e.g., Hormone-beef) show that the Dispute settlement mechanism is likely to be less effective in cases of conflicting standards (Josling, Roberts, and Orden 2004).

on the question of regulating products according to their process and production methods (Josling, Roberts, and Orden 2004). Recent trade disputes have created precedents (Tuna-Dolphin and Shrimp-Turtle Disputes) but there is a general lack of agreement, especially in the case of standards for non-product related process and production methods (i.e., production attributes that cannot be verified in the product itself). At the same time, many national regulations covering GM foods are based on production process: for instance, they do not apply to any product produced with conventional agriculture methods, even if this product is exactly identical to a GM product. In other words, herbicide resistant crops, with the exact same property and characteristics as certain GM products, but obtained through conventional breeding methods (including induced mutagenesis) would not be subject to approval and marketing regulations in many countries. Moreover, a few countries (the EU, Brazil and China) require labeling of GM ingredients even in highly processed products where there is no available precise method to quantify transgenic DNA or proteins synthesized by novel DNA. This raises the issue of regulation enforcement: if all final products are virtually unidentifiable, it is impossible to ensure that they were produced with GM or non-GM ingredients.

Secondly, the SPS agreement bases safety standards on a scientific assessment of existing risks, which goes against the strict application precautionary principle supported by the EU (based on the presence of unknown risks). The SPS Agreement has two main objectives: first to recognize the right of nations to set up their own domestic regulations with respect to health and second to ensure that these measures are not unnecessary barriers to trade. In particular, WTO members are not allowed to ban imports of products they consider risky for an extended period of time unless they are able to scientifically demonstrate the existence of significant risk or to prove that they are conducting a significant effort in scientific research to evaluate these risks. In

other words, the SPS agreement allows countries to use precautionary measures but only during a provisional period, and provided they show effort of evaluating the risk of the products.¹² In the case of the Hormone-Beef WTO dispute, which was raised by the United States against a ban of beef by the EU on the basis of unknown risk associated with the consumption of beef raised with growth hormones, the WTO settlement body ruled against the EU, because the EU was unable to provide scientific evidence of the presence of risk to human health in a sufficiently time manner.¹³

Thirdly there is no clear rule for or against mandatory labeling, but rather open rules under the TBT agreement. The TBT Agreement includes two main clauses relevant to the case of mandatory labeling of GM food (Heumueller and 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 (making GM food labeling a TBT illegal regulation only in some cases such as countries of Group 3) 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

¹² The question then becomes how long is ‘provisional’? Josling et al. (2004) mention the case of a forty-eight-year-long regulation of Japan against U.S. exports, which the Dispute Settlement body ruled as too long to be considered ‘provisional.’

¹³ For a more complete analysis of this case, see Josling et al. (2004)

objective as compared to other measures (such as educational programs or 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.

WTO members have to notify new or changed SPS measures that may affect trade and that are not based on international recognized standards (Wolff 2001). At the end of April 2005, 111 notifications related to genetically modified food or crops had been deposited at the SPS committee from twenty-two countries (the EU being counted as one country), as shown in Table 4. Similarly, WTO members have to notify the TBT committee when they adopt new technical measures (such as labeling or other information requirements) that may affect trade.

Table 4--Notification by WTO members of changes in regulations on genetically modified plants, food and organisms to the SPS and the TBT (01/1993 -04/2005)

WTO member	SPS notifications (number)	TBT notifications (number)
Argentina		GM plants and animals (2)
Australia	Food, processed foods (11)	GM food, food derived from GM, processed foods (5)
Brazil	Food products (1)	Packed food (1)
Canada	Novel food, biotech, enzymes (9)	Novel food (1)
Chile	Plant products (1)	Labeling GM food (1)
China	GM food, plants, and labeling (7)	
Colombia	Rice (1)	
Czech Republic	Seeds (1)	
European Union	GM food and feed, products derived from GM food and feed (13)	GM food, GM feed, labeling (15)
Germany		Foodstuffs (1)
Guatemala	GM organisms (1)	
Hong-Kong		GM food (1)
Indonesia		GM food labeling (2)
Japan	Food, feed and processed food (11)	GM food, labeling (5)
South Korea	Food, feed, additives, labeling (7)	GM food, labeling (8)
Malaysia	GM food (1)	GM food (2)
Mexico	GM organisms (1)	
Netherlands		Non-GM food (1)
New Zealand	Novel foods, GM organisms, food derived from GM (18)	Food derived from GM, processed food (10)
Norway	GM organisms (2)	GM organisms, GM food (3)
Singapore	Plants and GM organisms (1)	
Slovenia	GM organisms and plants (4)	GM organisms (2)
South Africa	GM food labeling (1)	GM food labeling (1)
Switzerland	Food and feedstuffs (3)	Food, feed, medicines (7)
Sri Lanka	GM food (1)	
Thailand	GM food and plants (3)	Maize (1)
USA	GM food, plants, and medicines (12)	

Source: WTO website (<http://www.wto.org/>)

But by April 2005, only sixty-nine notifications had been made at the TBT committee by nineteen countries (the same caveat applies). The presence of labeling notification under both TBT and SPS agreements provide an evidence of the relative lack of clarity on the application of one or the other agreement on labeling. In addition, this table shows that forty-seven of the one hundred and forty-eight members of the WTO have adopted domestic regulations (counting twenty-five countries for the EU) on GM food based on their own standards.

In 1998, EU members decided to ban imports of new GM varieties for precautionary reasons, waiting to obtain data about the safety of these varieties. As a result the EU applied a de facto moratorium on any new GM varieties, thus blocking the entrance of GM corn from the United States for four years. In 2003, the United States, Argentina and Canada have filed a WTO dispute over the EU moratorium. This dispute is important in the sense that it will provide a precedent regarding GM food and standards based on process and production methods. Bernauer (2005) argued that in view of both sides and WTO precedents with the SPS and TBT agreements, it is probable that the WTO would not rule completely against the EU moratorium, in part because they lift this measure in 2004, while replacing it with traceability and labeling regulations. But, at the same time, six EU countries decided to keep the moratorium in place. After delaying its decisions five times, the WTO panel sent a confidential settlement report to the four Parties on February 7 2006. According to the press, the Dispute Settlement Body ruled in favor of the complainants (Cage, 2006). But at the time of this paper's publication, there was no detailed information about the complex decision outlined in the one-thousand-page-long report. It is likely that the EU will appeal to the decision, which would delay the final ruling until the end of 2006.

DISCUSSION

In the current state of international agreements, the political view on GM food has remained polarized by the EU and the United States. At the international level, the harmonization effort is led by the two transatlantic powers through the Cartagena Protocol on one side—supported by the EU—and the WTO dispute on the other, which was launched by the United States. In addition, both the United States and the EU are indirectly pushing for a change in rules in their favor, at the BSP and WTO SPS, respectively. Discussions at the Codex may balance the two powers, because the Codex is by nature a UN body that sets standards recognized by the WTO, but it is doubtful that it will generate a consensus in the short run.

In the meantime, regional factors have pushed the globe towards local harmonization of labeling and approval procedures in Asia, Europe and North America. The three members of the North American Free Trade Agreement (NAFTA) have decided to agree on a common information scheme for transboundary movements of GM crops, on the basis of a “May Contain” GM and an informal 5 percent threshold level. European countries outside of the EU have progressively moved their import and labeling regulations toward EU standard in order to facilitate trade (Switzerland), or as a measure helping them make their case for accession to the EU (Croatia). In Asia, Thailand and Indonesia have adopted labeling regulations that are very similar to the ones of Japan.

International institutions have made significant progress on approval and biosafety procedures. The Codex Commission published official recommendations for the approval of GM food, and the Cartagena Protocol provides recommendations for environmental regulations on GM crops as recognized by over one hundred countries. Yet on the question of marketing regulations (labeling, segregation, traceability), there are no explicit rules in any international

agreement; discussions have not advanced at the Codex Commission and the Cartagena Protocol does not clearly propose specific requirements.

In this context, three factors could affect the choice of regulations and technologies in developing countries. First, the final outcome of the WTO dispute will clearly send a signal to the rest of the world by setting a precedent. Bernauer (2005) argues that a clear ruling in favor of GM producing countries would set a signal that EU like policies will not be accepted in the WTO. On the other hand, a ruling in favor of (or not against) the EU policy would clearly show that countries have the right to have stringent regulations, and even ban those crops if they consider it necessary. Secondly, the United States Government has announced several times that it was also considering launching a WTO dispute against the new labeling and traceability regulations 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. Thirdly, if the BSP adopts stringent information requirements, large exporters of GM crops such as the United States, Canada and Argentina could dispute these requirements at the WTO, and create an international conflict between agreements.

In this particular eventuality, the relevant question would be whether the BSP can act as a binding international agreement and thus be recognized as a reference in WTO rulings. If the Codex Commission was able to find a consensus on labeling, it could be recognized as a reference standard by the SPS agreement of the WTO. But would the BSP prevail in a WTO trade dispute? According to Cors (2000), under the Vienna Convention on the Law of Treaties, the latest agreement should rule. Unless a new statement is introduced in the SPS, the Biosafety Protocol should prevail. But at the same time, Cors argue that the WTO and SPS will only

recognize the BSP if all WTO members are also members of the BSP. Since this is not the case, there are two possibilities depending on the countries involved in the dispute:

- if both countries are WTO and BSP members, the BSP will rule;
- if one country is a non-party to the BSP and the other is a party to the BSP, the WTO and SPS agreement will rule, and will not recognize the BSP.

Cors concludes that to avoid confrontation and to harmonize the SPS agreement of the WTO with the BSP, the easiest thing would be to include in the BSP a rule that would only allow temporary “provisional” use of precautionary measures for importers. But since this article, the BSP has been implemented and did not include such SPS type of measure. Other authors have argued that the BSP and the WTO are in conflict. Phillips and Kerr (2000) argue that the BSP is inconsistent with WTO rules because it allows trade restrictions based on process and production methods. More recently, Winham (2005) argues that the regime conflict between the WTO and the BSP over food safety and GMOs is singularly different than any other previous trade and environmental regime conflicts and could have very dramatic effects in the future.

International organizations are setting up rules on information and risk related requirements for the products of agricultural biotechnology that will be determinant for developing countries. In particular, the Cartagena Protocol on Biosafety offers to use its mechanism as a default policy for all transition and developing countries without domestic regulations. Many countries in Africa and Asia have followed the BSP’s requirements. For developing countries members of the Protocol the question will then be the cost of implementation of a regulatory system consistent with the BSP (which should be partially funded by the Protocol) and the long run costs of implementation and enforcement. In addition we argued that the Biosafety Protocol is not necessarily consistent with WTO rules. In particular, the

upcoming decision on information requirements will play a crucial role in determining whether the BSP will incur a significant cost on country members and non-members and likely distort international trade of unprocessed GM food and feed.

4. MAJOR IMPORTERS REGULATIONS¹⁴

Apart from their international obligations, developing countries may be influenced by the choice of regulations of their international trade partners. In particular, exports of agricultural products can provide a substantial source of income for developing countries, and agriculture remain a sector where they may have a competitive advantage over developed countries. In recent years, several rich countries (particularly the European Union) importing large volumes of agricultural products have raised their food safety standards, and developing countries seeking to maintain their exports had to comply with these standards to maintain market access. Some of these new measures may be legitimately based on food safety risks but others may only be new types of non-tariff barriers. As in the case of GM food, large importers have raised significant standards requiring approval, labeling and traceability for consumer safety, but that could potentially be considered trade restrictive measures.

In this section, we focus on two large importers with significant economic and political influence on the developing world: the European Union and Japan. GM food regulations in these two countries are representative of larger regions. In particular, most non-EU countries in Europe (e.g., the Eastern European nations) are adopting regulations similar to those in the EU. Switzerland is changing its threshold level to become compatible with EU standards. Similarly the Japanese labeling requirements may have influenced other Asian countries in their choice of GM labeling regulations. Thailand, Indonesia and South Korea have similar requirements to Japan's; Vietnam and Malaysia are considering similar labeling policies.

¹⁴ This section is largely drawn from Carter and Gruere (forthcoming).

THE EU'S REGULATIONS

The EU regulatory approach is precautionary, process related, and includes mandatory labeling traceability requirements- it belongs to category 1. Requirements include food and feed crops, unprocessed or processed. Only non-food GM products (unseeded), such as textile or other industrial products are not subject to any requirement.

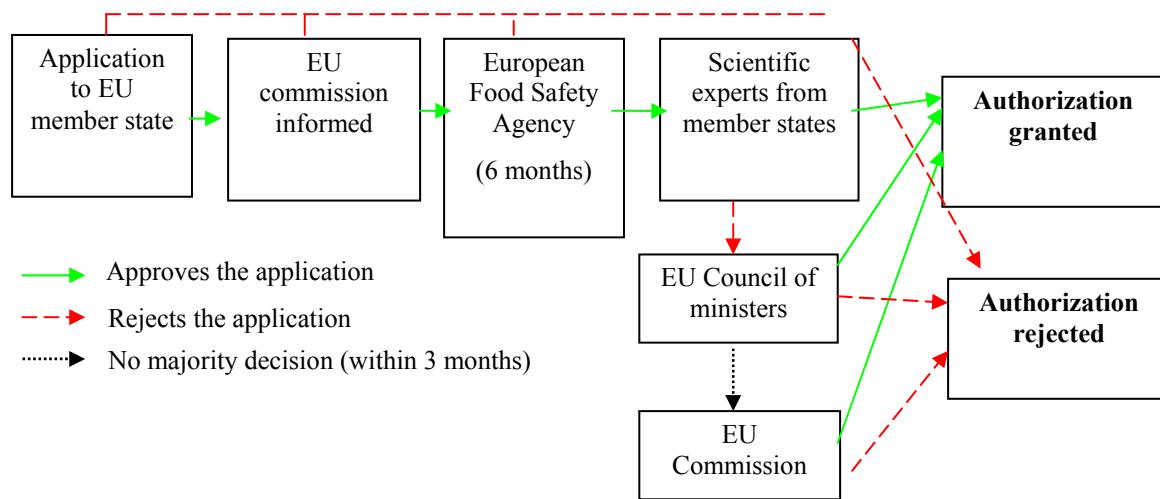
The EU regulatory system for GM foods has become increasingly more stringent. In 1990, the European Council adopted Directive 90/220 on the deliberate release of GM organisms into the environment. The directive regulated approval of GM crops for field trials and cultivation, and it also governed the approval of GM food. This first regulation did not define any specific approval procedures or labeling regulations. In 1997, the EU Parliament and the EU Council adopted Regulation 258/97, entitled the Novel Foods Regulation. This regulation applied to new food products including GM foods, and it defined approval procedures requiring proof that any GM food is safe for human consumption. Later, the EU commission and the Council published Regulations 1813/97 and 1139/98, which required the labeling of food products containing approved GM soybeans and GM corn. These regulations were augmented by Regulation 49/2000, introducing mandatory labeling of GM food and GM ingredients at the 1 percent level and Regulation 50/2000, extending the labeling requirements to food ingredients containing GM additives and flavorings.

The EU's most recent laws on GM food authorization (Regulation 1829/2003 and Regulation 1830/2003) took effect on April 18, 2004. These regulations established procedures for evaluating potential risks from GM food, and laid down rules on labeling of GM food and feed. Approvals are now granted for a period of 10 years, renewable. There is a 0 percent threshold for unapproved GM crops. Labeling is extended to animal feed, food sold by caterers, and food derived from GM ingredients even if the end product has no significant traces of

transgenic DNA or proteins. One major addition is the traceability requirements for GM and non-GM food: any food potentially containing GM material has to be tracked all the way from the farm to the consumer. This requires food companies to keep track of all shipments and to conduct DNA or protein tests at different stages. There is no labeling requirement for products such as meat, milk or eggs produced from animals fed with GM feed. The threshold for labeling is 0.9 percent.

Under the new EU authorization system, as described in Commission Regulation 641/2004 of April 6, 2004 (Figure 2), a company that intends to market a GM food product in the EU must follow four successive steps (Reuters).

Figure 2--The EU authorization process in 2005



First, the company must apply to the relevant authority of the EU member state where the product is first to be marketed, and provide a full risk assessment, a monitoring plan, a labeling proposal and a detection method. Second, if the authority gives a favorable opinion, the member state informs other member states via the European Commission. Thirdly, if there are no

objections by other member states, the notifying state or its national food safety authority may authorize the product for marketing throughout the EU. Fourth, a decision is required at the EU level and the following procedure is initiated. The Commission asks the independent European Food Safety Authority (EFSA) for an opinion based on a risk assessment procedure. The EFSA must give an opinion within 6 months. If the opinion is favorable, the Commission submits a draft decision to the Standing Committee on the Food Chain and Animal Health, made up of scientific experts from the member states. If the committee approves the authorization, the Commission adopts the decision and authorizes the new GM food product. If the committee does not agree, the Commission sends its draft approval to the Council of Ministers (agricultural or environmental ministers), who has three months to reject or adopt it. If they do not act within this time, the Commission may adopt its own decision and authorize the new GM food product.

Globally, the EU has the most comprehensive regulations on GM food. The new labeling and traceability regulation was introduced to force member states to end the *de facto* 4-year moratorium on new GM crops and to respond to the pressure imposed by the United States and other countries when they launched a WTO dispute on the moratorium. Since then, the EU has approved only three new GM varieties,¹⁵ and it is now the labeling regulations that have become the new *de facto* trade barrier for targeted “food” products. Although labeling was introduced to provide consumer choice, the mandatory labeling system encouraged all food processors and retailers to avoid GM ingredients entirely.

According to surveys and polls, a majority of EU consumers claim that they do not want to eat GM food, but at the same time some empirical studies (Noussair, Robin, and Ruffieux 2004; MORI 2002) have shown that a positive share of consumers would be willing to purchase GM products in the EU. Carter and Gruère (2003) argued that the EU mandatory labeling system

¹⁵ AGBIOS Biosafety database, <http://www.agbios.com>, as of October 2005.

has acted as a majority voting system where the winner takes all. Currently, it is almost impossible to find products derived from GM ingredients in the EU (Gruère forthcoming). GM animal feed is available because animal products are not required to be labeled. It is unlikely that the positions of the retailers and food processors will change, except if there is an abrupt shift in consumer acceptance (Knight, Mather, and Holdsworth 2005).

JAPAN'S REGULATIONS

Japan's regulations include mandatory safety assessment and mandatory labeling based on differences in products and with a number of exemptions. Labeling is based on the end products, which means that highly processed products are exempt from labeling. Japan can be considered in category 3 of Figure 1

In 2000, Japan introduced regulations defining the authorization procedure. The Ministry of Health Labor and Welfare (MHLW) is in charge of the approval procedure for GM food. All GM food, GM processing aids, and GM food additives are subject to pre-marketing safety assessment. The safety assessment includes information regarding the host, the vector, the inserted gene, the recombinants, and the toxicity levels. If the application to MHLW is complete, it is then submitted to the Expert Panel of the Biotechnology Subcommittee within the Food Sanitation Committee. The Panel reviews and makes recommendations to the Biotechnology Subcommittee, which then passes its judgment on to the Food Sanitation Committee. This committee makes a recommendation to MHLW's minister, and if approved the new variety is announced in the Japanese Gazette. It usually takes about one year to go through the regulatory process.

The MHLW enforces standards under the Food Sanitation Law (FSL), and it samples and tests imported foodstuffs at ports of entry. The testing focuses on GM foods approved abroad but

not in Japan. There is a 0 percent tolerance for unapproved GM material. After the Starlink corn food scare, Japan increased the frequency of food safety inspections on corn from 5 to 50 percent of all cargoes.

The Ministry of Agriculture, Fisheries and Forestry (MAFF) is responsible for environmental safety approval, feed safety assessment and biotech labeling rules. The MAFF's environmental assessment is voluntary but all companies comply. The MAFF's feed safety assessment is mandatory, from April 1, 2003. All applications for feed approval are reviewed by the Feed Division of MAFF, and then sent to the Expert Committee of the Agricultural Materials Council. There is a 1 percent tolerance level for the unintentional presence of GM feed that has been approved in other countries, under the condition that the exporting country's safety assessments are deemed equivalent to Japan's.

Japan's mandatory labeling scheme was introduced on April 1, 2001 under the Law on Standardization and Proper Labeling of Agricultural and Forestry Products, which was introduced into the Japanese Agricultural Standards (JAS). Labeling is required for all GM food if DNA/protein can be detected in the finished food products and if the GM ingredient is one of the top three ingredients and accounts for more than 5 percent of the total weight. This 5 percent tolerance level is informal but currently applied. The MAFF list of products subject to mandatory labeling included 30 foods in 2003. Importantly, there are no labeling requirements for soy oil or corn oil, except if the oil has special properties (such as high oleic soy oil). The labeling regulations are enforced jointly by MAFF and MHLW under the JAS and the FSL, respectively. In addition to the mandatory GM labeling requirements, there is a voluntary labeling option for non-GM, subject to identity preservation procedures.

Overall, the Japanese policy can be described as pragmatic, in the sense that it requires the labeling of GM food but the regulations do not cover all products and the tolerance levels are higher than in other countries. Food processors and retailers in Japan have typically avoided products with GM labels. As in the EU, most GM products are used for animal feed, but unlike in the EU, many highly processed products derived from GM ingredients (e.g., soy oil) are sold without labels.

DISCUSSION: INTERNATIONAL EFFECTS OF THE EU AND JAPAN'S REGULATIONS

Labeling and approval regulations in major trading countries have affected international trade in all GM crops except cotton (because most cotton products are not edible and thus not subject to food safety and labeling requirements). In particular, regulations in the EU and Japan—two large importers of these crops—have impacted trade. Furthermore, the choice of regulations in the EU and Japan may have discouraged the development of new GM food varieties and at the same time encouraged third countries to adopt labeling requirements similar to those in the EU.

The EU regulations managed to halt almost all corn imports during the *de facto* moratorium between 1998 and 2004. U.S. corn growers contend the ban has blocked around \$300 million in annual sales of corn (King 2003). U.S. exports of corn byproducts to the EU also fell. But at the same time—even during the moratorium—the EU still imported a relatively large volume of GM soybeans for feed, mainly because meat from animals fed with GM crops is exempt from EU labeling requirements. Since the Bovine Spongiform Encephalopathy (BSE) crisis, EU farmers are required to use only vegetable feed, and the EU is incapable of producing enough soybeans for its animals. Thus EU farmers import GM soybeans from Brazil, the United States, and Argentina.

In the EU, food processors have switched to non-GM ingredients while farmers have been discouraged from adopting GM crops. For instance, Dewar et al. (2003) showed that the use of GM sugar beets would provide significant yield and environmental benefits but no EU farmer will adopt GM sugar beets because no sugar company would buy their product. Spain is the only EU country with significant GM crop production. In addition, Paarlberg (2002) argued that many developing countries have delayed or rejected crop biotechnology because of the stringent regulations of importers such as the EU.

In contrast, Japanese regulations have not had a dramatic impact on imports of soybeans, corn, and canola because of pragmatic regulations and exemptions to the labeling requirements granted to soy and canola oil, and other processed products. Although there are no official data, up to 20 percent of Japan's annual soybean imports (of 5 mmt) may be non-GM. The non-GM soybeans are mainly used for tofu, which unlike soybean oil, is subject to Japan's GM labeling regulations. In addition, Japan imports non-GM corn each year from the U.S. and China. This corn is used in food products (such as snack foods) that are subject to the GM labeling rules. Most of Japan's imported corn is GM, which is used for animal feed and the final meat product does not have to be labeled there.

It is difficult to find GM labeled products at the retail level in Japan, but many products labeled as non-GM are available to consumers. The selective mandatory labeling regulations have acted as an intermediate set of rules—between voluntary labeling of non-GM (like in Canada or the United States) and a mandatory labeling of GM (like in the EU). In fact, a substantial amount of food eaten in Japan contains GM but it doesn't have to be labeled. These products include cheese, soya sauce, some baked goods and numerous manufactured foods.

5. EFFECTS OF INTERNATIONAL REGULATIONS BY TYPE OF PRODUCT

The previous three sections reviewed the most relevant current and future potential national and international trade related regulations of GM food. This exercise shows the complexity of trade related rules on GM food. National and international regulations share their objective and scope: regulate food safety risks and information on GM food (as defined in the introduction). But it appears that regulations differ significantly by country and institution. This section demonstrates that regulations also critically depend on the types of products.

Table 5 provides a synthesis of international trade related regulations by type of GM product.

Table 5--Trade related regulations by type of product

Type of traded GM product	Import approval	Information requirements on traded GM	Labeling requirements for GM	Traceability requirements for GM
Upprocessed food products	EU, Japan, many others, Codex, BSP, WTO/SPS	BSP rules (120 BSP members)	EU, Japan, many other countries, WTO/TBT?	EU
Processed food products derived from GM				
-with quantifiable traces of transgenic DNA/protein	EU, Japan, many other countries, Codex, SPS	None	EU, Japan, many other countries, TBT?	EU
-highly processed: insignificant traces of transgenic DNA/protein	EU, Japan		EU, few other countries	EU
Unprocessed feed products	EU, Japan, many others, Codex, BSP, SPS	BSP rules (120 BSP members)	EU, few other countries, TBT?	EU
Processed feed products derived from GM	EU, Japan, few others (highly processed not covered by SPS)	None	EU, few others (highly processed may not be covered by TBT)	EU

Currently, with low BSP information requirements, unprocessed food products face the most regulatory requirements than a subset of processed food products, unprocessed feed products, highly processed food products, and processed feed products.¹⁶ Highly processed products derived from GM ingredients do not present detectable differences. These products could be ruled “like products,” in which case, discrimination based on GM non/GM would not be allowed under WTO rule.¹⁷ The introduction of stringent BSP information rules would create a heavy burden on unprocessed food and feed compared to all other products, given that it would directly affect imports of agricultural commodities in one hundred and twenty countries.

To assess the economic stakes of these regulations, we can match the regulatory burden with estimates of total trade value by type of product. Currently, based on approximate data on uses and trade of the four main GM crops,¹⁸ simple calculations show (see Table 6) that unprocessed feed products represent the highest trade value at about \$17 billion/yr, followed by processed feed products at \$13 billion/yr, unprocessed food products estimated at \$5.5 billion/yr, and processed food products at \$3 billion/yr.

¹⁶ In addition, meat and animal products from animals fed with GM (as products derived from GM) can be considered products derived from GM crops.

¹⁷ Highly processed GM products with no significant traces of transgenic DNA are excluded from SPS issues, and are not explicitly covered by TBT rules so long as they are considered like products. For a more complete discussion of standards based on non product related process and production method standards, see Josling et al. (2004).

¹⁸ To our knowledge there is a lack of accurate data on the use of traded commodities, such as maize for feed. Instead, we obtained shares of feed in total world use (processed and raw) to derive the approximate estimates shown by crop in Table 6.

Table 6--Derived estimates of five-year average trade value by food and feed uses

Total import value \$ million	Maize	Soybeans	Rapeseed	Cottonseed	Total four crops
Unprocessed food	2,682	2,476	346	32	5,536
Processed food	348	1,925	518	25	2,816
Unprocessed feed	6,456	9,353	1,298	149	17,256
Processed feed	839	10,531	1,204	81	12,655

Source: Author's derivations, using FAOSTAT for uses and UN Comtrader trade data. Note: other uses can be derived as the residual difference between estimates of Table 3 and Table 6.

Thus, under current regulations, and for current GM crops, products with the highest traded value (feed) are not subject to the most stringent requirements. In addition, as mentioned in Section 4, the fact that meat and animal products are excluded from labeling requirements in many countries including the EU make animal feed relatively untouched by labeling regulations.

This may be due to exogenous and endogenous factors. Current GM crops were the first developed arguably because they represent a higher total economic value (Charles 2001), and that the improvement with agricultural biotechnology was expected to have a significant impact on productivity, not because they are mainly used for feed. Furthermore, unprocessed products containing seeds are the focus of environmental regulations because of their potential use for planting. On the other hand, the focus of stringent regulations may have been decided selectively because of endogenous economic reasons. Processed food is excluded from labeling in many countries; meat fed with GM is not subject to labeling in the EU most probably because of the economic stake of avoiding GM soybeans for animal feed.

But if major transgenic "food" crops were adopted in the near future, such as wheat or rice, they would likely be subject to a very comprehensive set of regulations. In other words, it is clear that the current GM crops will not be affected as much as large sets of potential future GM crops primarily used for food and traded unprocessed.

6. EFFECTS OF INTERNATIONAL REGULATIONS ON DEVELOPING COUNTRIES' POLICYMAKING

In this final section, we relate our findings on international regulations to the question of determining the best regulations of GM food for developing countries. First, we discuss the effects of regulations derived from international agreements on developing countries policy making. Secondly, we identify two types of spillover effects of importers' regulations through international trade linkages. Thirdly, based on these political constraints, we analyze potential policy solutions for developing countries to address simultaneously multiple economic objectives.

INTERNATIONAL AGREEMENTS AND DEVELOPING COUNTRIES

The most direct effect of international regulations on developing countries comes from the application of the relevant international agreements (presented in Section 3). Developing countries that are not member of any of these agreements can be affected by international regulations because of international trade linkages. But the more numerous developing countries that are members of the UN Codex Alimentarius, the BSP or the WTO have the right to participate to the design of new rules within these agreements. So theoretically, most developing countries should be actively contributing to the design and implementation of international agreements. But the question becomes whether or not they actually participate and influence the design of international rules to their own benefit. Three factors may affect their participation: first, their capacity to do so, secondly their willingness to do so, and thirdly the institutional rules affecting the modality of participation.

In terms of capacity, even if the United Nations and the WTO offer the possibility for any member country to actively take part into the decision making process, it remains questionable whether all developing countries are actually able to affect international decision making as much as developed countries. First, their personal participation (in terms of representative body) may be limited due to restricted public funding. Second, even if they have a full participating body, they may not have sufficient information because they lack a support body reporting ex ante analysis of potential decisions, which most developed countries have.

Reports from recent conflicts on information requirements at the BSP, and on labeling requirements at the Codex Commission, show that at least a few developing countries from East Africa (Ethiopia and Kenya) actively participated in the process of policy making. So even if many developing countries may be standing behind others, UN arenas seem to provide a room for discussions and arguments for developing countries. At the same time, it is not sure that every country following the majority in these fora –in favor of strict information requirements at the BSP and mandatory labeling for all GM food at the Codex- is fully informed about the economic consequences of such measures.

Secondly, even if they are fully informed, and if they have the capacity to influence decisions, developing countries are not forced to take position and support their own cause, i.e., their representation also comes from their willingness to participate. Countries that represent major international economic powers can use their influence to encourage developing countries to support their positions or at least to discourage them to publicly oppose their positions.

Diplomatic efforts to obtain political support in exchange of other type of political support,¹⁹ preferential or future bilateral trade agreements, development aid, or economic and financial ties can play a role. In addition, developing countries may decide to stand behind other countries for

¹⁹ For example, trading UN support for WTO support, or WTO/UN support for political visits before elections.

strategic purposes without any explicit or implicit deal- for example in order to gain future political credit. Because these interactions usually remain secret, there is no clear evidence of these political games for agricultural biotechnology. Yet, several authors have argued that the EU and the United States have used their political influence to support their position since the beginning of their political opposition on biotechnology (Bernauer 2003; Miller and Conko 2004; Isaac 2002).

Thirdly, the rules of the game may play a role, pushing for a specific representation of national actors in international forums. In the case of agricultural biotechnology, in many countries the agricultural and food ministry, the environment ministry, and often the science and technology ministry play conflicting roles in regulatory design and implementation. This has both advantages and inconveniences, it may help adopt a balanced view of risks and opportunities of agricultural biotechnology, but it can also end up creating a conflicting two- or three-headed representation of power practically blocking the implementation of biosafety and biotechnology regulations. This conflict is translated at the international level, where BSP participants are only environmental ministries, WTO participants may include agricultural and trade ministries, and Codex Alimentarius participating members may include agricultural and food or consumer protection government agencies. As a main observable consequence, trade related measures at the BSP are discussed in the context of environmental risks. Thus, many developing countries' environmental ministers, whose mandate is to limit risks with the help of the international community, consider information requirements as necessary measures for the environment. Trade or agricultural consequences of strict information requirements may totally elude from the considerations, despite their likely negative economic impacts.

Thus, many factors can contribute to creating a significant difference between regulations decided in international forums and the needs and ideal regulatory system for individual developing countries. As a consequence, international regulations appear as an exogenous constraint for many developing countries, affecting their decisions on regulation and adoption of agricultural biotechnology. We do not argue that international agreements are not beneficial for these countries overall or even in the area of agricultural biotechnology, because in many cases they do benefit from these regulations. Instead, we argue that international regulations are influential on most developing countries' decisions, and because of imperfect participation or representation, may force them to decisions that are not necessarily optimal.

More specifically, the Codex and the Biosafety Protocol do not have the same potential effects. On the one hand, guidelines approved at the Codex Alimentarius do not provide mandatory requirements for developing countries; instead they allow any country to comply with such guidelines while being in compliance with the WTO SPS agreement. Thus, Codex guidelines for comprehensive labeling requirements of GM food would allow any developing country that is a WTO member to have its own mandatory labeling regulation while staying in compliance with the WTO. At the same time, such measure would potentially encourage other countries, including current and future food importers (WTO or non-WTO members) to adopt mandatory labeling policies. Currently, the majority of Codex members, including a very large number of developing countries officially support the inclusion of comprehensive labeling for GM food in the Codex Alimentarius. Their position is consistent with large importers that are not producing GM crops like the EU or Japan and not consistent with countries that are willing to grow GM and keep market access in all other countries.

On the other hand, the Cartagena Protocol on Biosafety is providing rules that become binding for all members. All developing countries will apply rules that are part of the Protocol. The current overwhelming support among poor and very poor countries for strict information requirements at the Protocol may reflect environmental interests, but may also reflect the fact that many of these countries are either not regarding GM crops as a potential technology for production, imports or export or not considering the cost it will impose on future exports particularly if they do adopt GM crops.

SPILLOVER EFFECTS OF IMPORTERS REGULATION ON DEVELOPING COUNTRIES

In addition of the influence of international agreements, we have identified two main spillover effects of national regulations of large importers on developing countries.

The export effect

Many developing countries have been discouraged of investment/ adoption of crops for fear of incurring large fixed costs (approval) and variable costs (traceability, segregation, labeling) for present and future exports of GM or non-GM crops. However, recent studies have argued that policy makers may actually overvalue this export loss. For example Anderson and Jackson (2004) show that under current crop production, the adoption of GM crops by various developing countries may not result in any serious losses offsetting the potential productivity gains of these crops. Paarlberg (2005) shows that under current trade conditions, African exports of crops that could be GM to the EU only represents a low share (4 to 10 percent) of total exports in these crops and a very low trade value compared to the overall benefits of using such technology to enhance crop productivity. Other country case studies are being studied, but this

export loss effect has likely been excessive in view of the actual trade flows of most of the crop concerns and the limited potential of the target export markets in the future.²⁰

In addition this fear is driven by the assumption that any segregation of GM and non-GM is infeasible. For example, several African countries have banned production or imports of GM crops or food derived from GM crops for fear that their introduction would make the whole production potentially GM from the perspective of current or future importers located in countries with stringent regulations and low thresholds of contamination (Paarlberg 2005). By adopting this reasoning, these African policy makers assumed implicitly that coexistence and segregation are infeasible or could only be achieved at a prohibitive cost. Yet, Brazil's experience with soybeans suggests that this is not necessarily the case in all developing countries; it may be possible to have producers of GM crops and producers of non-GM crops exporting to rich importers in the same country. Furthermore, Knight et al. (2005) reports that large food importers in the EU do not pay attention to the adoption of other GM crops when importing agricultural products from a particular country.

The regulatory harmonization effect

To facilitate trade, adopting the same standards as the country of exports can be costly but could supposedly help to keep market access. This may be the case for policies that are not market distorting, such as approval and biosafety field regulations. Adopting internationally recognized or mutually recognized standards or importers' standard can help reduce the cost of application and approval to access a given market. For example, the Philippines use similar types of standards as the U.S. standards for safety approval and thus do not reject imports from U.S maize or soybeans after reviewing the safety applications. So far the United States has not been

²⁰ Of course, this depends on the producing country and the particular products, and should be evaluated on a case-by-case basis.

importing GM food, being large exporters of all GM crops, but mutual recognition would imply that the United States also recognizes the validity of the approval standards used by the Philippines or by any other countries with similar standards.

However, the case of mandatory labeling is much more complex. In view of current regulations, adopting mandatory labeling regulations that are similar to the main importers likely reduces the domestic consumption of GM, the production of GM, raises costs for non-GM that are intended for domestic use, for the sake of exports to specific countries with stringent regulations. In contrast, voluntary labeling and certification with segregation could provide access to the countries with non-GM premium such as Japan or the EU, as organic products, fair trade and eco-labeled products already do, while letting the non exporters decide which technology to use. These voluntary mechanisms let market demand drive the production and adoption of approved GM crops and may result in a proportion of adoption that reflects more directly consumer demand.

IDENTIFYING POLICY SOLUTIONS TO SATISFY DOMESTIC AND INTERNATIONAL OBJECTIVES

We just showed that international agreement and domestic regulations of large importers affect policy decisions on adoption of GM crops and regulatory decisions in developing countries. This influence is translated in two ways, first as an external constraint to political decision making because of compliance to requirements, and second through a shift in the objectives of policymakers, e.g., to assure market access in large importing countries. We will now take a step back by considering how policy making in developing countries can respond to these two types of influence, by analyzing what policies can help these countries achieve multiple objectives while taking into account the trade related regulatory environment.

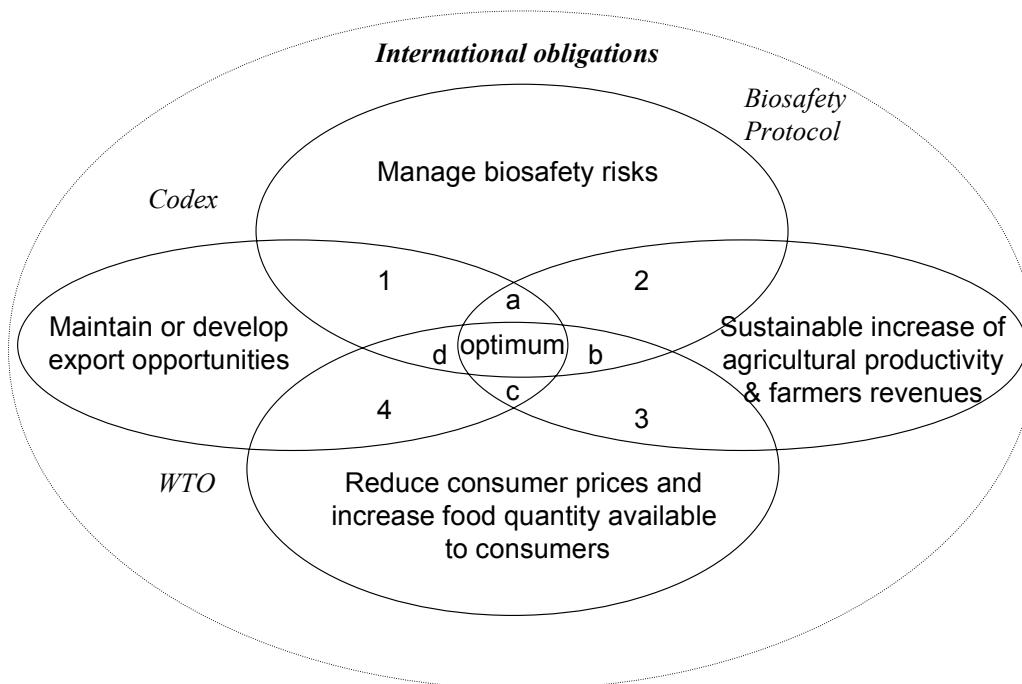
Policy makers should be able to consider a wide set of objectives when deciding whether to adopt selected GM crops or to introduce any type of biosafety or marketing regulation. We use a Venn diagram to represent a possible set of four policy objectives for a typical developing country in Figure 3. We assume that most countries try to 1) maintain or increase their market access to all importing countries, including those with stringent regulations on GM food, 2) find solutions to increase agricultural productivity, including the use of beneficial GM crops, 3) maintain low consumer price and sufficient food availability for consumers, and 4) manage biosafety risks (food safety and environmental) related to GM crop technology, while satisfying their international obligations. The ideal set of regulation should be able to satisfy simultaneously all objectives together, as least to a certain extent.

Currently, most developing countries seem to be focusing their effort on one, two or three of these objectives without including the remaining one or two or without completely satisfying their international obligations (see Section 2). At the same time (see Section 3 and 6), international agreements provide a regulatory framework limited to some of these objectives. The WTO is concerned with export and imports, and try to maintain countries into a state that allow them to plainly benefit from trade (i.e., maintain countries within the set defined by zones 4, d, c, or optimum). The Codex Alimentarius provides recommendations that facilitate trade and limit food safety risks (i.e., encourage countries to stay within the set defined by zone 1, a, d, and optimum). Proactive international regulations tend to move countries away from the optimum (see Section 6). The BSP officially provides biosafety regulations to limit environmental risks related to the production of GM crops, (i.e., encouraging countries to stay within the set defined by zone 2, a, b, and optimum). But at the same time, we have argued that current and pending decisions at the BSP also create new entry costs for technology, discouraging countries to adopt

transgenic crops. Large importer's regulations affect the realization of export related objectives for developing countries, which is translated into approval strategies and policies in many countries (such as GM moratorium or rejection of any GM food crop) that may impede on the realization of production objectives (see Sections 4 and 6). In other words they arguably push countries horizontally to the left.

We will now consider the case of each zone in the figure to identify policy options that may help move towards the target or optimum. The four numbered zones in Figure 3 represent areas where countries have achieved two of the four objectives.

Figure 3--Combining developing countries policy objectives for decision making on the adoption of production technologies and regulations of GM food



- Zone 1: Countries in this zone have adopted national and international biosafety regulations, potential import restrictions or bans of GM food without adopting any GM crops. Example: Zambia.

- Zone 2: These countries have adopted national and international biosafety regulations, including potential import restrictions, but have also started to adopt successful GM crops without segregation or without mechanism to export these crops to importers of non-GM. For example, Bt maize was introduced in Spain or Eastern Europe before the application of any coexistence rule, because these crops are approved for animal feed, and not used for exports.
- Zone 3: These countries have adopted GM crops without segregation, labeling, or import restrictions and with limited biosafety regulations for GM crops. No countries got into this position on purpose, but because of illegal transboundary seed movements happening before the setting up of biosafety rules, Brazil, India and a few other countries have been in this position at least temporarily in recent years.
- Zone 4: These countries have not adopted any GM crops, but import certain GM food without specific approval regulation. Several African countries are in this case.

The four zones defined by letters in Figure 3 represent areas where countries may have achieved three objectives out of four:

- Zone a: These countries have introduced biosafety regulations for GM crops and GM food, stringent labeling and import approval regulations, produce certain GM crops with few export restrictions (such as cotton) or are able to segregate non-GM from GM crops for exportable commodities. Example: Brazil, China.
- Zone b: These countries have adopted safety regulations, produce approve GM crops, and consume GM food without specific stringent marketing regulations on substantially equivalent products, but do not have any segregation scheme, such as the Philippines.
- Zone c: Countries in this zone would have adopted GM crops with loose biosafety regulations, while producing only exportable GM crops (cotton or approved soybeans) or being able to achieve segregation for exported non-GM crops. To our knowledge no country corresponds to this situation.

- Zone d: These countries have introduced comprehensive biosafety regulations, but did not approve GM crops or only approved GM cotton, and do not restrict imports of GM food or have limited consumer regulations, such as India, Indonesia, Bangladesh.

Based on this preliminary analysis, we identify four necessary conditions to achieve the defined optimum:

1. Adopt a comprehensive but practical approval biosafety regulatory process for GM crop production and GM food for consumption based on international standards;
2. Adopt approved GM crops adapted to regional constraints and preferences that offer significant productivity increases;
3. Import and consume approved GM food without further potential trade or costly restrictions (e.g., no stringent mandatory labeling or stringent information requirements, but possible voluntary labeling to let consumer choose and certification for exports)
4. Adopt policies and strategies that help segregate GM and non-GM crops for exportable markets and potentially for the domestic market (non-GM niche).

In addition, each country needs to respond to its international obligations, which depend on its membership to the WTO and to the BSP. Membership to the WTO does not prevent using these four policy options, whereas the BSP may already prevent countries from achieving consumption and production objectives, especially if stringent information requirements mechanisms are introduced. If these requirements were introduced, it would be much more costly to reach the defined optimum.

Practically, the implementation of these four policy conditions still needs to be defined for a given country and the feasibility of these options will depend on their cost. First, for import

safety approval (condition 1), following the example of the EU and Japan (see section 4) would require not only testing for each new import approval but also implementing tests for all incoming traded shipment, which would be highly costly for developing countries. Very low threshold of adventitious presence risks making the regulation unenforceable. In contrast, the Philippines use standards of approval that are similar to North American ones, and receive the application files from private company for each new transgenic corn in the U.S. that will potentially be imported there. The ideal policy will gain from standardized efforts on new GM crops, such as the use of Codex standards, and pragmatic testing depending on the crop.

Secondly, the adoption of GM crops (condition 2) depends on an efficient system of biosafety regulations, which model we will not discuss in detail in this paper. It is clear that GM crops (crop/trait combinations, not necessarily varieties) have to be evaluated on the case by case basis. Research prioritization should help the public sector to direct their effort towards poverty reducing technology and complement private companies' innovation efforts.

The third condition is less costly to implement than mandatory labeling or strict information requirements. In many countries, the demand for non-GM food and for labeling requirements arguably seems to be politically supported by clear opponents to the technology. The economic effects of mandatory versus voluntary labeling will greatly depend on 1) the purchasing power and sensitivity of consumers and 2) the structure and organization of the food chain. Many developing countries have large populations of poor consumers (some of them illiterate), low standards of safety, rare food labels, and unstructured industry, where mandatory labeling would likely be very costly, and unenforceable. As mentioned in Section 6. (the regulatory harmonization effect), there is no evidence that the adoption of stringent mandatory labeling requirement similar to large importers really helps for export, thus this should remain a

domestic decision based on domestic objectives (comparing the cost of implementation to the benefits of consumer information and consumer choice is likely to help achieve these targets).

Finally the fourth condition, which is related to segregation may require significant public investments, but may not be infeasible in many countries given the existence of a real premium for non-GM in the domestic or international market, and the investment of vertically integrated companies into non-GM market chains. Segregation could be implemented without much public investment, as part of traceability initiatives in international private sector supply chain (particularly for export), as was the case in Brazil for soybeans (or to a certain extent in the United States for soybeans). In many Asian countries, certification and segregation is already occurring for export markets, for example in the case of organic varieties. Besides, our analysis by type of products shows that the effects of regulations depend on the type of product, so that the adoption of non-food and feed GM products would not affect significantly exports in the long run even without segregation. So in the short run, it is clear that certain GM crops will be less risky and less costly to introduce.

We have argued through several examples in this paper (GM wheat, sugarbeet, maize) that because of stringent regulations certain food crops were not introduced because of market rejections (see section 1 and 4). But this should not be generalized, particularly for the case of developing countries: all crops grown in developing countries are not (and nor will they likely be) exported to particularly sensitive markets, all products are not affected by import regulations (see section 5), and all potential loss in particular markets should be compared to the net productivity and welfare gains for producers and consumers domestically. These examples reflect cases of developed producing countries where large shares of market revenues were at stake, where no segregation strategy was considered, and for the two rejections of introduction,

where the productivity gains with the technology were not dramatic compared to the potential market losses. Developing countries, who in many cases, do not export a very large share of production to sensitive countries, could greatly improve productivity with particular transgenic crops would benefit from segregation schemes allowing them to keep market access for non-GM exports while adopting GM crops destined for other less sensitive countries and for domestic consumption.

The proposed set of policy solutions balance the need for complete and effective regulations for biosafety approval and segregation, with a more relax and less costly consensus based on private initiatives for measures related to consumer information and adoption of GM crops. This set of regulations should allow developing countries to address safety and economic risks, while making the room for adoption of beneficial crops for the benefit of poor producers and consumers.

7. CONCLUSION

In this paper, we analyzed international trade related regulations on the food and feed products derived from transgenic crops, generically called genetically modified (GM) food. We focused on product regulations as opposed to crop or plant regulations, reviewed regulations of large importers, defined by international agreement, and analyzed their effects on international agricultural trade. Based on this review, we then identified their effects on developing countries' decision making, and suggested policy solutions to maximize multiple domestic objectives under these regulatory constraints.

There is a large heterogeneity in regulations of GM food among countries. Developing countries tend to be in the process of developing regulations based on their own objectives, but

also on their international obligations and on their international trade partners' own regulations. While internationally harmonized safety approval regulations have been finalized, there is no consensus on labeling and marketing regulations for GM food. We reviewed the regulations of two large importers, Japan and the European Union, and showed that the Japanese regulation is more pragmatic and less trade distorting than the EU's one. We argued that these two regulations tend to affect other countries' choice of regulations. In particular, we identified two spillover effects of importers' regulations on developing countries choice of production and regulations: the fear of export loss, linked with the belief that segregation is infeasible, and the regulatory harmonization effect, linking domestic policy choice to market access.

We also showed that the effects of trade related regulations depend critically on the type of products they target: unprocessed and processed food products tend to bear more requirements than other types of products. At the same time, without stringent information requirements at the BSP, the most traded products are unprocessed feed products. Thus, the likely economic cost of regulations is less for current crop than what it will be for future GM "food" crops mostly traded unprocessed, and the introduction of the BSP would have a significant impact both on current (mostly unprocessed feed) and future GM products (mostly unprocessed food).

We then suggested four policy arrangements to enable developing countries to simultaneously satisfy production, consumption, international trade and risk management objectives simultaneously, based on two critical measures: the practical and efficient use of harmonized safety standards for imports and the setting up of segregation strategies of GM versus non-GM for sensitive export commodities and to respond to domestic or international consumer demand. Based on our review, we showed that these proposed policies may help mitigate the observed effects of trade related regulations, allowing developing countries to

benefit from productivity enhancing technology. At the same time, we raised the issue that the Biosafety Protocol, by entering into commodity trade regulations through suggested strict information requirements may prevent these countries from achieving consumption and production related objectives.

Finally, we acknowledge that quantitative studies are needed to assess the effects of international regulations on developing countries and to evaluate the benefits of adopting specific trade related regulations of GM food in developing countries. We plan to address these issues in the near future. We have initiated country case studies in South and South-East Asia to evaluate the effects of international regulations and simulate the effects of policies on the benefits of adopting future GM crops. In parallel, we have also started an economic analysis on the effects of strict information requirements on international agricultural trade and in developing countries to complement existing cost analysis for large exporters of GM food.

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