SUITABLE MANAGEMENT MEASURES FOR THE IMPORTATION OF GMOs PRODUCTS

KOSIT SUKSOMJIT

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SUITABLE MANAGEMENT MEASURES FOR THE IMPORTATION OF GENETICALLY MODIFIED ORGANISM (GMO) PRODUCTS

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ABSTRACT

The objective of this thematic paper is to compare import regulation of Genetically Modified Organism (GMO) in Asian and European countries with Thailand and to propose a suitable management program.

This research selected China and Philippines as Asian representative countries, and England as a representative Europeans country. The reviews GMO import statistics and information on Thailand and the countries mentioned as well as import procedures and regulation on GMO products.

The study found that Thailand is a large importer and exporter of agricultural products. It also found that Philippines and United Kingdom have better more comprehensive regulation than Thailand and China. However, most of the countries have difficulties in enforcement and implementation, particularly Thailand because people do not have sufficient knowledge and misunderstand many points of GMO products.

GMO issues and regulation need to be handled by professional working groups. The regulations need to be clear. Risk assessment and monitoring plan are also significantly essential for implementation of GMO import regulation. A reasonable penalty should be placed on any violation.

KEY WORDS: IMPORT REGULATION / GMOs / MEASUREMENT

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มาตรการที่เหมาะสม สำหรับการจัดการการนำเข้า สิ่งมีชีวิตตกแต่งพันธุกรรม และผลิตภัณฑ์
(SUITABLE MANAGEMENT MEASURES FOR THE IMPORTATION OF GENETICALLY MODIFIED ORGANISM (GMO) PRODUCTS)

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บทคัดย่อ

การศึกษาครั้งนี้มีจุดมุ่งหมายเพื่อ ศึกษามาตรการการนำเข้าของสิ่งมีชีวิตตกแต่งพันธุกรรม และ ผลิตภัณฑ์ของประเทศในกลุ่มอาเซียนและกลุ่มยุโรปโดยเปรียบเทียบกับมาตรการทางกฎหมาย ของ ประเทศไทย นอกจากนี้และได้มีการนำเสนอมาตรการที่เหมาะสมในการจัดการการนำเข้า สำหรับ สิ่งมีชีวิตตกแต่งพันธุกรรมและผลิตภัณฑ์ เพื่อเป็นแนวทางในการพัฒนากฎหมายต่อไป

การวิจัยครั้งนี้เลือกประเทศจีน และ ฟิลิปปินส์ เป็นตัวแทนประเทศในกลุ่มอาเซียนและประเทศอังกฤษเป็นตัวแทนประเทศในกลุ่มสมาพันธ์ยุโรป โดยทบทวนเอกสารทางสถิติและ ข้อมูลการนำเข้า รวมไปถึงขั้นตอนและกฎหมายนำเข้าของกลุ่มประเทศศึกษาเปรียบเทียบกับ ประเทศไทย

จากการศึกษาพบว่า ไทยมีการนำเข้าผลิตภัณฑ์ทางการเกษตรในปริมาณมากจากหลายประเทศ ซึ่งส่งผลกระทบต่อธุรกิจการนำเข้าและส่งออกของผลิตภัณฑ์ทางการเกษตรด้วยเช่นกัน และยังพบว่า ประเทศฟิลิปปินส์ และอังกฤษ มีมาตรการการนำเข้าที่เข้มงวด กว่าประเทศจีน และประเทศไทย แต่อย่างไรก็ตาม ในหลาย ๆ ประเทศยังคงประสบปัญหาเกี่ยวกับการบังคับใช้ เนื่องมาจากความไม่ เข้าใจของประชาชนในหลาย ๆ จุดของสิ่งมีชีวิตตกแต่งพันธุกรรม และผลิตภัณฑ์

อย่างไรก็ตาม กฎหมายการนำเข้าสินค้าตกแต่งพันธุกรรมที่ทรงประสิทธิผลจะมาจากการมีคณะทำงานที่มีประสิทธิภาพ ตัวกฎหมายต้องมีความชัดเจนและครอบคลุม รวมไปถึงรายงานการวิเคราะห์ ความเสี่ยงของการนำเข้าและมาตรการควบคุมดูแลสิ่งมีชีวิตตกแต่งพันธุกรรมและผลิตภัณฑ์ อย่างไรก็ตามการกำหนดบทลงโทษที่รุนแรงจะเป็นอีก ทางออกหนึ่งที่ทำให้ผู้ละเมิดกฎหมายมีความ เกรงกลัวในการฝ่าฝืนกฎหมายด้วยเช่นกัน

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CHAPTER I

INTRODUCTION

Development and improvement of biotechnology and its application have involved several sectors such as chemical, pharmacy, medical, agriculture, and environment. Modification of genetic materials by genetic engineering or recombinant technology was first developed in 1970s. This technique has enabled to isolate or multiply the particular genes and insert genes into another organism, which can be plant, animal, and microorganism with natural or conventional breeding. These transgenic organisms can not be able to process any characteristics. Besides, benefit of transgenic plant include the reduction the of agrochemical usage due to insert herbicide resistance; improve product quality such as delayed ripening (Rao S.R., 2002B). This technique can offer advantage as an alternative supply for human food. However, there are various aspects of concern about releasing of genetically modified organisms (GMOs) into the environment. These transgenic products are not only natural and possibly carry ambiguous risks but also can possess risk to human health, food consumption, economy, law and human rights (Anthony J. C. et al, 2003).

The conflict and confusion under GMOs issue has become a big problem affecting people at wider scale. Moreover, this matter tends to influence the overall economy and community around the world. At present, Thailand has been facing with GMOs issue. However, Thai government has not been able to find the solution by setting up suitable policy under this circumstance to cope with such problem. Therefore, Thailand should rush towards a clear direction of GMOs policy in order to eliminate current dilemma on GMOs research and improving Thai's business in future.

According to the public hearing report about "Thailand's situation on GMOs" there are many arguments about GMOs in area of environment, consumer safety, trade, and ethics that are based on unclear information". However, one economic analysis from U.S.A. reported that cost of GMOs plantation have been towards

substantial increase in income. It has also been reported that consumers have advantage to buy high product quality or product of high nutrition (ISAAA and University of Illinois, 2003).

Nowadays, a few countries have already set up GMOs regulations including United State of America, Japan, Canada, Mexico and Korea, etc. Moreover, regulation on product labeling has also been launched in Canada, Japan and some European countries such as Norway, Switzerland and Netherlands. However, this topic remains highly unclear in World Trade Organization (WTO) (Donna H. M. et al, 1999).

Although international trading and Thailand's stand point have not much been affected main problem may be a management failure. Even though, there is no significant affect from GMOs trading in particular an import in GMOs products into Thailand. But from an inappropriate management regulations concerned an import and export business in holistic view. For example, some agricultural products were exported to European or Middle East countries that have requested certification to guarantee that all of products are GMOs free.

This can imply that Thailand is significantly affected by productions and wholesales under many promulgations. Consumers are getting worried about food safety and some of them have still requested more on product information concerning GMOs effecting to line production and their labeling.

As a result, Thailand should have clear GMOs import regulation to indicate that it is well preparation for GMOs management in order to gain respect from trade partners. Therefore, this study will focus on GMOs regulation for Thailand import by comparing with the regulation of some Asian and European countries. At the end, this study also aims to propose suitable management strategies for importation of GMOs products in Thailand.

Objectives

1. To study introduced GMOs in selected Asian and European countries as well as its current situations and existing regulations regarded to GMOs.
2. To analyze strengths and weaknesses of Asian and European countries concerned about GMOs not only their enforcement and implementations but also results and consequences of the regulation.
3. To recommend the suitably manageable measures for importing GMOs product into Thailand and to propose alternative improvement of Thai's regulations which could support running import and export agriculture product among international trade.

CHAPTER II

LITERATURE REVIEW

2.1 GMOs products and their advantages

Genetic engineering is a precious method of biotechnology which has rapidly developed around the world. All scientists have put their best efforts in studying and doing research in order to improve quality of life in nutrition, medication and health known as “genomic revolution”. GMOs have now been improved and utilized in several following ways (ISAAA, 2002).

1. For agriculture

Transgenic plants could be able to create new species that resist inappropriate environment such as herbicide tolerance, pesticide tolerance, or drought tolerance. In addition, anti rottenness is one of the factors that prolong shelf life of agricultural products.

2. For consumer

A genetic technology is able to create high quality products such as nutritious cereal, fruits and vegetables with more vitamins C. Moreover, to create precious productivities or create new species of plant such as blue rose with bigger size, strength – looking even more endure than conventional species.

3. For industry

To diminish chemical usage, increase productivity and lower cost. Moreover, some raw materials of food industry take longer time to be produced from GMOs product such as enzyme Chymosin for cheese production or Pectinase for fruit and

vegetable juice. Presently, in some pharmaceutical industries have also created vaccines or hormones from GMOs product to squeeze more production

4. For environment

Whenever plant increases pest resistance, rate of chemical usage for agriculture will decrease that reduces environmental contamination from chemicals. It also reduces risk for farmers when they will use less chemicals. It could be accepted that improvement in species is one of contribution of GMOs toward more variation and high biological diversity as well.

2.2 Global GMOs product

Total area of global GMOs cultivation in years 1996 to 2002 was over 2.35 million hectares. This had already met the expectations of small and large farmers in both industrial and developing countries.

In the year 2002, the global area in sixteen countries for transgenic plant cultivation was 58.7 million hectares. Mostly these areas were in small resources - poor farmers of developing countries. U.S.A had the largest growth rate of growing GMOs crops, followed by Argentina, Canada, and China respectively (Figure 1).

The global status of GMOs crops in 2003 was reported that the areas of transgenic plant crops were increasing at a sustained double – digit growth rates of 15% compared with 12% since 2002. In 2003, estimated global area of GM crops was 67.7 million hectares. This also included provision from Brazil, where the government approved for planting GM soybean for the first time around 3 million hectares

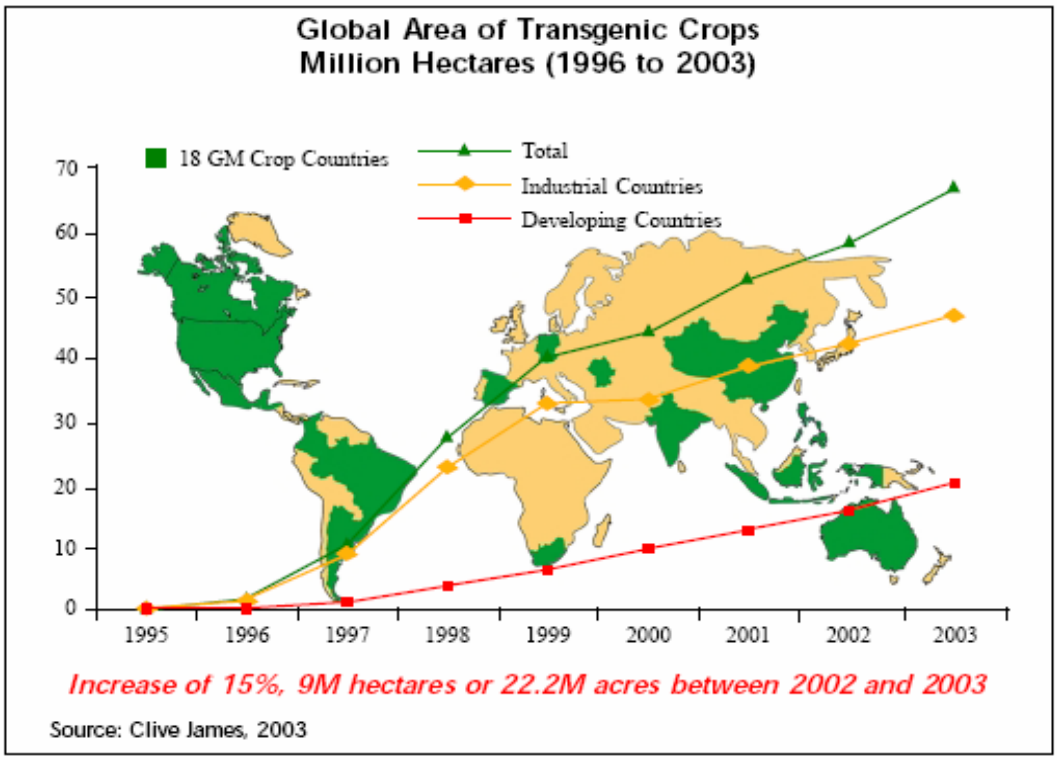

Figure 1: The global area of transgenic crop 1996 – 2003 and area of GMOs plantation (Clive J., 2003)

Even if provisional conservation of Brazilian GMOs soybean was excluded, a double – digit rate of 10% growth has still sustained. In 2003 the global GM crops area increased by 7 million farmers in 18 countries and increased from 6 million farmers of 16 countries since 2002. In addition, during 1996 – 2003, global area of transgenic crop increased from 1.7 million hectares to 67.6 million hectares. Almost one – third of global transgenic crop area, 67.7 million hectares, which is equals to 20 million hectares were grown in developing countries. The growth rate of GMOs crops area between 2002 and 2003 was as same as in developing and industries countries. It could be concluded that the increased area between 2002 and 2003 was approximately 15%, which is parallel to 9 million hectares (Clive J., 2003).

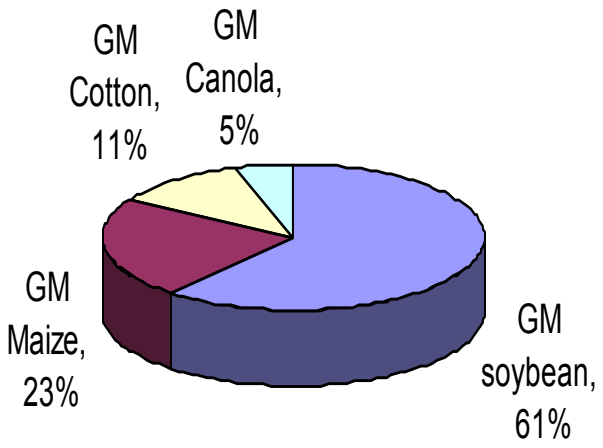

Figure 2: Comparing GM crop with global GM area (Clive J., 2003)

The major GMOs products continued to be soybean, maize, cotton, and canola. Regarding to global GMOs crops areas, 36.72 million hectares were maize and 3.0 million hectares of canola (Figure 2). The most dominant trait of the global GM crops in 2002 was herbicide tolerant followed by insect resistant and stacked genes of herbicide tolerant and insect resistance (Clive J., 2002).

2.3 Overall effects of imported GMOs products

Any of technology has both advantages and disadvantages. In case of GMOs, they have some weaknesses in terms of risk and management. Apart from environmental impacts or biodiversity collapse, health impacts and economic consequences on international trade are also involved with GMOs import.

Currently, government policies related to GMOs products were reviewed in order to summarize available scientific information, trend and status of GMOs in foreign countries and in Thailand. All these information's were used for impact assessment of government policies in particular with international trade (Traynor, L. P.,1999).

2.4 The importation of Thailand

Based on Thailand's trade statistics, most of the imported products are capital assets, industrial raw materials and consumer commodities, including agricultural products such as rapeseed oil, soybean, maize, and cereals from overseas. Main importing markets into Thailand are United States (Table 1), Japan and some European countries

Table1: Imported amounts of some agricultural products of Thailand

Unit: Tons

Product / Sources	Rapeseed cake			Rapeseed oil			Instant grain cereal		
	2001	2002	2003	2001	2002	2003	2001	2002	2003
Asian	0.03	0	0	4.67	3.88	2.84	11.18	13.4	14.2
Europe	0	0.1	0.34	0	0	0.82	13.56	11.63	15.7
Japan	0	0	0	0	0.01	0	1.97	1.84	1.77
U.S.A.	15.69	13.42	5.34	40.04	49.22	44.5	22.89	24.62	22.2

Source: Ministry of Commerce, 2001 – 2003

Along with commercial statistics of Thailand and trade partners indicate that, Thailand has exported products to United Kingdom, Netherlands, and Germany and also imported various products in descending order from Germany, United Kingdom, and France. Likewise, an Asian partner, Japan is the biggest importer and exporter of Thailand.

According to the both trade statistics between Thailand and China, the amount of imports and exports are relatively increasing. Besides, total import – export summary between Thailand and Philippines, is also comparatively growing. On the other hand, import and export markets between Thailand and United Kingdom are rather different. Thailand has been exporting products to United Kingdom higher than imports since 1997s until now. Types of products Thailand have imported including machines, computers and electronic parts, industrial raw materials, fruit and vegetable.

Additionally, based on specifics of imported products, increasing rates of cereal and readymade food grain from 2000s until now are continually increasing.

Similarly, the increasing rates of rapeseed oil during 2000s until now are increasing also. It could be said that, Thailand has been importing massive amounts of agricultural products from overseas. However, these products are highly controversial GMOs products in international trade (Table 2).

Table 2: Statistic ratio the amount of GMOs and total production of soybean, cotton and maize in United State of America

Year / Products	2000	2001	2002	2003	2004
Soybean	54 %	68 %	75 %	81 %	85 %
Cotton	61 %	69 %	71 %	75 %	76 %
Maize	25 %	26 %	34 %	40 %	45 %

Source: Ministry of Commerce 2000 - 2004

2.5 GMOs and biosafety guideline

Argument of GMOs impact has been influenced by international trading amongst European markets. As a result, many countries have established their own regulations in order to get rid of limitations from European trade partner. Not only local guideline for GMOs regulation, but also an international guideline has been placed for the state of the parties in their corporation.

2.5.1 International agreement related to GMOs and Biosafety guideline

Basically, all agreement intends to standardize in the same direction. Not only to harmonize but also to avoid duplicate. Presently, multilateral agreements regarding GMOs are illustrated as following. (Sue M. and Andy S, 2004)

1. Biosafety Protocol (Appendix A)

Biosafety protocol is an international agreement, under the 'Convention on Biological Diversity' (CBD) of 1992 that directly involves GMOs. The objective of this protocol is to control the safety of transboundary appropriately. Moreover, it also regulates GMOs usage and management of modern biotechnology that may impact

conservation and sustainable use of biodiversity. This regulation becomes effective 90 days after at least 50 parties rectify it. This can be inferred that 'Catagena Protocol on Biosafety' is the first international regulation to control organism from genetic engineering. There are some interesting points of this protocol as follows.

1.1 The objectives of Catagena protocol in Article 1 "*In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.*" (Catagena protocol, 2000)

Principle 15 of Rio Declaration on Environment and Development (Rio Declaration on Environment and Development, 1992) "*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be use as a reason for postponing cost – effective measures to prevent environment degradation*" (Appendix B)

Therefore importing countries can reject GMOs contaminated products without any scientific approvals that might affect human health and environment under the "Precautionary approach"

1.2 Article 7 "Application of the advance informed agreement procedure (AIA)" indicated that AIA procedure shall apply prior to the first intentional transboundary movement of living modified organism for intentional introduction into the environment of the Party of import. In this article is specify in Article 8, 9, 10 and 12 which are Notification, Acknowledgement of receipt of notification, Decision procedure and Review of decision respectively (Figure 3).

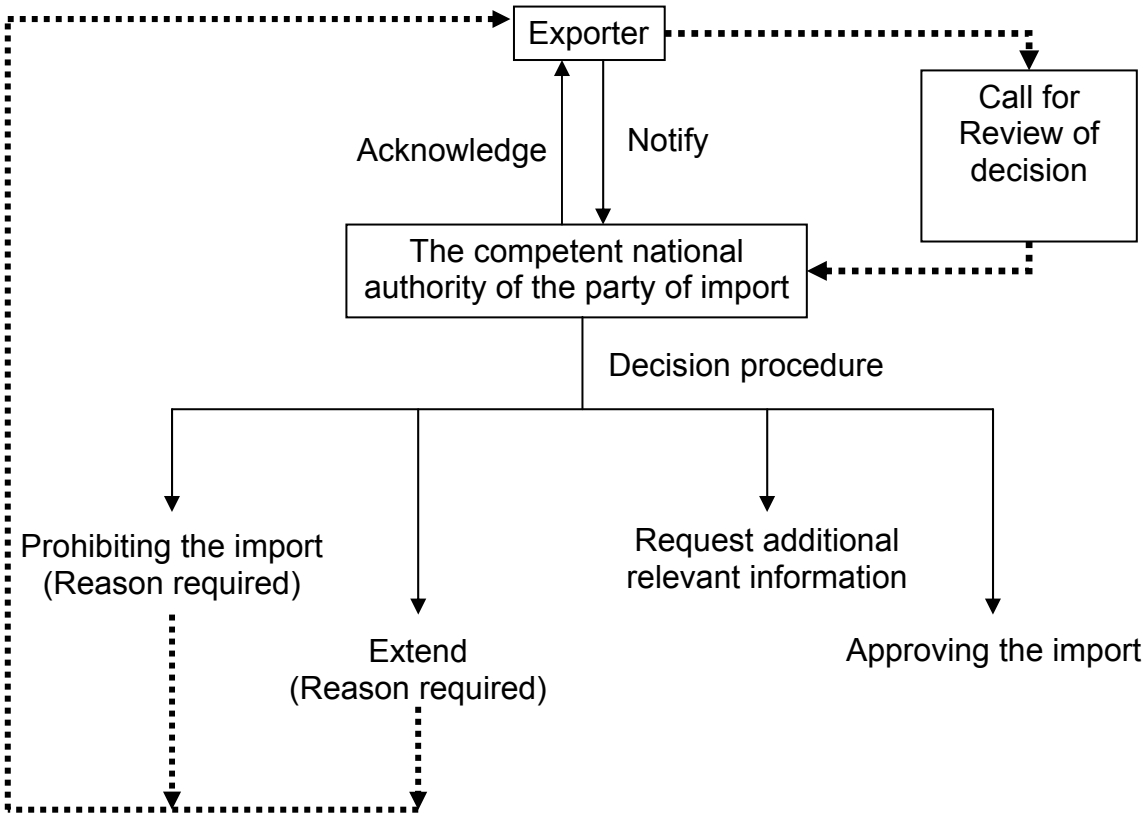

Figure 3: AIA procedure (Catagena protocol, 2000)

The exporter shall notify the competent national authority of the Party of Import prior to the national transboundary movement of a living modified organism, along with a legal requirement of the accuracy of information. Then the party of import shall acknowledge receipt of the notification within 90 days. Decision taken by the Party of import in 4 alternatives which are approving the import, prohibiting the import, request additional relevant information in accordance with its domestic regulatory framework, and extend a decision period as well as inform notifier by defined a period of time. However, "Review of decision in Article 12" indicated that Party of export or a notifier may request the Party of import to review a decision it has made in respect of it. And Party of import shall respond their request within 90 days and set out the reason for its decision.

1.3 In Article 11 "Procedure for living modified organisms intended for direct use as food or feed or for processing (FFP)" said a party that make a final decision shall inform the Parties through the Biosafety – Clearing – House (BCH)

within 50 day of making decision. A party of import may take a decision under its domestic regulatory framework that consistent with the objective of the protocol. In case of developing country Party may in the absence of the domestic regulatory framework, and in exercise of its domestic jurisdiction, declare through the BCH in decision to the first import which taken the decision according to a risk assessment within predictable timeframe, not exceeding 270 days.

1.4 This protocol requests to set up a coordination centre in order to incorporate and exchange information of CBD in Article 19 "Competent National Authorities and National Focal Points" indicates that "*Each party shall designate one national point to be responsible on its behalf of liaison with the Secretariat. Each party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this protocol and which shall be authorized to act on its behalf with respect to those function. A party may designate a single entity to fulfill the functions of both focal point and competent national authority.*"

2. Codex standard about food – safety assessment and labeling

Since 1989, Codex is an international corporation concerned with food consumption from food processing. Then, Biotechnology Food Labeling committee was formed in order to draft "Recommendations for labeling of food obtained through biotechnology"

Proposed draft recommendation for the labeling of food obtained through biotechnology (Proposed draft amendment to the general standard for the labeling of prepackaged foods) in Section 4.2.2 "*The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed 4.2.1.4* (Appendix C) *shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labeling the food containing the allergen should not be marketed.*" (CODEX, 2000) These could be summarized as following

:

2.1 Do careful label of GMOs product that contains allergens.

2.2 Consider labeling swine fat or cattle fat contained with GMOs products.

2.3 If any food is not adequate in terms of ingredients, usage, and nutrition compared with conventional food. Should be appropriately labeled.

Furthermore, one of the working groups was formed to consider standardization and measurement about food produced from biotechnology called 'Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnolology'. The goal of this group was to indicate food safety assessment from biotechnology, to be accepted from international and to protect human health and sustain international trade (Mark W. R. et al, 2001).

3. World Trade Organization

From a study of Agreement of World Trade Organization (WTO) regarding GMOs product found that, regulation to control GMOs product trading has not specified yet because this is rather a new development and is still not clear in management. However, during Uruguay summit, GMOs have discussed elaboratively as following topics.

3.1 The exceptional Article 20 of GATT (GATT: 1986) shall allow all parties are not required to follow the conditions of WTO in order to protect health of human animal and plants

Article XX "*General Exception*" Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(a) necessary to protect public morals;

(b) necessary to protect human, animal or plant life or health;

(c) relating to the importations or exportations of gold or silver; (GATT, 1986)

3.2 Agreement on applications of Sanitary and Phytosanitary Measurers (SPS) (Appendix D) shall allow parties to restrict goods that might cause human life and their health including plants and animals. On the other hand, if scientific evidence can prove or comply other international standards, parties shall use others regulation. Additionally, if the exception in Article 5.7 could not be proved, it may allow parties to use provisional measures based on available information from international organization and health measurement from all others countries that have regulated GMOs. But the parties should have more research in order to provide risk assessment.

Article 2 "*Basic Rights and Obligation*"

1. Member have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measure are not inconsistent with the provisions of this Agreement.

2. Member shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

3. Member shall ensure that their sanitary and phytosanitary measures do not arbitrary or unjustifiable discrimination between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

4. Sanitary or phytosanitary measure which conform to the relevant provision of this Agreement shall be presumed to be in accordance with the obligation of the Members under the provision of Article XX (b)

Article 5 "*Assessment of Risk and Determination of the Appropriate Level of Sanitary of Phytosanitary Protection*"

Paragraph 1; Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

Paragraph 2; In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

Paragraph 3; In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

Paragraph 5; With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

Paragraph 7; In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time (WTO, 1994C).

3.3 Agreement on Technical Barriers to Trade (TBT) aims to protect life and health of human, plants, animals and promote environmental conservation. Based on indoctrination of adequate use under scientific support that covers product quality, processing methods, package and labeling (Appendix E).

Article 2 "*Preparation, Adoption and Application of Technical Regulations by Central Government Bodies*"

Paragraph 2; Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non – fulfillment would create. Such legitimate objectives are, *inter alia:* national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia:* available scientific and technical information, related processing technology or intended end-uses of products (WTO, 1994B).

3.4 Article 27: Agreement on Trade Related Aspect of Intellectual property (TRIPs) to protect the right of study's result regarding biotechnology. However, GMOs are new innovative product and owner may need property right but in exceptional cases it will not protect property right of research if it posses danger for

humans, animals and plants or environmental damage likewise Article 27.3 (b). (Frederick W. C. 2001).

In section5: Patent, Article 27 "*Patentable Subject Matter*"

1. Patents shall be available for any inventions whether products or processes, in all fields of technology, provided that they are new, involve inventive step and are capable of industrial application. Patent shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their laws.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro – organism, and essentially biological processes for the protection of plants or animals other than non – biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents of by an effective *sui generic* system or by any combination thereof. The provisions of this sub paragraph shall be reviewed four years after the date of entry into force on the WTO Agreement (WTO, 1994A).

2.5.2 Domestic Biosafety guideline and national law

Several countries have already formed their national guidelines to control GMOs product either for import or export. For example, Australia issued 'Gene Technology Act 2000' which received Royal Assent on December 21, 2000 and come into force in June 2001. There are some interesting points such as to regulate all

‘dealing’, that is, research, manufacture, production commercial release, and import, with live, viable organisms that have been modified by techniques for gene technology, including the progeny of such GMOs that also share a genetically modified trait. And also create a centralized, publicity available database of all GMOs and genetically engineered products approved in Australia. The provisions of the Gene Technology Act are “in addition to, and not in substitution for, the requirements of any other law of the Commonwealth (whether passed or made before of after the commencement of the Act.) (World Bank, 2003). Philippines figured out the ‘Philippines Biosafety Guideline’ (PBG), and European Union has produced ‘Direction on Contained Use’ and ‘Deliberate Release into the Environment of GMOs’. Nevertheless, all of these guidelines are intended to propose regulation related with international agreements. As well as, indicate their own outstanding point and support their local business among the international trade. Basically, regulations not only concern human health, and environmental damage, but also concern benefits and potential impacts of international trade. Along with emphasizing on measurements, some of the consideration points include source of GMOs product, monitoring system, import procedure, and traceability, as well as labeling which provide alternative for consumer. Furthermore, others details would be discussed in Chapter 4.

CHAPTER III

METHODOLOGY

3.1 Focused groups of the study

This study separates target groups into two main categories consisting of study group and comparison group.

- *Selection of main category groups*

Similarly, study group was divided into two subcategories which are Asian and European.

1. Asian; China and Philippines were selected in this study.

2. European; England was chosen as representative country.

- *Comparison group*

Thailand was chosen as comparison group for this study, in order to accomplish research objectives. Along with the comparison with study group to clearly indicate the dissimilarity in various point and prepare a revision possibility practices from successful enforcement and implementation.

3.2 Gathering data

For gathering data, process will be divided into three groups of information as following.

1. *Import data*

In order to assemble data and obviously indicate key research question, all import statistics and several market information would be composed as following.

- Thailand import – export statistics
- Import – export commodities
- Market trend
- Market resources
- Specific commodities import – export statistics
- Bilateral market statistics between Thailand and studied countries
- Market statistics between Thailand and other corporations

2. *International agreement*

Based on GMOs issue becoming a dilemma among international trade, many international agreements have been set up, to solve the problem in advance or are precaution step. The study will review relevant legal documents and regulation papers as following:

- Catagena Protocal (Biosafety Guildeline)
- Codex standard
- WTO commitment

3. *Domestic regulation and national law*

Many countries have already set up their own regulations regarding GMOs measurement to conform to the international agreement. This step will look at present local regulation about GMOs measurement of all focused groups countries that are China, Philippines, England and Thailand.

3.3 Analysis and discussions

After reviewing all necessary information, the last step would involve discussion in holistic views of import regulation and analysis of the regulation.

1. General information

- Introduction GMOs
- Existing GMOs
- Current information

2. An information of import regulation

- Safety assessment
- Permission detail
- Import procedure
- Supporting regulation
- Related government of working group
- Harmonization of international agreement

3. Analytical points

- Strengths and weaknesses
- Enforcement and implementation
- Consequences

Final part would discuss the import different between Thailand and studied group (China, Philippines, and England). Moreover, impacts between studied group and their international trade will also be discussed. Nevertheless, effects of imports into Thailand and the difficulty of import – export business with trade partner will be explained along with solutions required necessary to work out the problems.

CHAPTER IV

RESULTS AND DISCUSSIONS

4.1 Import regulation of China

4.1.1 Import procedure

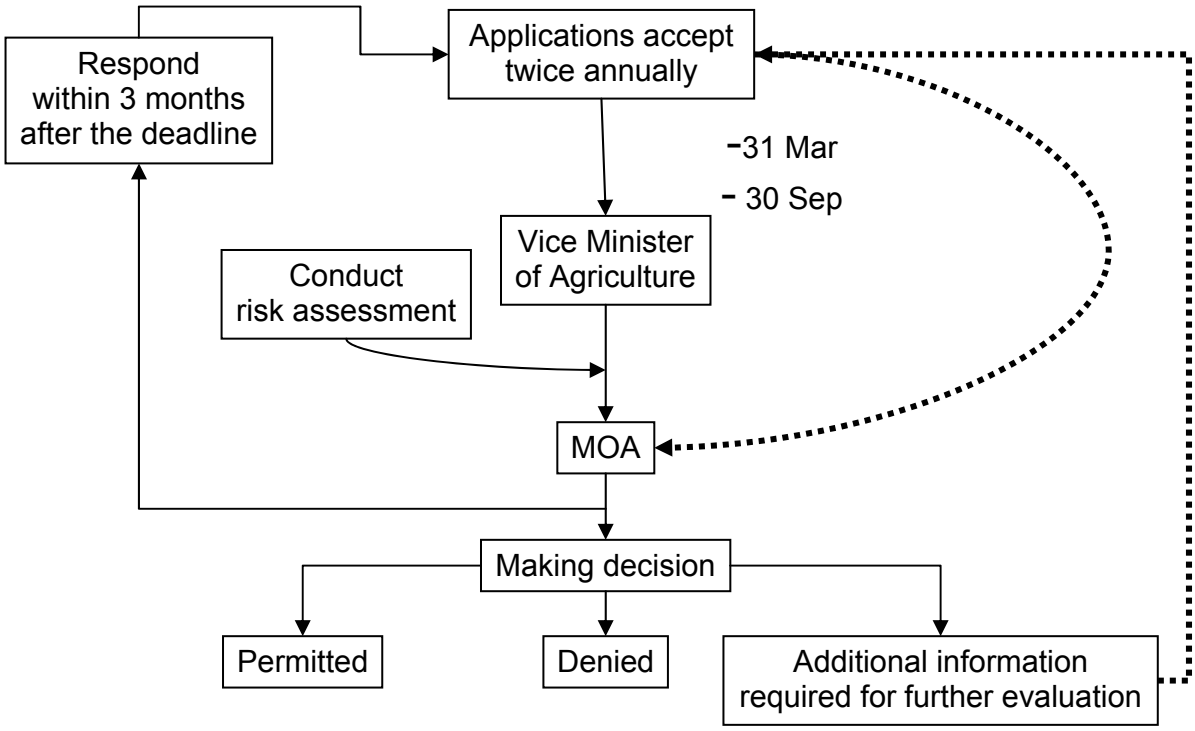

Figure 4: Registration procedure for GMOs import in China (Jingen C., 1998)

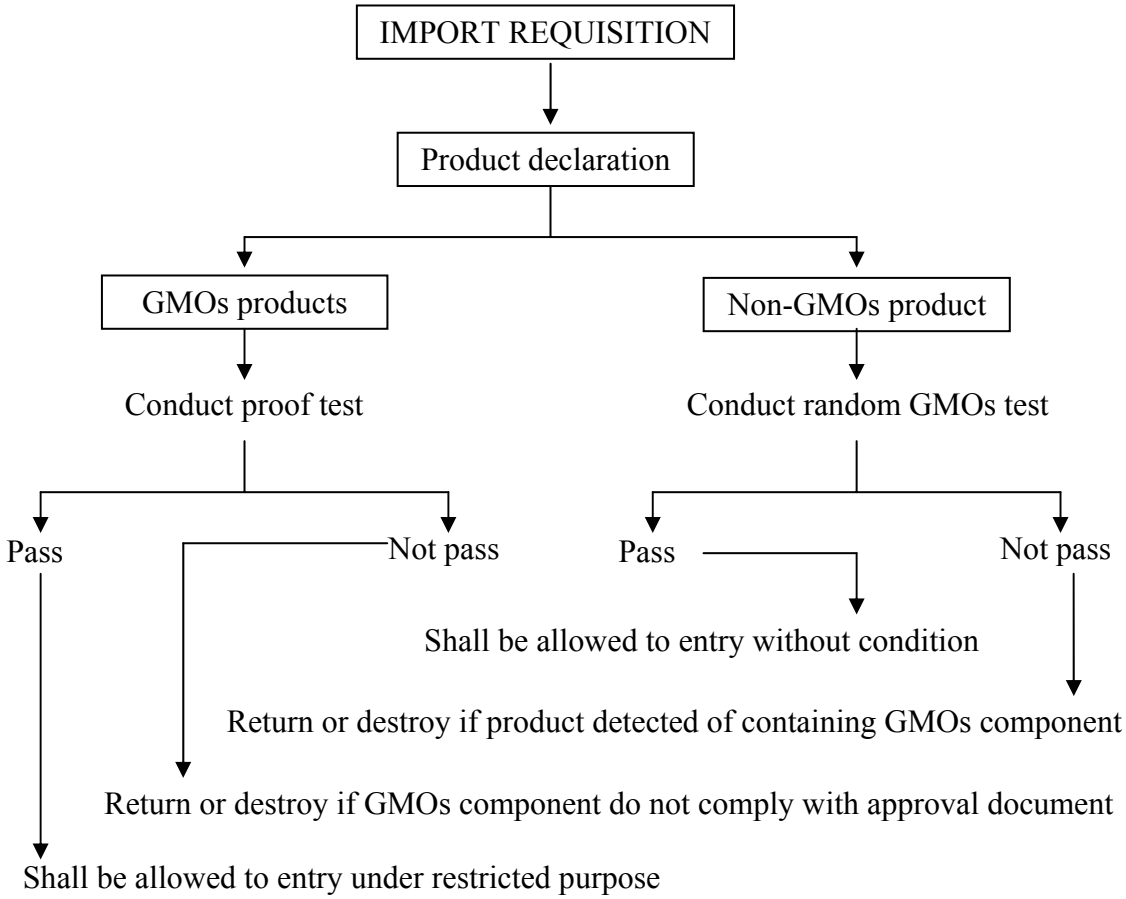

Figure 5: Import procedure of China (Ralph G., WU B., 2004)

The import procedure of China separate in 3 main steps which are submit import requisition (Figure 4), product declaration and product determination. Particularly declaration product is a key significant for import permission (Figure 5).

4.1.2 Imported permission details

Import permission details have involved with Article 6, 7 and 10 of Administrative Measures of Inspection and Quarantine on Entry – Exit GM Products. These could be concluded that, person who imports GMOs products should indicate in column of "goods name". Moreover, all relevant documents and certificates should be provided. After products passed GM test with irregularity condition, person who import GM products would be informed to return or destroy the goods. (Jikun H., and Qinfang W., 2002)

"Article 6: AQSIQ will adopt a GMO declaration system for entry animals, plants, microorganisms, their products, and foods."

"Article 7: The consignees or their agents should indicate whether the entry goods are GM products under the column of "goods name" in the Declaration Form for Entry Goods when applying for inspection and quarantine. If declared as GM product, the consignee or his/her agent shall, in addition to providing relevant documents and certificates, also supply a law-required Safety Certificate for Agricultural GMOs issued by competent authorities (or relevant approval documents, hereinafter referred to as approval documents) and the Review and Approval Document for the Labeling of Agricultural GMOs"

"Article 10: Entry products that have passed GM tests shall be allowed entry. In the case of one of the following situations, the inspection and quarantine agency should inform the consignee or his/her agent to return or destroy the goods.

1. Declared as GM product, but the detected GM components do not comply with the approval documents.

2. Declared as non-GM product, but it has been detected of containing GM components."

4.1.3 Safety assessment

Based on Article 9 of Administrative Measures of Inspection and Quarantine on Entry – Exit of GM Products need to indicate the safety assessment of import regulation for GMOs product of China has been described as follows (Xiang Q., and John W., 2000).

"For entry GM products that are listed in the agricultural GMO catalogue subject to labeling (drafted and published by agricultural administrative department under the State Council), if declared as GM products, the inspection and quarantine agency should conduct proof tests; if declared as non-GM products, the inspection and quarantine agency should conduct random GM tests. For entry animals, plants,

microorganisms, their products and foods that are not listed in the catalogue, the inspection and quarantine agency may conduct random GM tests based on circumstances."

4.1.4 Involved government

According to Article 4; *"The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (hereinafter referred to as AQSIQ) is responsible for nationwide management of inspection and quarantine on entry-exit GM products. AQSIQ's local entry-exit inspection and quarantine agencies (hereinafter referred to as "inspection and quarantine agencies") are responsible for the inspection and quarantine and monitoring of entry-exit GM products within their jurisdiction"*. (Frederick W.C., 2001) However, due to lack of charity on food safety regulation, working group of China's government has been formatted to enforce and implement law and relevant regulation (Figure 6) (Xiang Q. and John W.: 2000). These government included;

1. The Nation Science and Technology Committee (NSTC)
2. The Ministry of Agriculture (MOA)
3. The ministry of Public Health (MPH)
4. The State Environment Protection Administration (SEPA)
5. The State Administration for Entry – Exit Inspection and Quarantine (ICQ)

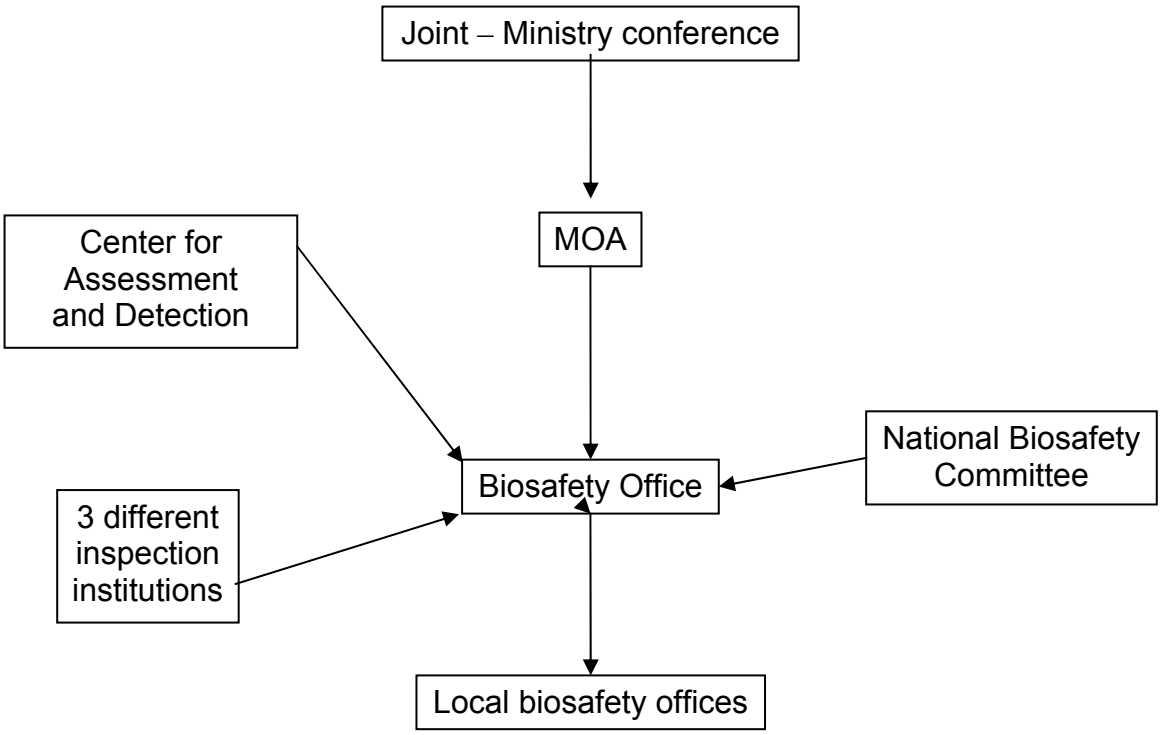

Figure 6: GMOs management system of China (Liu Y. and Wang C., 2004)

4.1.5 Supporting and relevant regulation

1. The Law of the People's Republic of China on Import and Export Commodity Inspection
2. The Food Hygiene Law of the People's Republic of China
3. The Law of the People's Republic of China on the Entry and Exit of Animal and Plant Quarantine and its Implementation Regulations
4. The Administrative Regulations on Agricultural GMO Safety
5. The Administration Rules For New Resource Food by MPH 1992, which is under Food Health Law
6. The Administration Framework for Biological Safety (AFBS)
7. The New Plant Varieties Protection Regulation by State for Council 1997

4.2 Discussion of China regulation

China is developing the Largent plant biotechnology capacity. China is one of the countries which has prepared national biotechnology program to support GMOs product by arranging some essential resource and also issuing the regulation.

4.2.1 Strengths

1. Set up many relevance governments in order to enforce the regulation that would cover area of GMOs importation.
2. Emphasize on labeling before import all restricted material. No entry is permitted if GM products do not have labeling.
3. Afford random check all entry products even to declared as non – GMOs product in order to recheck and ensure all imported products are non – GMOs.
4. Provide import permit in case of exhibition material in order to public relation and knowledgeable support for their people.

4.2.2 Weaknesses

1. The world of “GM product” in the regulation was narrowly defined as “the agricultural genetically modified organism”. Therefore some gaps of the regulation could be used as appreciation.
2. China does not have any regulation regarding import or export products that contain GMOs ingredients.

At present, China still has limited human capacity, institution, and financial support in terms of GMOs. These are still far away from the necessary requirement to support the regulation. Moreover, concerning to related group of people such as farmers and government officers, they tend to have very little knowledge on GMOs issue. Hence, several problems had occurred during the past few years. For example, farmers might not known that the plant they were growing being seeds from gene modified or not. Besides, they have no ideas on what should be the further process to deal with GMOs seeds.

4.2.3 Result and consequence

In spite of GMOs regulations in China covering many points of importing GMOs products, there are some indicators point out that they have not considered some stages as weaknesses. The points they have not stated any regulations to control GMOs in food ingredients which may affect import – export business of China if trade partners raise the point of ingredient contained GMOs internationally.

Starting from small factors on linkage of the knowledge and misunderstanding about GMOs, this case may lead to a huge effect at the international stage. For example, if farmers have no ideas about the process to notify its crops to the government in case they have planted GMOs seeds. Their produces may be rejected from import country once they random check imported products which can be outcomes the business relate with China. (Rao S.R., 2002A).

4.3 Import regulation of Philippines

4.3.1 Import procedure

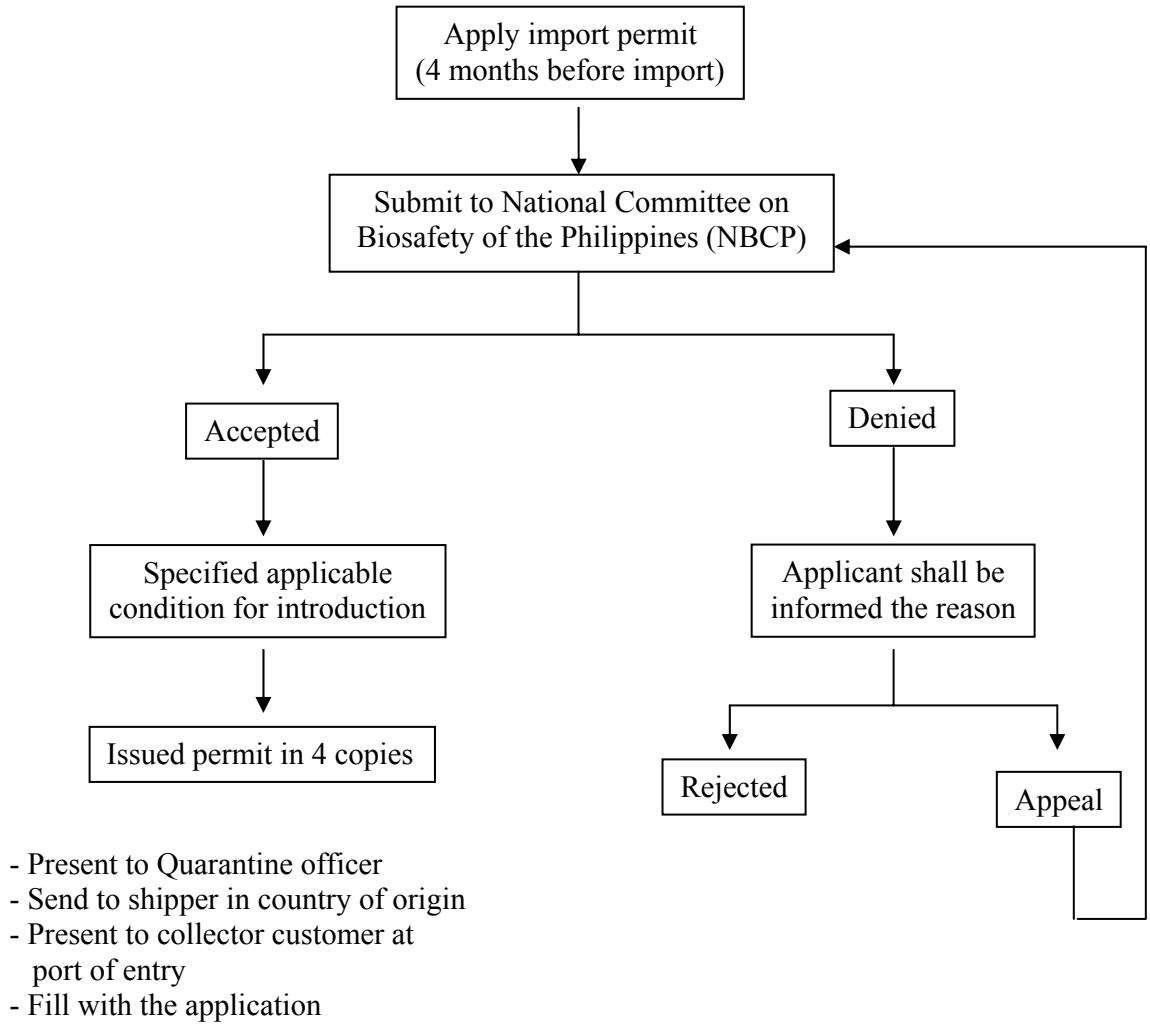

Figure 7: Import procedure of Philippines (The University of the Philippines at Los Banos (UPLB), International Rice Research Institute (IRRI) and Department of Agriculture (DA),1991)

The first edition of Philippines Biosafety Guideline (PBG) was published in 1991 which originated from Report of the Ad – hoc Committee. The committee is comprised of UPLB, IRRI and DA representatives by based on Biosafety guideline of Australia, United State and Japan (Figure 7).

4.3.2 Imported permission detail

1 Introduction of Regulated Materials

1.1 Any introduction of regulated materials should be authorized by an import permit

1.2 Approval or denial of an import permit shall be based on the following guidelines for evaluation:

1.1.2.1 Responsible person or persons involved

- Name, title, address, telephone number and signature
- Name, address and telephone number of the person(s) who developed and/or supplied the regulated materials

1.1.2.2 Materials to be introduced

- Quantity of the regulated material(s) to be introduced and proposed schedule and number of introductions
- All scientific common, trade names and all designations necessary to identify the regulated material
- Country and locality where the regulated material was collected, developed and produced
- Known potential to cause an epidemic (survival and reproductive rates, dispersal, etc.)
- Known potential to cause losses
- Known potential hosts or alternative hosts
- Known ability to evolve
- Known vector of organisms
- Known mode of spread and conditions for epidemic
- History of epidemics

1.1.2.3 Genetically Modified Micro-organisms

- Nomenclature and characteristics of donor, recipient and vector organisms
- Detailed description of the molecular biology of the systems. For example donor-recipient-vector that is or will be used to produce the regulated materials
- A description of the anticipated or actual expression of the altered genetic material in the regulated materials; an explanation of how that expression differs from the expression in the non-modified parental organism such as morphological or structural characteristics, physiological activities and processes, number of copies inserted in the genetic material; the physical state of this material inside the recipient organism (integrated or extra – chromosomal), products and secretions, growth characteristics
- Detailed description of the processes, procedures, and safeguards that have been used or will be used in the country of origin and in the Philippines to prevent contamination, release and dissemination in the production of the donor organism, recipient organism, vector or vector agent, regulated materials and a constituent of each regulated material which is a product.

1.1.2.4 Others

- A detailed description of the usage and the purpose for introducing the regulated material, including a detailed description of the proposed experimental and/or production design
- History of similar introductions
- A description of transfer of the regulated material for example mail, common carrier, baggage or hand carried.

- A detailed description of the intended destination (including final and all intermediate destinations) and/or distribution of the regulated material such as greenhouse laboratory or growth chamber location field trial location, pilot project location, production, propagation and manufacture location; proposed sale and distribution location.
- A detailed description of the proposed procedures, processes and safeguards that will be used to prevent escape and dissemination of the regulated material at each of the intended destinations
- A detailed description of any biological materials such as culture medium or host material accompanying the regulated material during movement.
- A detailed description of the proposed

2 Movement of Regulated Materials. A person who has been issued a permit for importation shall comply with the following guidelines for movement of regulated materials:

2.1 Marking and Identification

2.1.1 General nature and quantity of the content

2.1.2 Country and locality where it was collected, developed, manufactured, reared, cultivated or cultured

2.1.3 Name and address of shipper, owner or person shipping or forwarding the organism

2.1.4 Name, address, and telephone number of consignee

2.1.5 Identifying shipper's mark and number

2.1.6 Written permit number authorizing the importation.

2.2 Container (Please refer to Part IV, Section 5 – Container requirements)

4.3.3 Safety assessment

In the Philippines Biosafety Guideline it was clearly specified that all person who is engaged with the experiment directly or indirectly should have adequate instruction under good biosafety practice. Not only aseptic technique instruction of biological experiment, but also the potential of biohazard should be understood clearly and willing to be followed (Robert J. H., 2001).

Moreover, all working group involved with restricted materials should conduct emergency plan along with describing procedures if accident will occur. Regard to restricted material, everyone should comprehend the emergency plan and willing to follow once unexpected situation will happen. (Reynaldo E., 2002)

4.3.4 Involved government

The National Committee on Biosafety of the Philippines (NCBP) has established the biosafety guidelines and it's responsible for regulation with authority over any violations (Figure 8). Furthermore, NCBP was also established in collaboration amongst proper national governments which have regulatory authorization over any such violations. The group of NCBP is comprised of 1 biologist, 1 environmental scientist, 1 physicist, 1 sociologist, 1 representative from Department of Agriculture, 1 representative from Department of Health, 1 representative from Department of Environmental and Natural Resource and 2 respected members of the community (Nares D., 1999).

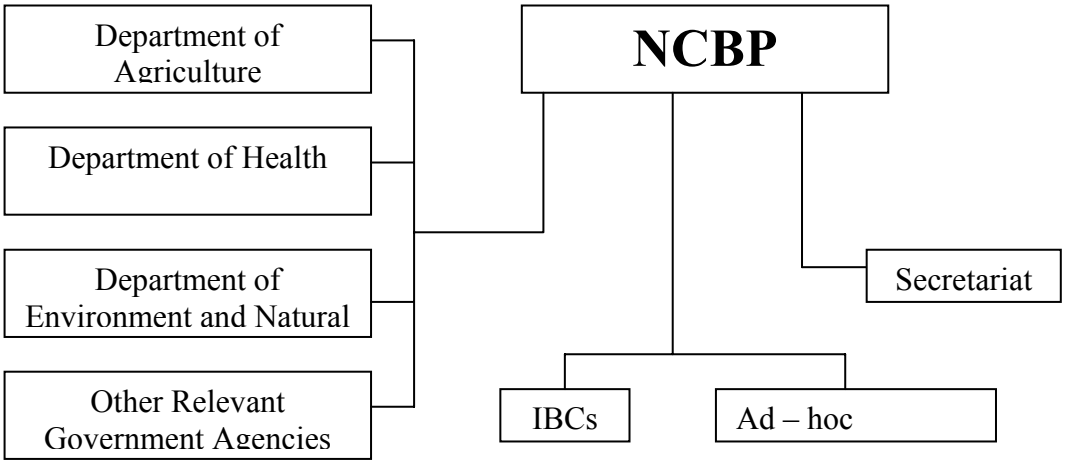

Figure 8: Coordination flowchart between NCBP and all concerned partners (Nares D.,1999)

The National Committee on Biosafety of the Philippines (NCBP) confines to the regulatory agencies of the government in compelling the guideline. The regulations of Biosafety implementation not only aims to avoid function duplicating, but also extends layer possibility of regulation. Each agency has enforcement regulation to establish the policy and necessary monitoring of work according the guideline (Saturnina C. H., 2000).

1. Department of Agriculture (DA)

   - Bureau of Plant Industry
   - Bureau of Animal Industry

Those play a significant role in guideline enforcement through quarantine services. Particularly, genetically modified organism and non – indigenous pathogenic organism movement are regulated and monitored. Moreover, NCBP is also involved with the Fertilizer and Pesticide Authority in Biological Control Agents legislation.

2. Department of Health (DH)

The Bureau of Food and Drugs (BAFD) of this department plays a significant role in human health effect once transgenic food products, drugs and animal feeds that are decisively imported into domestic market. Although BFAD does not have any direct guidelines subjected to transgenic product, NCBP shall closely coordinate with BFAD and also offer technical assistance to the regulatory agencies in order to create the guideline of transgenic products.

3. Department of Environment and Natural Resources (DENR)

DENR is involved in managing risk associated with GMOs and their potential impact on genetic resource and biodiversity under the Convention on Biological Diversity (CBD). Similarly, DENR is considering on Environmental Impact Assessment (EIA) and monitoring referring to NCBP.

Any representative can be designated as a member of NCBP. The principle function of NCBP is to formulate, review or amend national policies relevant to the guidelines.

4.3.5 Supporting and relevance regulation

Biosafety guidelines involve genetic engineering and activities required importation, introduction, field release, breeding of non – indigenous organism as well as not genetically modified organisms. The content in biosafety guideline includes the organizational structure for biosafety, procedures for evaluation of proposals with biosafety concerns, procedures and guideline on the introduction, movement and field release of restricted material, and physico – chemical and biological containment and procedures. Therefore, Philippine does not have any supporting plans regarding to the Biosafety Guideline. (Augusto L et al, 2004)

4.4 Discussion of Philippines regulation

The Philippines has rapid development in genetic engineering becoming of its national research institute such as IRRI or ISAAA. The National Committee on Biosafety of the Philippines (NCBP), created in 1990, carries out functions dealing with the implementation of national biosafety guideline and risk assessment of GMOs. The NCBP has a regulatory role not only in research on GMOs but also on the import and commercial use of GM products.

4.4.1 Strengths

1. National Committee on Biosafety of the Philippine was conducted from many sides such as biologist, environmentalist, physicist, some of government representative, and also local representative. Based on these various types of human resources in Philippine's national committee, it has results on the effectiveness of the guideline.
2. Citizen could be able to involve with Biosafety guideline through the process of public consultation. Furthermore, this guideline must be reviewed regularly in order to improve and develop its weakness areas.
3. The guideline has indicated "Feed back mechanism" in order to adjust itself.
4. Regard the biosafety guideline, proper packaging and container were specified, as well as marking and identification standard of import materials.
5. The guideline could be applied for domestic transport such as between institutions for research and study purpose.

4.4.2 Weaknesses

Philippines do not have any plans to support the importing measurement for GMOs. Even though, Philippine's biosafety guideline is one of the restricted

regulations in the world, current situation of Philippines does not have any documented trials.

4.4.3 Result and consequence

Policy gap is discrimination between regulation and practical ways which definitely is one of obstacles of Philippines. Hence, GMOs realized that field trial, which is approved from government, may affect health and environmental security then they can discontinue research.

From the strong point of Philippine about public participation, people seem to pay a lot of attention to their regulations. This can be used as an example to apply in other countries. Unfortunately, the country has a very useful biosafety regulation but it has a slow growth in average because of interfere from NGOs in this country. Related to the overall Philippine's guideline, it seems to be a few minor weaknesses when comparing with other countries' regulation. However, this guideline can not be able to apply and reach its maximum utility (Nares D., 1999).

4.5 Import regulation of United Kingdom

4.5.1 Import procedure

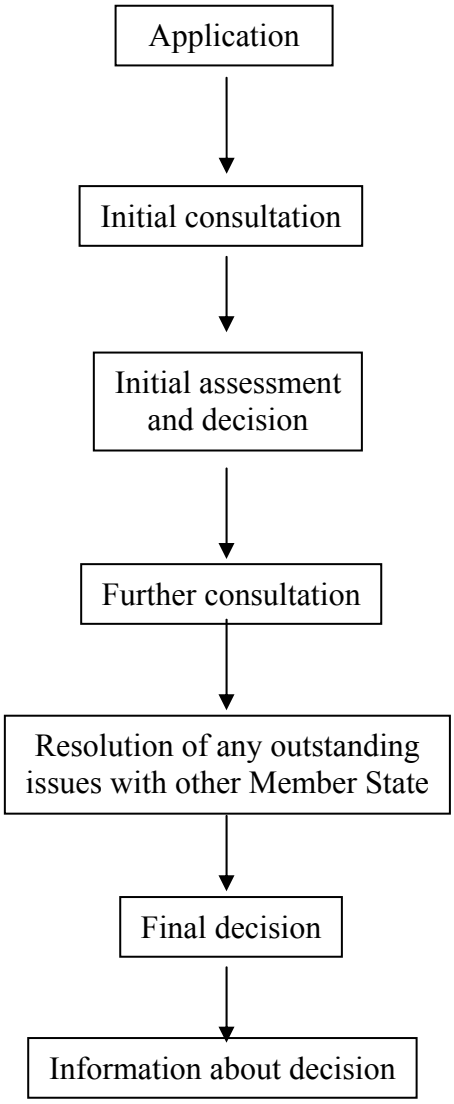

Figure 9: Registration procedure for GMOs import in United Kingdom (GM Co-ordination Team, 2002)

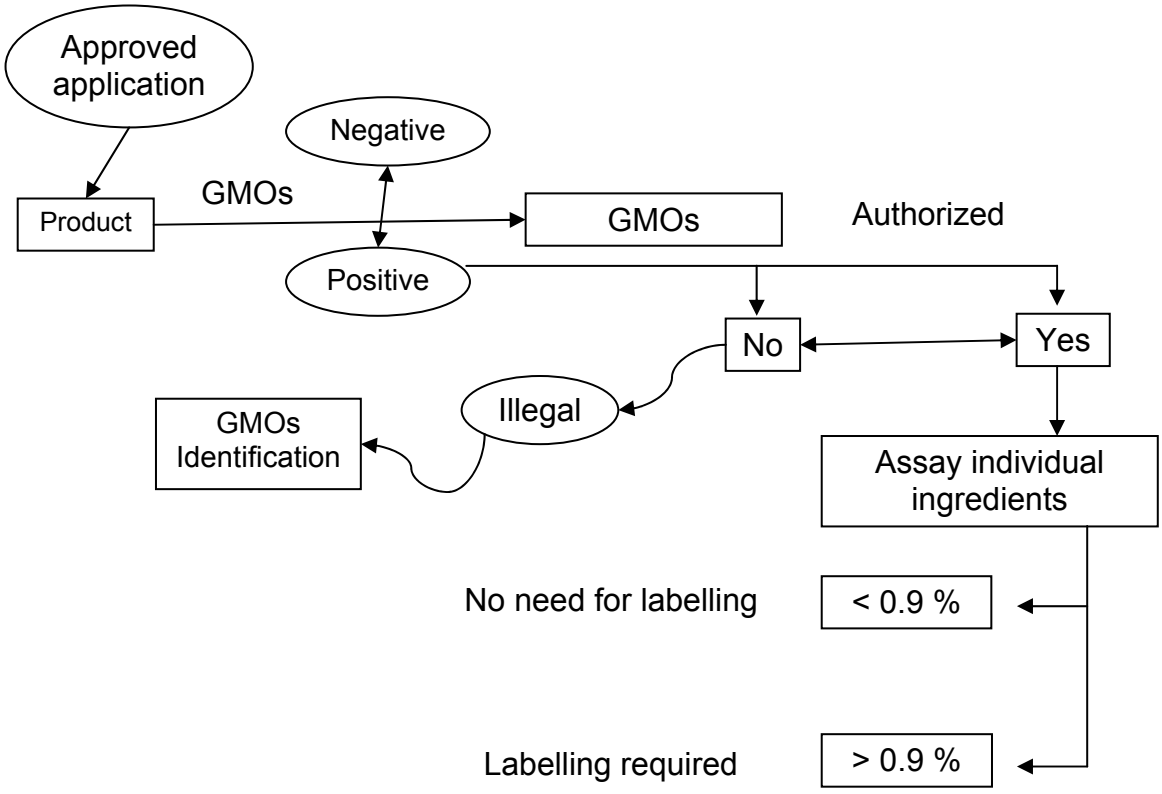

Figure 10: Import procedure of United Kingdom
(Department for Environment, 2000)

Import procedure of GMOs was enforced by Scottish Ministry. However, this based on Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms which is consisted of 7 stages as mentioned on above flowchart (GM Co-ordination Team, 2002).

4.5.2 Imported permission detail

Refer to Article 13 of Directive 2001/18/EEC "Notification procedure", a notification shall be submitted to the competent authority of the Member State where such a GMOs to be placed on the market for the first time before a GMOs or GMOs combination of GMOs as or in products is placed on the market. Notification shall contain following information (HSE: 2000).

- Information on data and result obtained form research and environmental release concerning the impacts of the release on human health and the environment
- The environmental risk assessment and the conclusion required
- The conditions for placing the product on the market, including specific conditions of use and handling
- A plan for monitoring, including a proposal for the time period of monitoring plan
- Proposal for labeling, packaging, and also a summary of dossier

According to above notification detail, competent authority will adopt “Criteria and information for specified GMOs” in Article 16 after consultation of relevant Scientific Committee in accordance with the procedure. The criteria and information requirement shall ensure a high level of safety to human health and the environment and be based on the scientific evidence available on such safety and on the experience gained from the release of comparable GMOs (Peter N., 2002).

4.5.3 Safety assessment

In Article 20 “Monitoring and handling of new information” described, notifier shall submit monitoring report according to the condition specified in the consent to the Commission and competent authorities of the Member State.

Moreover, new information has become available with regard to the risk of the GMOs to human health or the environment, notifier shall take the measure necessary to protect human health and environment and inform the competent authorities (Department for Environment, 2000).

The competent authorities and Commission may discuss any outstanding issues with an aim of arriving at an agreement within 75 days from date of circulation of the assessment report.

Additionally, "Labeling" which indicated in Article 21 was set up to ensure that all stages of labeling and packaging of GMOs placed on the market as in products comply with the relevant requirements specified in the written consent.

4.5.4 Involved government

1. The Department of Health (DH) has responsibility for the general human health and food safety aspects of GMOs, including medical applications of GM technology. It provides the secretariats for the Gene Therapy Advisory Committee (GTAC) which assesses protocols in gene therapy trials for the United Kingdom

- Xeno – transplantation Interim Regulatory Authority (UKXIRA) regulates all activities involving the transplants from one species to another.

- The Medicines Control Agency (MCA) has responsibility for the safety, quality and efficacy of medicines.

2. The Home Office regulates the use of protected animals (ie all vertebrates and *Octopus vulgaris*), including those that have been genetically modified, for experimental or other scientific purposes.

3. The Department of Trade and Industry (DTI) has overall responsibility for sponsoring the industrial application of biotechnology. It is also responsible for ensuring that the implications for industrial competitiveness are taken into account in the formulation of Government policy in this area. DTI publishes the BioGuide which provides the biotechnology community with an essential summary of current regulations and procedures and the support available from the Government and elsewhere (Anthony J. C. et al, 2003).

4.5.5 Supporting and relevance regulation

There is only one supporting regulation related with Directive 2001/18/EC, which is Directive 90/219/EEC on the contained use of genetically modified micro – organism. In order to be reflect up – to – date developments in GM technology and,

experience of operating the previous regulations indicated ways in which the administrative procedures might be made more straightforward. The overriding objective was to maintain and improve standards of protection for human health and environment. The revision also reflects a major amendment of the European Community Directive on contained use of genetically modified micro-organisms (Directive 90/219/EEC as amended by Directive 98/81/EC).

The term 'contained use' covers any activities involving GMOs in which measures are taken to limit contact between them and people or environment. It relates to the actual process of genetic modification, and also to the use, storage, transport and destruction of GMOs. Typical contained use facilities would be microbiology laboratories, animal houses, greenhouses or industrial production facilities. GMOs are deliberately introduced into environment for experimental purposes, or placed on the market, for example, as food or for medical purposes, are obviously not contained (GM Co-ordination Team, 2002).

4.6 Discussion of United Kingdom regulation

4.6.1 Strengths

1. All import regulations are based on the new Europeans direction 2001/18/EC which is established on October 27, 2002 to protect human health and environment across EU from any adverse effects that may be caused by the deliberate release into the environment of GMOs.
2. Regulator's advises are significant on decision-making related to import procedure. Moreover, these are also taken into scientific evidence, which will be presented to the public.
3. Many countries have issued their own regulations. Most of them are strong and powerful in order to bargain with trade partners.
4. Clear indicator of the procedure when GMOs can be release into the environment and contained use

5. The Directive 2001/18/EC has already indicated monitoring procedure as well as traceability and labeling for entry.
6. The Directive provided public participation part by consultation process and information to the public.

4.6.2 Weaknesses

1. Deliberate Release of GMOs: Failure to obtain relevant approval to release or market the product may lead to trial, in which case a fine or detention would be result pending the severity of conviction.
2. Lacking of environmental protection is presented by the UK regulation on the contained use of GMOs for assessing environmental risk. The importance of the risk assessment is protecting the environment, and it is largely the responsibility of the user. As results, their assessments have insignificant effect by the HSE.
3. The releases of GMOs have been evaluated the potential risk on environment only address single case of risk in the short – term. This should be narrowed down case – by – case to allow risk assessment to develop.
4. Lacking of consideration in cooperative impact of releases can be shown in a review of their decision relate to Plant Genetics System's application to market GM herbicide tolerant crop.

4.6.3 Result and consequence

Although, regulation of the United Kingdom has been amended a couple of times to provide improvements, new amendments will be practice in their attempt to safeguard environment from the impacts of GMOs. The failure to impose mandatory inactivation, maximum release limits and long-term monitoring requirements means that large-scale releases of GMMs could become routine. Thus, it is recommended that all waste, which is supposed to have GMMs, be inactivated to eliminate any types of environmental and human risks.

Two topics could be addressed regarding the damage caused by GMOs. Firstly companies who are marketing and releasing GMOs should be held strictly liable where a causal linkage can be established between a release and the harm. Secondly, it is proving this linkage seems not be possible, an industry compensation fund should be created, funded may charge by the seed industry based on the weight of GM seed sold or the area of GM seed introduced (Rao S.R., 2002A).

4.7 Import regulation of Thailand

4.7.1 Import procedure

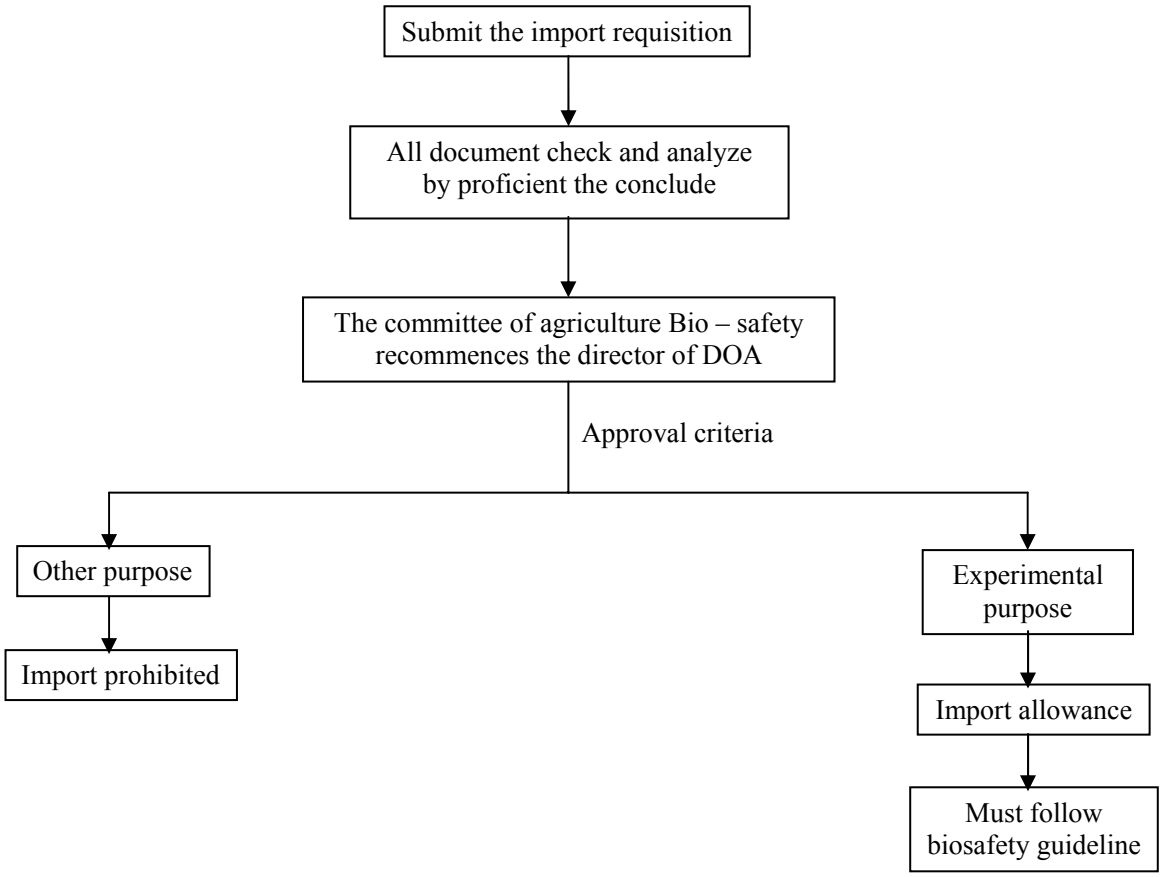

Figure 11: Import procedure of Thailand

(Ministry of Agriculture and cooperative society, 2003)

The import procedure of Thailand as show in figure 11 is similar with China procedure that divides into 3 main steps. But Thailand needs ratification from the director of DOA before pass through approval criteria.

4.7.2 Imported permission detail

According to a promulgation of Agricultural department about guideline for import or in-transit restricted material indicated required information for import regulated material as follow. (Nares D., 2000)

- Entry reasons
- Previous experimental result
- Related information
    - Variety of genetic resources
    - Method of modification
    - Source and base sequence of genetic material
    - Vector
    - Determination method for transgenic organism
- Project detail along with name lists of responsible person
- Other information under consideration of Department of Agriculture

In addition, based on import requisition for restricted material, the director of Department of Agriculture shall allow import for research and study purpose only. The importation of transgenic plant should attach Phytosanitary Certificate from country of origin. However, person who import should fill genetic modification resource that had already degenerated in “Additional Declaration”. In case, responsible organizations are unable to endorse a Phytosanitary Certificate, research institute who import shall certify (Ministry of Agriculture and cooperative society, 2003).

4.7.3 Safety assessment

Thailand has not set up safety assessment but only safety guideline for research and study in laboratory and field trial was issued by National Biosafety Committee (NBC). That generally describes practice of modification gene, and GMOs creation as well as guideline for releasing GMOs into environment.

4.7.4 Involved government

The only one central agency that handles GMOs in Thailand is National Biosafety Committee (NBC) which is in charge for control of using GMOs in research and study to comply with the biosafety guidelines.

- Co ordinate with import organization in order to control GMOs
- Specify safety factors about gene modification research
- Indicate hazard level
- Prevent related function may effect from risk possibility
- Channel a biosafety for requested or related institutes
- Assist and provide regulation or measurement for assessment and manage biosafety
- Afford public relation for biosafety knowledge
- Cooperate with international organization in order to ensure that Thailand regulations are harmonize with other trade partners

4.7.5 Supporting and relevance regulation

Main regulation of GMOs control in Thailand is Plant Quarantine Act 1964 (amended 1999) which has some enactments about pest protection and control. However, there are some related regulations regarding to GMOs control as following.

1. Promulgation of Agricultural department about guideline for import or in-transit restricted material indicates required information for import regulated material 1994
2. Promulgation of Ministry of Agriculture about indication plants, pest, or carrier from restricted resource and exception 1994
3. Plant conservation Act 1999

4.8 Discussion of Thailand regulation

4.8.1 Strengths

1. Certificate or labeling commitment will be made between exporter and importer. Therefore, a conflict among trade partnership might be decreased such as rejection because both importer and exporter do accept the same agreement.
2. GMO's plantation areas have been specified for research purposes only, which means crop area would control in a particular location. Especially for research purposes, all experimental plants are going to be monitored closely.

4.8.2 Weaknesses

1. Plant Quarantine Act (1964) had been set up by the Department of Agriculture in order to monitor the releasing of GMOs in field and surrounding environment. However, it might not include a holistic point of views about GMOs such as import – export business. Hence, it is necessary for Thai government to observe GMOs leakage.
2. Currently, Thailand's regulation has controlled GMOs import for study and research purpose only. In the near future, it is possible for Thai partnership to change their importable requirements or launch new regulations for GMOs. Once Thailand has to face such a situation, it might result in creating some difficulties to the country's trade because Thailand does not have any preparation plan to support the export procedure.
3. Lacking of public information on GMOs issue due to the knowledge under this circumstance becomes an unclear topic for Thai society because of its complicated details. The development on GMOs technology moves slowly in Thailand. Therefore the knowledge

based on GMOs seems to be limited among scientists or some other groups that get involved with GMOs directly.

4.8.3 Result and consequence

Thai people seem not to have been familiarized with GMOs regulation. Probably, ordinary people may have no ideas about GMOs products and keep though it as they are not involved with it in their daily activities. Nevertheless, GMOs regulation is a new topic for legislation theme. All topics are still under the discussion and consideration of Thai government. Issuing a GMOs product regulation or even adjusting the existed regulations is required to maximize regulation's effectiveness for practice. Unfortunately, Thailand has not issued any regulation, regard to control modified animal and microorganism yet, as well as all export GMOs product until now. Thus, this could be concluded that Thailand seems not be ready to deal with GMOs product neither import nor export (Nares D., 2002).

This research found out that different countries have different point of views as well as situations, location, culture, and belief; therefore the regulations are also different. But in some outstanding points from each country could be point out as following:

1. The regulation should well prepare a guideline and regulation to cover as many as related topics about GMOs not only import but also export like Philippines. Moreover, several representatives who participate in creating the regulation and citizens could get involved with improving and developing the regulation is another way to make regulation effective.
2. EU has influential regulations that have been adopted by many countries which is strong and powerful to work bargaining with trade partners to have maximum advantage over other countries

There are some weakness points from studied countries should be avoid as follow

1. It was found that coordination among government organization were not enough in some standard countries. Implementer may not reach the goal of regulation; therefore, overall measurements may get stuck in process.
2. Each country has promulgated the major regulation but in each regulation need supporting plan for encouragement. But the study was found that all major regulation was promulgated without supporting plan or ineffectual plan.
3. Some of the consequences of regulation regarding to penalty of illegal activities might not strong enough to legalize the laws. It is a gap of regulation that is easy to violence and ignores a penalty.
4. Even though, China is one country that has courageously attempted to growth modified plant to research problems and solves the problem directly. But they could not success because NGOs is one of obstacle that interfering the government.

In conclusion, Thailand is one of a big food exporter particularly in agricultural products and has some effects from import partnership about GMOs contamination in agricultural food production.

4.9 Fate of Thailand as a great food exporter and agricultural products

Based on currently situation, there are several problems regarding to GMOs products, which could be divided into 2 main categories.

1. Internal problem
    - Uncover regulation related to Plan Quarantine Act is emphasized on modified plant, but food ingredient contained GMOs has not paid enough attention.
    - Inadequate measurement of import materials
    - Lack of public relation about an understanding of GMOs, including the negative promotion from media to people

- Research and study on the GMOs impacts in order to demonstrate the GMOs consequence was misunderstood by people
- Unclear policy from the government causes risks and intends to slow down the investment

2. External problem
    - Each country has concerns on imported products and refuses to accept agricultural products from countries that still have unclear policy, particularly Thailand's that is one of the biggest agricultural products exporters.
    - Presently, some groups of countries have formed alliance to bargain with trade partners. If Thailand not allows to import agricultural products, it may be under disadvantage from the alliance. For example, if United Kingdom refuse Thai products by indicating that product may contain GMOs materials, all EU countries may refuse Thai products until Thai could prove that product is non – GMOs
3. Suggestion and recommendation
    - To expedite the completion of Thai regulation in point of import food product measurements
    - To increase understanding with people and represent the both positive and negative facts and incorporate with NGOs to have participation from people
    - To Expedite the research and study in GMOs impacts under restriction by related government
    - To promulgate outstanding point in order to carry out the business relation

4.10 The alternatives for Thailand's food export in case of unsuccessful regulation

Once the regulations are unsuccessfully to control the importation of GMOs product and their derivatives, Thailand may be affected from many sides. First of all,

Thailand will have to ensure that internal managements are in good steps, in order to make certain with trade partners and encourage them to invest in Thailand.

Otherwise, in unsuccessful measurement of the importation, Thailand might need to focus carefully on export section. By considering partner conditions and adjusting to their export measurement by making them realize about Thai products. On the other hand, research and study should be encouraged by regarding to GMOs impacts, so that certainty can be attained with trade partnership.

4.11 Trading with Catagena protocol's parties and impact possibilities

According to commerce with CBD parties regard to Biosafety Protocol under Convention of Biological Diversity, there are negligible effects due to many exceptional regulations as of following:

1. To focus on transboundary of Living Modified Organism between countries particularly food processing, medical materials and research raw materials.
2. GMOs products that might be used as raw materials, (which may be ensure that, its unable to release into environment) that the above condition should indicate clearly that it may be contained GMOs material.

In Thailand, brainstorming from each related side, (the government, private sector, business, and specialist) have been provided by committee and subcommittee, to consider the labeling of GMOs products. The conferences of Thai NBC have decided to present this agreement to the Minister of Public Health in order to sign and announce it in Thai royal gazette and, one year after the approval, this announcement will be able to apply and implement.

Incidentally, the problems in terms of international trade have risen. Moreover, it tends to be concerned with human risks in terms of health because Thailand is an exporter for agricultural products. European countries have banned agricultural products from Thailand because they have assumed that produce may be from GMOs organism or contaminated by alien genes.

Related to the market competition, Thailand cannot deny any allegations from European countries' barrier because Thailand has no strong political support. Moreover, there are not clear measurements that can be guidelines to control and distinguish GMOs products. The market competitors' particularly European countries have assaulted this weakness. However, this may not be the major problem as it should be controlled appropriately at the first stage of importing goods into the country. Hence, before exporting such a product, all required document and information should be attached in order to complete the export process. Therefore, other countries cannot avoid Thai agricultural products by imposing unclear information to any further extent.

CHAPTER V

CONCLUSION

The study it found that all studied countries have set up their regulations in the same direction in order to protect their people's health as well as environment. However, in some details may not be emphasized adequately. For example, not only import process that should be considered, but also monitoring system and traceability process after GMOs products have imported into their counties. The following are causes – effects and some alternatives resolution form the regulation of GMOs products in administrative level.

1. Incomplete regulation

   Incomplete regulation is one of the obstacles for implementation of the regulation. Possibly, many people may not understand or be in doubt and get wrong inference to the regulation. Furthermore, incomplete regulation may have a gap or some weak points for violation. Hence, a step of issuing regulation is very important, detail and description should be indicated clearly along with the penalty.

   Implementation consequences of regulation signify the success. Therefore public hearing is one of the famous alternative ways to solve by reviewing the regulation due to the public hearing is the sound from people that depends on regulation. A public hearing accomplishment should be consisted of various sectors of people for maximizing benefits of regulation after input from public hearing.

2. Improper planning and governmental mismanagement

   Mismanagement scenario is a consequence of governmental organizing problems which consist of several root causes. For example, the existing

governmental organizations are not able to handle innovative technology that are taking place and have become a problem in several countries. Besides, duplicate work in difference functions is also a gap of management as well as complication among organizations that causes difficulties for coordination.

Reorganization or forming a working group to directly work out this innovative technology might be a better solution. Furthermore, decentralization of management could be an easy way to crack a problem. However, policy gap should be cleared and decreased duplicate work by the government to monitor and improvement.

3. Public participation and knowledge

People are significant keys for legal implementation because if people do not understand or comprehend the regulation, then the regulation is obvious useless. This will make a lot of difficulties for problem resolving because if they wrongly understand, they will not pay attention or participate in any promotions. Furthermore, if people were given incorrect information regarding to GMOs technology from any resources such as newspaper, TV or advertisement, the ways to solve a problem are obstructed by misunderstood people.

As a result, public relation from concerned function is the way to provide people on knowledge not only for situation but also for any problems. After people understand, then the way to implement or improvement the regulation will be much easier while government may gain more participation from people.

Proposing the guideline for GMOs product management (Figure 12)

There are three main steps to issue a regulation.

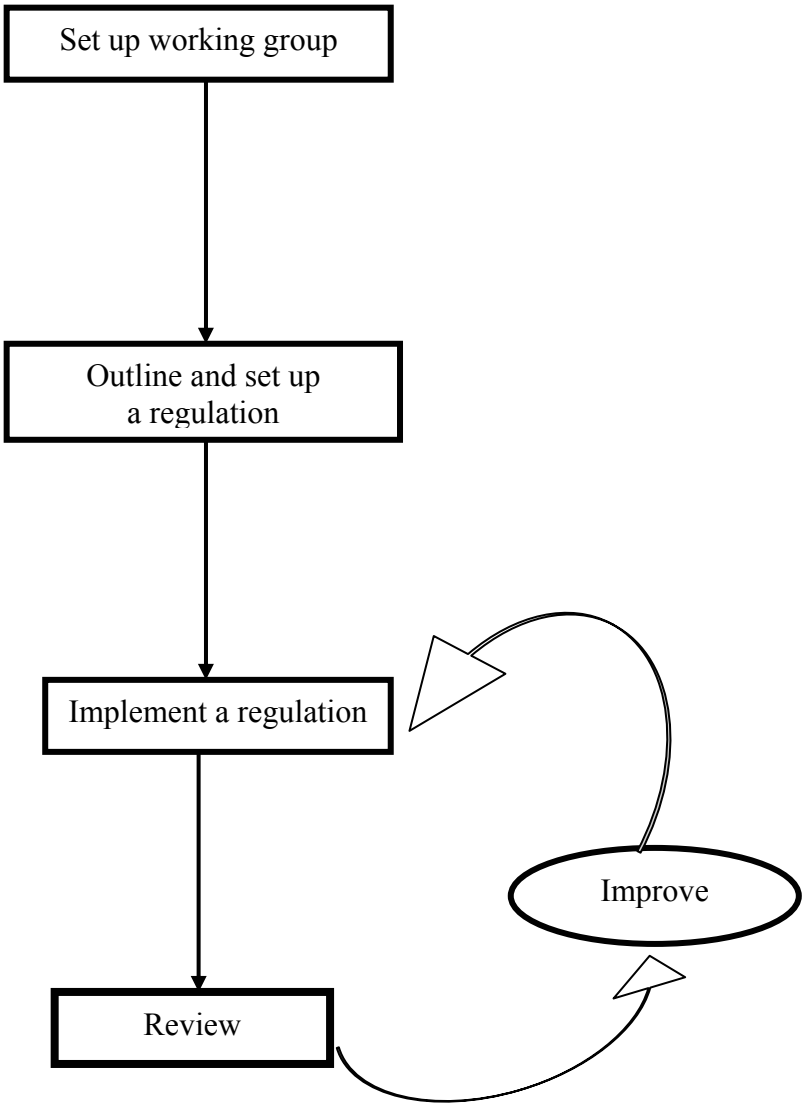

Figure 12: Main process for issuing regulation

1. Set up a working group

A working group to handle directly with GMOs regulation shall be formed by various social categorizations in order to achieve a country demand. Additionally, a working group shall be an information center of all GMOs issues which is easy way to

deal with all relevance topics of GMOs. On the other hand, a working group shall decentralize function to existing governmental organization in specific areas.

2. Outline and set up a regulation

Outlining step should be obviously clarified in terms of definition of entire GMOs topics. In particular, proposed regulation will be easy to implement and not complicated. However, recheck and monitor are significant procedures to review and improve the regulation.

3. Enforce and implement

In practical, enforcement and implementation should be along with public relation and announcement before and during implementation. Otherwise, misinformed people may not cooperate toward regulation.

4. Import procedure (Figure 13)

In the procedure, after notifier proposes import requisition along with all relevance information such as place of origin, species etc, notifier should submit risk assessment report to the concerned department. For example, Import Department of Ministry of Commerce or Air / Sea imported checkpoint. Then a quarantine station will preliminarily check all available - imported documents and pass them through laboratory both document and specimens. Laboratory will check all description of GMOs products to relate with document, otherwise laboratory will random check Non – GM declaration products. If a result is found that genes were modified as declaration along with completed documents, a state shall allow importing under inspection and monitoring as well as randomly check unable determine GMOs. On the other hand, a state shall reject a requisition or destroy the product if a description is not related with imported document or declared as non – GMOs and found that genes were modified or derived from indigenous species. Furthermore, if GMOs found from randomize check, a state should place a penalty for notifier who swindles; for example, revoke an import permit for 1 year, etc.

At the end, this is an ideal procedure, if this process shall be implemented, it need some adjustments appropriated with other country's factors, such as situation, location, culture and belief of each country.

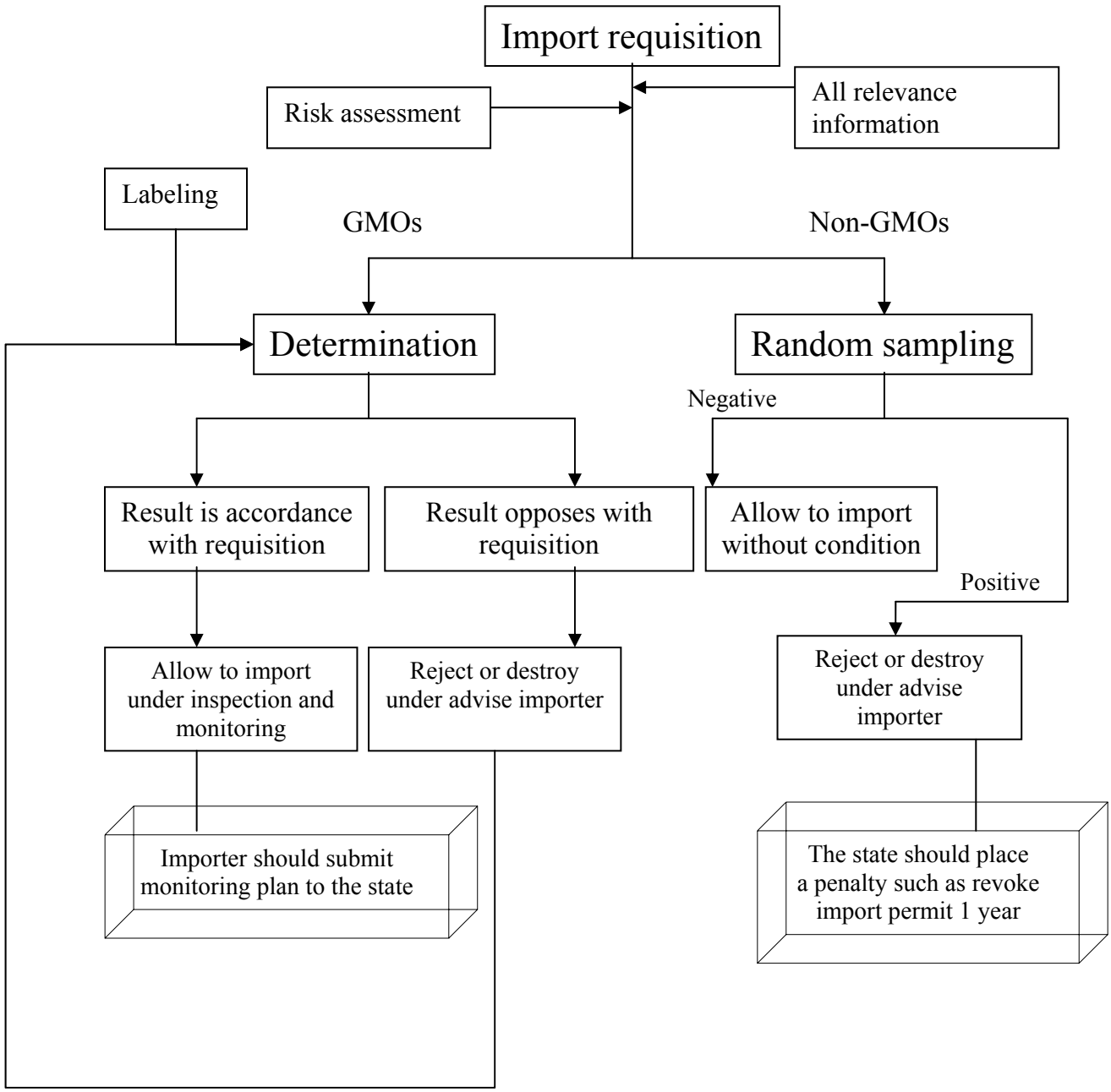

Figure 13: Import procedure recommendation

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APPENDIX

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1

OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology

that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2

GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3

USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8

NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10

DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13

SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account

risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26

SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27

LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the

request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

APPENDIX B

THE RIO DECLARATION

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ORIGINAL: ENGLISH

REPORT OF THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT

(Rio de Janeiro, 13-14 June 1992)

Annex I

RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT

The United Nations Conference on Environment and Development,

Having met at Rio de Janeiro from 3 to 14 June 1992,

Reaffirming the Declaration of the United Nations Conference on the Human Environment, adopted at Stockholm on 16 June 1972, a/and seeking to build upon it,

With the goal of establishing a new and equitable global partnership through the creation of new levels of cooperation among States, key sectors of societies and people,

Working towards international agreements, which respect the interests of all and protect the integrity of the global environmental and developmental system,

Recognizing the integral and interdependent nature of the Earth, our home,

Proclaims that:

Principle 1

Human beings are at the center of concerns for sustainable development.

They are entitled to a healthy and productive life in harmony with nature.

Principle 2

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and development policies, and the responsibility to ensure that activities

within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits the national jurisdiction.

Principle 3

The right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations.

Principle 4

In order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it.

Principle 5

All States and all people shall cooperate in the essential task of eradicating poverty as an indispensable requirement for sustainable development, in order to decrease the disparities in standards of living and better meet the needs of the majority of the people of the world.

Principle 6

The special situation and needs of developing countries, particularly the least developed and those most environmentally vulnerable, shall be given special priority. International actions in the field of environment and development should also address the interests and needs of all countries.

Principle 7

States shall cooperate in a spirit of global partnership to conserve, protect and restore the health and integrity of the Earth's ecosystem. In view of the different contributions to global environmental degradation, States have common but differentiated responsibilities. The developed countries acknowledge the responsibility that they bear in the international pursuit of sustainable development in view of the pressures their societies place on the global environment and of the technologies and financial resources they command.

Principle 8

To achieve sustainable development and a higher quality of life for all people, States should reduce and eliminate unsustainable patterns of production and consumption and promote appropriate demographic policies.

Principle 9

States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies.

Principle 10

Environmental issues are best handles with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.

Principle 11

States shall enact effective environmental legislation. Environmental standards, management objectives and priorities should reflect the environmental and development context to which they apply. Standards applied by some countries may be inappropriate an of unwarranted economic and social cost to other countries, in particular developing countries.

Principle 12

States should cooperate to promote a supportive and open international system that would lead to economic growth and sustainable development in all countries, to better address

the problems of environmental degradation. Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided.
Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus.

Principle 13

States shall develop national law regarding liability and compensation for the victims of pollution and other environmental damage. States shall also cooperate in an expeditious and more determined manner to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control to areas beyond their jurisdiction.

Principle 14

States should effectively cooperate to discourage or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health.

Principle 15

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Principle 16

National authorities should endeavor to promote the internalization of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution, with due regard to the public interest and without distorting international trade and investment.

Principle 17

Environmental impact assessment, as a national instrument, shall be undertaken for proposed activities that are likely to have a significant adverse impact on the environment and are subject to a decision of a competent national authority.

Principle 18

States shall immediately notify other States of any natural disasters or other emergencies that are likely to produce sudden harmful effects on the environment of those States. Every effort shall be made by the international community to help States so afflicted.

Principle 19

States shall provide prior and timely notification and relevant information to potentially affected States on activities that may have a significant adverse transboundary environmental effects and shall consult with those States at an early stage and in good faith.

Principle 20

Women have a vital role in environmental management and development. Their full participation is therefore essential to achieve sustainable development.

Principle 21

The creativity, ideals and courage of the youth of the world should be mobilized to forge a global partnership in order to achieve sustainable development and ensure a better future for all.

Principle 22

Indigenous people and their communities and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. States should recognize and duly support their identity, culture and interest and enable their effective participation in the achievement of sustainable development.

Principle 23

The environment and natural resources of people under oppression, domination and occupation shall be protected.

Principle 24

Warfare is inherently destructive of sustainable development. States shall therefore respect international law providing protection for the environment in times of armed conflict and cooperate in its further development, as necessary.

Principle 25

Peace, development and environmental protection are interdependent and invisible.

Principle 26

States shall resolve all their environmental disputes peacefully and by appropriate means in accordance with the Charter of United Nations.

Principle 27

States and people shall cooperate in good faith and a spirit of partnership in the fulfillment of the principles embodied in this Declaration and in the further development of international law in the field of sustainable development.

APPENDIX C

Draft Recommendations for the Labelling of Foods that can cause Hypersensitivity (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods)

Section 4.2.1.3

Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 25% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

Section 4.2.1.4

The following foods and ingredients are known to cause hypersensitivity and shall always be declared as such:

1. Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
2. Crustacea and products of these;
3. Eggs and egg products;
4. Fish and fish products;
5. Peanuts, soybeans and products of these;
6. Milk and milk products (lactose included);
7. Tree nuts and nut products; and
8. Sulphite in concentrations of 10 mg/kg or more.

(Current sections 4.2.1.4 and 4.2.1.5 become respectively 4.2.1.5 and 4.2.1.6)

Section 4.2.2.1

Except for those ingredients listed in section 4.2.1.4, and unless a general class name would be more informative, the following class names may be used ..... (remainder of section as is)

Section 4.2.3.2

A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in section 4.2.14

AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)[1];

Hereby agree as follows:

Article 1

General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.

2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.

[1] In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

3. The annexes are an integral part of this Agreement.

4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2

Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3

Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[2]

[2] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4

Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.[3]

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6

Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as

[3] For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7

Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8

Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9

Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10

Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11

Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12

Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, *inter alia*, to the experience gained in its implementation.

Article 13

Implementation

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14

Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

ANNEX A

DEFINITIONS[4]

1. *Sanitary or phytosanitary measure* - Any measure applied:

   (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

   (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

   (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

   (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. *Harmonization* - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. *International standards, guidelines and recommendations*

   (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and

[4] For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

ANNEX B

TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations[5] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

(c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals[6] of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

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[5] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

[6] When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

(a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

ANNEX C

CONTROL, INSPECTION AND APPROVAL PROCEDURES[7]

[7] Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

(a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

(b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

(c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

(d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;

(e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

(f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;

(g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;

(h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

(i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

AGREEMENT ON TECHNICAL BARRIERS TO TRADE

Members,

Having regard to the Uruguay Round of Multilateral Trade Negotiations;

Desiring to further the objectives of GATT 1994;

Recognizing the important contribution that international standards and conformity assessment systems can make in this regard by improving efficiency of production and facilitating the conduct of international trade;

Desiring therefore to encourage the development of such international standards and conformity assessment systems;

Desiring however to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade;

Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;

Recognizing that no country should be prevented from taking measures necessary for the protection of its essential security interest;

Recognizing the contribution which international standardization can make to the transfer of technology from developed to developing countries;

Recognizing that developing countries may encounter special difficulties in the formulation and application of technical regulations and standards and procedures for assessment of conformity with technical regulations and standards, and desiring to assist them in their endeavours in this regard;

Hereby *agree* as follows:

Article 1

General Provisions

1.1 General terms for standardization and procedures for assessment of conformity shall normally have the meaning given to them by definitions adopted within the United Nations system and by international standardizing bodies taking into account their context and in the light of the object and purpose of this Agreement.

1.2 However, for the purposes of this Agreement the meaning of the terms given in Annex 1 applies.

1.3 All products, including industrial and agricultural products, shall be subject to the provisions of this Agreement.

1.4 Purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies are not subject to the provisions of this Agreement but are addressed in the Agreement on Government Procurement, according to its coverage.

1.5 The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

1.6 All references in this Agreement to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments thereto and any additions to the rules or the product coverage thereof, except amendments and additions of an insignificant nature.

TECHNICAL REGULATIONS AND STANDARDS

Article 2

Preparation, Adoption and Application of Technical Regulations by Central Government Bodies

With respect to their central government bodies:

2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia:* national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia:* available scientific and technical information, related processing technology or intended end-uses of products.

2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.

2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

2.7 Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

2.8 Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

2.9 Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;

2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;

2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;

2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

2.10 Subject to the provisions in the lead-in to paragraph 9, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 9 as it finds necessary, provided that the Member, upon adoption of a technical regulation, shall:

2.10.1 notify immediately other Members through the Secretariat of the particular technical regulation and the products covered, with a brief indication of the objective and the rationale of the technical regulation, including the nature of the urgent problems;

2.10.2 upon request, provide other Members with copies of the technical regulation;

2.10.3 without discrimination, allow other Members to present their comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

2.11 Members shall ensure that all technical regulations which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them.

2.12 Except in those urgent circumstances referred to in paragraph 10, Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.

Article 3

Preparation, Adoption and Application of Technical Regulations by Local Government Bodies and Non-Governmental Bodies

With respect to their local government and non-governmental bodies within their territories:

3.1 Members shall take such reasonable measures as may be available to them to ensure compliance by such bodies with the provisions of Article 2, with the exception of the obligation to notify as referred to in paragraphs 9.2 and 10.1 of Article 2.

3.2 Members shall ensure that the technical regulations of local governments on the level directly below that of the central government in Members are notified in accordance with the provisions of paragraphs 9.2 and 10.1 of Article 2, noting that notification shall not be required for technical regulations the technical content of which is substantially the same as that of previously notified technical regulations of central government bodies of the Member concerned.

3.3 Members may require contact with other Members, including the notifications, provision of information, comments and discussions referred to in paragraphs 9 and 10 of Article 2, to take place through the central government.

3.4 Members shall not take measures which require or encourage local government bodies or non-governmental bodies within their territories to act in a manner inconsistent with the provisions of Article 2.

3.5 Members are fully responsible under this Agreement for the observance of all provisions of Article 2. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of Article 2 by other than central government bodies.

Article 4

Preparation, Adoption and Application of Standards

4.1 Members shall ensure that their central government standardizing bodies accept and comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 to this Agreement (referred to in this Agreement as the "Code of Good Practice"). They shall take such reasonable measures as may be available to them to ensure that local government and non-governmental standardizing bodies within their territories, as well as regional standardizing bodies of which they or one or more bodies within their territories are members, accept and comply with this Code of Good Practice. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such standardizing bodies to act in a manner inconsistent with the Code of Good Practice. The obligations of Members with respect to compliance

of standardizing bodies with the provisions of the Code of Good Practice shall apply irrespective of whether or not a standardizing body has accepted the Code of Good Practice.

4.2 Standardizing bodies that have accepted and are complying with the Code of Good Practice shall be acknowledged by the Members as complying with the principles of this Agreement.

CONFORMITY WITH TECHNICAL REGULATIONS AND STANDARDS

Article 5

Procedures for Assessment of Conformity by Central Government Bodies

5.1 Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members:

5.1.1 conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation; access entails suppliers' right to an assessment of conformity under the rules of the procedure, including, when foreseen by this procedure, the possibility to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system;

5.1.2 conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, *inter alia*, that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.

5.2 When implementing the provisions of paragraph 1, Members shall ensure that:

5.2.1 conformity assessment procedures are undertaken and completed as expeditiously as possible and in a no less favourable order for products originating in the territories of other Members than for like domestic products;

5.2.2 the standard processing period of each conformity assessment procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the assessment in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the conformity assessment if the applicant so requests; and that, upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

5.2.3 information requirements are limited to what is necessary to assess conformity and determine fees;

5.2.4 the confidentiality of information about products originating in the territories of other Members arising from or supplied in connection with such conformity assessment procedures is respected in the same way as for domestic products and in such a manner that legitimate commercial interests are protected;

5.2.5 any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body;

5.2.6 the siting of facilities used in conformity assessment procedures and the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents;

5.2.7 whenever specifications of a product are changed subsequent to the determination of its conformity to the applicable technical regulations or standards, the conformity assessment procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the technical regulations or standards concerned;

5.2.8 a procedure exists to review complaints concerning the operation of a conformity assessment procedure and to take corrective action when a complaint is justified.

5.3 Nothing in paragraphs 1 and 2 shall prevent Members from carrying out reasonable spot checks within their territories.

5.4 In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate for the Members concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

5.5 With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures.

5.6 Whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not in accordance with relevant guides and recommendations issued by international standardizing bodies, and if the conformity assessment procedure may have a significant effect on trade of other Members, Members shall:

5.6.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular conformity assessment procedure;

5.6.2 notify other Members through the Secretariat of the products to be covered by the proposed conformity assessment procedure, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;

5.6.3 upon request, provide to other Members particulars or copies of the proposed procedure and, whenever possible, identify the parts which in substance deviate from relevant guides or recommendations issued by international standardizing bodies;

5.6.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

5.7 Subject to the provisions in the lead-in to paragraph 6, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 6 as it finds necessary, provided that the Member, upon adoption of the procedure, shall:

5.7.1 notify immediately other Members through the Secretariat of the particular procedure and the products covered, with a brief indication of the objective and the rationale of the procedure, including the nature of the urgent problems;

5.7.2 upon request, provide other Members with copies of the rules of the procedure;

5.7.3 without discrimination, allow other Members to present their comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

5.8 Members shall ensure that all conformity assessment procedures which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them.

5.9 Except in those urgent circumstances referred to in paragraph 7, Members shall allow a reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.

Article 6

Recognition of Conformity Assessment by Central Government Bodies

With respect to their central government bodies:

6.1 Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:

6.1.1 adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;

6.1.2 limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member.

6.2 Members shall ensure that their conformity assessment procedures permit, as far as practicable, the implementation of the provisions in paragraph 1.

6.3 Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures. Members may require that such agreements fulfil the criteria of paragraph 1 and give mutual satisfaction regarding their potential for facilitating trade in the products concerned.

6.4 Members are encouraged to permit participation of conformity assessment bodies located in the territories of other Members in their conformity assessment procedures under conditions no less favourable than those accorded to bodies located within their territory or the territory of any other country.

Article 7

Procedures for Assessment of Conformity by Local Government Bodies

With respect to their local government bodies within their territories:

7.1 Members shall take such reasonable measures as may be available to them to ensure compliance by such bodies with the provisions of Articles 5 and 6, with the exception of the obligation to notify as referred to in paragraphs 6.2 and 7.1 of Article 5.

7.2 Members shall ensure that the conformity assessment procedures of local governments on the level directly below that of the central government in Members are notified in accordance with the provisions of paragraphs 6.2 and 7.1 of Article 5, noting that notifications shall not be required for conformity assessment procedures the technical content of which is substantially the same as that of previously notified conformity assessment procedures of central government bodies of the Members concerned.

7.3 Members may require contact with other Members, including the notifications, provision of information, comments and discussions referred to in paragraphs 6 and 7 of Article 5, to take place through the central government.

7.4 Members shall not take measures which require or encourage local government bodies within their territories to act in a manner inconsistent with the provisions of Articles 5 and 6.

7.5 Members are fully responsible under this Agreement for the observance of all provisions of Articles 5 and 6. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of Articles 5 and 6 by other than central government bodies.

Article 8

Procedures for Assessment of Conformity by Non-Governmental Bodies

8.1 Members shall take such reasonable measures as may be available to them to ensure that non-governmental bodies within their territories which operate conformity assessment procedures comply with the provisions of Articles 5 and 6, with the exception of the obligation to notify proposed conformity assessment procedures. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies to act in a manner inconsistent with the provisions of Articles 5 and 6.

8.2 Members shall ensure that their central government bodies rely on conformity assessment procedures operated by non-governmental bodies only if these latter bodies comply with the provisions of Articles 5 and 6, with the exception of the obligation to notify proposed conformity assessment procedures.

Article 9

International and Regional Systems

9.1 Where a positive assurance of conformity with a technical regulation or standard is required, Members shall, wherever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein.

9.2 Members shall take such reasonable measures as may be available to them to ensure that international and regional systems for conformity assessment in which relevant bodies within their territories are members or participants comply with the provisions of Articles 5 and 6. In addition, Members shall not take any measures which have the effect of, directly or indirectly, requiring or encouraging such systems to act in a manner inconsistent with any of the provisions of Articles 5 and 6.

9.3 Members shall ensure that their central government bodies rely on international or regional conformity assessment systems only to the extent that these systems comply with the provisions of Articles 5 and 6, as applicable.

INFORMATION AND ASSISTANCE

Article 10

Information About Technical Regulations, Standards and Conformity Assessment Procedures

10.1 Each Member shall ensure that an enquiry point exists which is able to answer all reasonable enquiries from other Members and interested parties in other Members as well as to provide the relevant documents regarding:

10.1.1 any technical regulations adopted or proposed within its territory by central or local government bodies, by non-governmental bodies which have legal power to enforce a technical regulation, or by regional standardizing bodies of which such bodies are members or participants;

10.1.2 any standards adopted or proposed within its territory by central or local government bodies, or by regional standardizing bodies of which such bodies are members or participants;

10.1.3 any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its territory by central or local government bodies, or by non-governmental bodies which have legal power to enforce a technical regulation, or by regional bodies of which such bodies are members or participants;

10.1.4 the membership and participation of the Member, or of relevant central or local government bodies within its territory, in international and regional standardizing bodies and conformity assessment systems, as well as in bilateral and multilateral arrangements within the scope of this Agreement; it shall also be able to provide reasonable information on the provisions of such systems and arrangements;

10.1.5 the location of notices published pursuant to this Agreement, or the provision of information as to where such information can be obtained; and

10.1.6 the location of the enquiry points mentioned in paragraph 3.

10.2 If, however, for legal or administrative reasons more than one enquiry point is established by a Member, that Member shall provide to the other Members complete and unambiguous information on the scope of responsibility of each of these enquiry points. In addition, that Member shall ensure that any enquiries addressed to an incorrect enquiry point shall promptly be conveyed to the correct enquiry point.

10.3 Each Member shall take such reasonable measures as may be available to it to ensure that one or more enquiry points exist which are able to answer all reasonable enquiries from other Members and interested parties in other Members as well as to provide the relevant documents or information as to where they can be obtained regarding:

10.3.1 any standards adopted or proposed within its territory by non-governmental standardizing bodies, or by regional standardizing bodies of which such bodies are members or participants; and

10.3.2 any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its territory by non-governmental bodies, or by regional bodies of which such bodies are members or participants;

10.3.3 the membership and participation of relevant non-governmental bodies within its territory in international and regional standardizing bodies and conformity assessment systems, as well as in bilateral and multilateral

arrangements within the scope of this Agreement; they shall also be able to provide reasonable information on the provisions of such systems and arrangements.

10.4 Members shall take such reasonable measures as may be available to them to ensure that where copies of documents are requested by other Members or by interested parties in other Members, in accordance with the provisions of this Agreement, they are supplied at an equitable price (if any) which shall, apart from the real cost of delivery, be the same for the nationals[1] of the Member concerned or of any other Member.

10.5 Developed country Members shall, if requested by other Members, provide, in English, French or Spanish, translations of the documents covered by a specific notification or, in case of voluminous documents, of summaries of such documents.

10.6 The Secretariat shall, when it receives notifications in accordance with the provisions of this Agreement, circulate copies of the notifications to all Members and interested international standardizing and conformity assessment bodies, and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10.7 Whenever a Member has reached an agreement with any other country or countries on issues related to technical regulations, standards or conformity assessment procedures which may have a significant effect on trade, at least one Member party to the agreement shall notify other Members through the Secretariat of the products to be covered by the agreement and include a brief description of the agreement. Members concerned are encouraged to enter, upon request, into consultations with other Members for the purposes of concluding similar agreements or of arranging for their participation in such agreements.

10.8 Nothing in this Agreement shall be construed as requiring:

10.8.1 the publication of texts other than in the language of the Member;

10.8.2 the provision of particulars or copies of drafts other than in the language of the Member except as stated in paragraph 5; or

10.8.3 Members to furnish any information, the disclosure of which they consider contrary to their essential security interests.

10.9 Notifications to the Secretariat shall be in English, French or Spanish.

10.10 Members shall designate a single central government authority that is responsible for the implementation on the national level of the provisions concerning notification procedures under this Agreement except those included in Annex 3.

10.11 If, however, for legal or administrative reasons the responsibility for notification procedures is divided among two or more central government authorities, the Member concerned shall provide to the other Members complete and unambiguous information on the scope of responsibility of each of these authorities.

Article 11

[1] "Nationals" here shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

Technical Assistance to Other Members

11.1 Members shall, if requested, advise other Members, especially the developing country Members, on the preparation of technical regulations.

11.2 Members shall, if requested, advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the establishment of national standardizing bodies, and participation in the international standardizing bodies, and shall encourage their national standardizing bodies to do likewise.

11.3 Members shall, if requested, take such reasonable measures as may be available to them to arrange for the regulatory bodies within their territories to advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding:

11.3.1 the establishment of regulatory bodies, or bodies for the assessment of conformity with technical regulations; and

11.3.2 the methods by which their technical regulations can best be met.

11.4 Members shall, if requested, take such reasonable measures as may be available to them to arrange for advice to be given to other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the establishment of bodies for the assessment of conformity with standards adopted within the territory of the requesting Member.

11.5 Members shall, if requested, advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the steps that should be taken by their producers if they wish to have access to systems for conformity assessment operated by governmental or non-governmental bodies within the territory of the Member receiving the request.

11.6 Members which are members or participants of international or regional systems for conformity assessment shall, if requested, advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the establishment of the institutions and legal framework which would enable them to fulfil the obligations of membership or participation in such systems.

11.7 Members shall, if so requested, encourage bodies within their territories which are members or participants of international or regional systems for conformity assessment to advise other Members, especially the developing country Members, and should consider requests for technical assistance from them regarding the establishment of the institutions which would enable the relevant bodies within their territories to fulfil the obligations of membership or participation.

11.8 In providing advice and technical assistance to other Members in terms of paragraphs 1 to 7, Members shall give priority to the needs of the least-developed country Members.

Article 12

Special and Differential Treatment of Developing Country Members

12.1 Members shall provide differential and more favourable treatment to developing country Members to this Agreement, through the following provisions as well as through the relevant provisions of other Articles of this Agreement.

12.2 Members shall give particular attention to the provisions of this Agreement concerning developing country Members' rights and obligations and shall take into account the special development, financial and trade needs of developing country Members in the implementation of this Agreement, both nationally and in the operation of this Agreement's institutional arrangements.

12.3 Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.

12.4 Members recognize that, although international standards, guides or recommendations may exist, in their particular technological and socio-economic conditions, developing country Members adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs. Members therefore recognize that developing country Members should not be expected to use international standards as a basis for their technical regulations or standards, including test methods, which are not appropriate to their development, financial and trade needs.

12.5 Members shall take such reasonable measures as may be available to them to ensure that international standardizing bodies and international systems for conformity assessment are organized and operated in a way which facilitates active and representative participation of relevant bodies in all Members, taking into account the special problems of developing country Members.

12.6 Members shall take such reasonable measures as may be available to them to ensure that international standardizing bodies, upon request of developing country Members, examine the possibility of, and, if practicable, prepare international standards concerning products of special interest to developing country Members.

12.7 Members shall, in accordance with the provisions of Article 11, provide technical assistance to developing country Members to ensure that the preparation and application of technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to the expansion and diversification of exports from developing country Members. In determining the terms and conditions of the technical assistance, account shall be taken of the stage of development of the requesting Members and in particular of the least-developed country Members.

12.8 It is recognized that developing country Members may face special problems, including institutional and infrastructural problems, in the field of preparation and application of technical regulations, standards and conformity assessment procedures. It is further recognized that the special development and trade needs of developing country Members, as well as their stage of technological development, may hinder their ability to discharge fully their obligations under this Agreement. Members, therefore, shall take this fact fully into account. Accordingly, with a view to ensuring that developing country Members are able to comply with this Agreement, the Committee on Technical Barriers to Trade provided for in Article 13 (referred to in this Agreement as the "Committee") is enabled to grant, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement. When considering such requests the Committee shall take into account the special problems, in the field of preparation and application of technical regulations, standards and conformity assessment procedures, and the special development and trade needs of the developing country Member, as well as its stage of technological development, which may hinder its ability to

discharge fully its obligations under this Agreement. The Committee shall, in particular, take into account the special problems of the least-developed country Members.

12.9 During consultations, developed country Members shall bear in mind the special difficulties experienced by developing country Members in formulating and implementing standards and technical regulations and conformity assessment procedures, and in their desire to assist developing country Members with their efforts in this direction, developed country Members shall take account of the special needs of the former in regard to financing, trade and development.

12.10 The Committee shall examine periodically the special and differential treatment, as laid down in this Agreement, granted to developing country Members on national and international levels.

INSTITUTIONS, CONSULTATION AND DISPUTE SETTLEMENT

Article 13

The Committee on Technical Barriers to Trade

13.1 A Committee on Technical Barriers to Trade is hereby established, and shall be composed of representatives from each of the Members. The Committee shall elect its own Chairman and shall meet as necessary, but no less than once a year, for the purpose of affording Members the opportunity of consulting on any matters relating to the operation of this Agreement or the furtherance of its objectives, and shall carry out such responsibilities as assigned to it under this Agreement or by the Members.

13.2 The Committee shall establish working parties or other bodies as may be appropriate, which shall carry out such responsibilities as may be assigned to them by the Committee in accordance with the relevant provisions of this Agreement.

13.3 It is understood that unnecessary duplication should be avoided between the work under this Agreement and that of governments in other technical bodies. The Committee shall examine this problem with a view to minimizing such duplication.

Article 14

Consultation and Dispute Settlement

14.1 Consultations and the settlement of disputes with respect to any matter affecting the operation of this Agreement shall take place under the auspices of the Dispute Settlement Body and shall follow, *mutatis mutandis*, the provisions of Articles XXII and XXIII of GATT 1994, as elaborated and applied by the Dispute Settlement Understanding.

14.2 At the request of a party to a dispute, or at its own initiative, a panel may establish a technical expert group to assist in questions of a technical nature, requiring detailed consideration by experts.

14.3 Technical expert groups shall be governed by the procedures of Annex 2.

14.4 The dispute settlement provisions set out above can be invoked in cases where a Member considers that another Member has not achieved satisfactory results under Articles 3, 4, 7, 8 and 9 and its trade interests are significantly affected. In this respect, such results shall be equivalent to those as if the body in question were a Member.

FINAL PROVISIONS

Article 15

Final Provisions

Reservations

15.1 Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

Review

15.2 Each Member shall, promptly after the date on which the WTO Agreement enters into force for it, inform the Committee of measures in existence or taken to ensure the implementation and administration of this Agreement. Any changes of such measures thereafter shall also be notified to the Committee.

15.3 The Committee shall review annually the implementation and operation of this Agreement taking into account the objectives thereof.

15.4 Not later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each three-year period thereafter, the Committee shall review the operation and implementation of this Agreement, including the provisions relating to transparency, with a view to recommending an adjustment of the rights and obligations of this Agreement where necessary to ensure mutual economic advantage and balance of rights and obligations, without prejudice to the provisions of Article 12. Having regard, *inter alia,* to the experience gained in the implementation of the Agreement, the Committee shall, where appropriate, submit proposals for amendments to the text of this Agreement to the Council for Trade in Goods.

Annexes

15.5 The annexes to this Agreement constitute an integral part thereof.

ANNEX 1

TERMS AND THEIR DEFINITIONS FOR THE PURPOSE OF THIS AGREEMENT

The terms presented in the sixth edition of the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities, shall, when used in this Agreement, have the same meaning as given in the definitions in the said Guide taking into account that services are excluded from the coverage of this Agreement.

For the purpose of this Agreement, however, the following definitions shall apply:

1. *Technical regulation*

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Explanatory note

The definition in ISO/IEC Guide 2 is not self-contained, but based on the so-called "building block" system.

2. *Standard*

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Explanatory note

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.

3. *Conformity assessment procedures*

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note

Conformity assessment procedures include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

4. *International body or system*

Body or system whose membership is open to the relevant bodies of at least all Members.

5. *Regional body or system*

Body or system whose membership is open to the relevant bodies of only some of the Members.

6. *Central government body*

Central government, its ministries and departments or any body subject to the control of the central government in respect of the activity in question.

Explanatory note:

In the case of the European Communities the provisions governing central government bodies apply. However, regional bodies or conformity assessment systems may be established within the European Communities, and in such cases would be subject to the provisions of this Agreement on regional bodies or conformity assessment systems.

7. *Local government body*

Government other than a central government (e.g. states, provinces, Länder, cantons, municipalities, etc.), its ministries or departments or any body subject to the control of such a government in respect of the activity in question.

8. *Non-governmental body*

Body other than a central government body or a local government body, including a non-governmental body which has legal power to enforce a technical regulation.

ANNEX 2

TECHNICAL EXPERT GROUPS

The following procedures shall apply to technical expert groups established in accordance with the provisions of Article 14.

1. Technical expert groups are under the panel's authority. Their terms of reference and detailed working procedures shall be decided by the panel, and they shall report to the panel.

2. Participation in technical expert groups shall be restricted to persons of professional standing and experience in the field in question.

3. Citizens of parties to the dispute shall not serve on a technical expert group without the joint agreement of the parties to the dispute, except in exceptional circumstances when the panel considers that the need for specialized scientific expertise cannot be fulfilled otherwise. Government officials of parties to the dispute shall not serve on a technical expert group. Members of technical expert groups shall serve in their individual capacities and not as government representatives, nor as representatives of any organization. Governments or organizations shall therefore not give them instructions with regard to matters before a technical expert group.

4. Technical expert groups may consult and seek information and technical advice from any source they deem appropriate. Before a technical expert group seeks such information or advice from a source within the jurisdiction of a Member, it shall inform the government of that Member. Any Member shall respond promptly and fully to any request by a technical expert group for such information as the technical expert group considers necessary and appropriate.

5. The parties to a dispute shall have access to all relevant information provided to a technical expert group, unless it is of a confidential nature. Confidential information provided to the technical expert group shall not be released without formal authorization from the government, organization or person providing the information. Where such information is requested from the technical expert group but release of such information by the technical expert group is not authorized, a non-confidential summary of the information will be provided by the government, organization or person supplying the information.

6. The technical expert group shall submit a draft report to the Members concerned with a view to obtaining their comments, and taking them into account, as appropriate, in the final report, which shall also be circulated to the Members concerned when it is submitted to the panel.

ANNEX 3

CODE OF GOOD PRACTICE FOR THE PREPARATION, ADOPTION AND APPLICATION OF STANDARDS

General Provisions

A. For the purposes of this Code the definitions in Annex 1 of this Agreement shall apply.

B. This Code is open to acceptance by any standardizing body within the territory of a Member of the WTO, whether a central government body, a local government body, or a non-governmental body; to any governmental regional standardizing body one or more members of which are Members of the WTO; and to any non-governmental regional standardizing body one or more members of which are situated within the territory of a Member of the WTO (referred to in this Code collectively as "standardizing bodies" and individually as "the standardizing body").

C. Standardizing bodies that have accepted or withdrawn from this Code shall notify this fact to the ISO/IEC Information Centre in Geneva. The notification shall include the name and address of the body concerned and the scope of its current and expected standardization activities. The notification may be sent either directly to the ISO/IEC Information Centre, or through the national member body of ISO/IEC or, preferably, through the relevant national member or international affiliate of ISONET, as appropriate.

SUBSTANTIVE PROVISIONS

D. In respect of standards, the standardizing body shall accord treatment to products originating in the territory of any other Member of the WTO no less favourable than that accorded to like products of national origin and to like products originating in any other country.

E. The standardizing body shall ensure that standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade.

F. Where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems.

G. With a view to harmonizing standards on as wide a basis as possible, the standardizing body shall, in an appropriate way, play a full part, within the limits of its resources, in the preparation by relevant international standardizing bodies of international standards regarding subject matter for which it either has adopted, or expects to adopt, standards. For standardizing bodies within the territory of a Member, participation in a particular international standardization activity shall, whenever possible, take place through one delegation representing all standardizing bodies in the territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardization activity relates.

H. The standardizing body within the territory of a Member shall make every effort to avoid duplication of, or overlap with, the work of other standardizing bodies in the national territory or with the work of relevant international or regional standardizing bodies. They shall also make every effort to achieve a national consensus on the standards they develop. Likewise the regional standardizing body shall make every effort to avoid duplication of, or overlap with, the work of relevant international standardizing bodies.

I. Wherever appropriate, the standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics.

J. At least once every six months, the standardizing body shall publish a work programme containing its name and address, the standards it is currently preparing and the standards which it has adopted in the preceding period. A standard is under preparation from the moment a decision has been taken to develop a standard until that standard has been adopted. The titles of specific draft standards shall, upon request, be provided in English, French or Spanish. A notice of the existence of the work programme shall be published in a national or, as the case may be, regional publication of standardization activities.

The work programme shall for each standard indicate, in accordance with any ISONET rules, the classification relevant to the subject matter, the stage attained in the standard's development, and the references of any international standards taken as a basis. No later than at the time of publication of its work programme, the standardizing body shall notify the existence thereof to the ISO/IEC Information Centre in Geneva.

The notification shall contain the name and address of the standardizing body, the name and issue of the publication in which the work programme is published, the period to which the work programme applies, its price (if any), and how and where it can be obtained. The notification may be sent directly to the ISO/IEC Information Centre, or, preferably, through the relevant national member or international affiliate of ISONET, as appropriate.

K. The national member of ISO/IEC shall make every effort to become a member of ISONET or to appoint another body to become a member as well as to acquire the most advanced membership type possible for the ISONET member. Other standardizing bodies shall make every effort to associate themselves with the ISONET member.

L. Before adopting a standard, the standardizing body shall allow a period of at least 60 days for the submission of comments on the draft standard by interested parties within the territory of a Member of the WTO. This period may, however, be shortened in cases where urgent problems of safety, health or environment arise or threaten to arise. No later than at the start of the comment period, the standardizing body shall publish a notice announcing the period for commenting in the publication referred to in paragraph J. Such notification shall include, as far as practicable, whether the draft standard deviates from relevant international standards.

M. On the request of any interested party within the territory of a Member of the WTO, the standardizing body shall promptly provide, or arrange to provide, a copy of a draft standard which it has submitted for comments. Any fees charged for this service shall, apart from the real cost of delivery, be the same for foreign and domestic parties.

N. The standardizing body shall take into account, in the further processing of the standard, the comments received during the period for commenting. Comments received through standardizing bodies that have accepted this Code of Good Practice shall, if so requested, be replied to as promptly as possible. The reply shall include an explanation why a deviation from relevant international standards is necessary.

O. Once the standard has been adopted, it shall be promptly published.

P. On the request of any interested party within the territory of a Member of the WTO, the standardizing body shall promptly provide, or arrange to provide, a copy of its most recent work programme or of a standard which it produced. Any fees charged for this service shall, apart from the real cost of delivery, be the same for foreign and domestic parties.

Q. The standardizing body shall afford sympathetic consideration to, and adequate opportunity for, consultation regarding representations with respect to the operation of this Code presented by standardizing bodies that have accepted this Code of Good Practice. It shall make an objective effort to solve any complaints.

BIOGRAPHY

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