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ABSTRACT

The UN Cartagena Protocol on Biosafety adopted in Montreal, 29 January, 2000 and opened for signature in Nairobi, 15-26 May, 2000 will exert a profound effect on international trade in genetically modified organisms (GMOs) and their products. In this paper, the background to the drafting and negotiation of the Protocol is outlined, and potential effects of various articles of the Protocol on international trade in GMOs are analyzed. Based on the present status of imports of GMOs and domestic research and development of biotechnology in China, likely trends in imports of foreign GMOs and related products after China accedes to WTO is explored. Also, China's strategies and countermeasures to control and regulate imports of GMOs in line with implementation of the Protocol are discussed.

Keywords: *biosafety, Cartagena Protocol, genetically modified organism, trade, China.*

Effects of the Cartagena Biosafety Protocol on Trade in GMOs, WTO Implications, and Consequences for China

Some 1500 diplomats and experts from 156 countries and the related international organizations met in Nairobi, 15-26 May, 2000 for the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP5). A highlight of the meeting was the signing of the Cartagena Protocol on Biosafety, an international legal document to control the transboundary movement, transit, handling and use of all living modified organisms (LMOs) that may have adverse effects on human health and the conservation and sustainable use of biological diversity. Sixty-four governments plus the European Community signed the protocol during the meeting, and the document will continue to be open for signature by nations and regional economic groups at the United Nations Headquarters in New York from 5 June, 2000 to 4 June, 2001. As it is signed and subsequently enters into force, the protocol will produce profound impacts on international trade in biotechnology and its products. This paper will focus on analyzing the potential effects of the protocol's implementation on global trade in genetically modified organisms (GMOs) and their products, especially the impacts of imports of GMOs in China. Accordingly, the paper will consider China's strategies and countermeasures to implement the Cartagena Protocol on Biosafety and regulate its import trade in GMOs.

1. Background and Foci of Cartagena Protocol Negotiations

1.1 *Biotechnology development and environmental safety*

Population growth, limited resources and deteriorating environments have become a fundamental concern for human survival and development. At the same time technical advance led by scientific research is regarded as an essential approach to overcome these concerns. Due to the development and wide spread application of techniques in genetic recombination and cell engineering since 1970s, biotechnology has entered a new modern stage, and is yielding huge economic benefits. Economic benefits are especially large because of the rapid growth of modern biotechnology industries based on genetic engineering. Industrialization of biotechnology has greatly promoted global trade in biotechnological products, especially in development and

application of agricultural biotechnology. For example, transgenic crops, such as genetically modified (GM) crops with insect resistance and herbicide tolerance, account for a large area of commercial production and the products have been widely and regularly exported to other countries. However, the environmental release of the genetically modified organisms (GMOs) may be potentially harmful to human health and biodiversity. Also the process of handling, packing, transportation, storage and application for GMOs may produce environmental risks. Particularly, some living GMOs used as food and consumed directly by human beings, could pose safety risks. Consequently, as the industrialization of biotechnology has increased, the safety issue of biotechnology has become a concern of international society and governments in most countries, and a major issue for environmental cooperation between countries. Many developing countries are afraid of those developments and have expressed caution and worry because they lack the necessary scientific or regulatory capacities in this field of biotechnology. Therefore, these countries placed their hopes for international legal, financial and technological support in an international biosafety agreement. Many developed countries, based on their situations in relation to trade in GMOs, also expressed the need for an international agreement. This led the development and final emergence of Cartagena Protocol on Biosafety.

1.2 *Relationship between the Convention on Biological Diversity and Cartagena Protocol on Biosafety*

The formulation of Cartagena Protocol is based on some Articles of the Convention on Biological Diversity (CBD), which was drafted and negotiated starting in 1988, and adopted in 1992 during the UNCED in Brazil. It entered into force on 29 December, 1993. So far, CBD has been ratified by 177 countries. During the inter-governmental negotiation of CBD, biosafety gradually became a core issue (Xue and Gao, 1995), and finally became an important part of the Convention. For example:

- Article 8(g) requests each Contracting Party to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts on biodiversity and human health.

- Article 19(3) asks the Parties to consider the need for and modalities of a protocol setting out appropriate procedures, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on biodiversity.
- Also, Article 19(4) requires each Contracting Parties to provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impacts of the specific organisms.

So, the Protocol is an international instrument under the Convention on Biological Diversity.

1.3 *Processes Resulting in the Drafting of the Protocol*

The Second Meeting of the Conference of the Parties to the CBD (COP2) held in Jakarta, Indonesia, November 1995 adopted Decision II/5 to develop a protocol on biosafety, specifically focusing on transboundary movement of any living modified organisms (LMOs) resulting from modern biotechnology. Then an open-ended ad hoc Working Group on Biosafety (BSWG) was formed to act as the negotiating body and was given the task of producing a final draft treaty by 1998. The Working Group met five times between 1996 and 1998, but failed to find sufficient common ground among the Parties. So BSWG reconvened for a sixth time in Cartagena, Colombia in 14-19 February 1999 to pave the way for the adoption of the Biosafety Protocol at an Extraordinary Conference of Parties to CBD (ExCOP) following on immediately from the Working Group meeting in Cartagena, 22-23 February, 2000. However, agreement was not reached. Later an informal meeting on the Biosafety Protocol was held in Vienna from 15 to 19 September, 1999 to narrow down the remaining contentious areas. An agreement for the Protocol's text was finally reached at the Resumed Session on the First ExCOP in Montreal, Canada, 24-29 January, 2000.

1.4 *Background to Negotiation of the Protocol*

Because of large differences between the extent of development of biotechnology by countries, as well as the need to deal with sensitive issues such as trade in biotechnological products and the

influence of biotechnology on biodiversity conservation and human health, most countries gave considerable attention to the inter-governmental negotiations of the Protocol's text. Long and difficult negotiations were involved with heated arguments. Considering their own interests, the participating countries had serious disagreements about the Protocol's text, and the negotiators had clearly divided themselves into five alliances in the end of Cartagena meeting in February 1999 (Gupta 2000, Falkner 2000, Cosbey and Burgiel 2000).

Seeing that their domestic capacity to deal with the safe use of biotechnology is weak, the majority of developing countries expressed caution and were worried about the transboundary movements of genetically modified organisms (GMOs)[1]. Developing countries insisted on precautionary principle and advocated the drafting of a strict international legislation to control and standardize transboundary movement of GMOs, in order to minimize the adverse affects of GMOs on biodiversity and human health. This coalition, called the Like-Minded Group, mostly consisted of G-77 countries and China.

Another group, the Miami Group, on the other hand, was worried that a strict protocol would hinder their huge benefits from exporting GM-crop products. Their interest was to have free trade in such GM products without burdensome bureaucratic approval procedures, and without allowing room for protectionist trade barriers in the name of environmental protection. The Miami Group represents the major exporters of GM seeds and crops, consisting of the six countries, namely Argentina, Australia, Canada, Chile, US and Uruguay.

Countries of the European Union (EU), as a group, strove for a strong Protocol and argued for strong language supporting the precautionary principle. EU advocated standardizing trade in LMOs and emphasized the protocol should not be subordinated to WTO agreements. As these countries, at present, are more importers than exporters and have developed systematic regional directives and national legislation covering all facets of trade, handling, and use of LMOs, they were, sometimes, inclined towards greater safeguards in the Protocol.

[1] To direct attention away from genetic engineering as the focus of regulatory attention, "living modified organisms resulting from biotechnology" (LMOs) replaced "genetically modified organisms" (GMOs) finally during the process of CBD and the Protocol development.

Another group, the Compromise Group mostly consisted of OECD countries which are not agricultural exporters and not part of the EU. They included Japan, Mexico, Norway, South Korea and Switzerland, and were later joint by Singapore and New Zealand. The Compromise Group tried to bridge the major gaps between the other negotiating groups by developing compromise positions and alternative formulations.

The remaining group consists of the Central and Eastern European countries. This Group generally took a middle-of-the-road position. While favoring the inclusion of GMO food or feed products and the precautionary principle in the Protocol, this Group focused primarily on the practicality and applicability of various proposals.

So, the final agreement about the text of the Protocol involved bargaining by the various interest groups, rather than initial consensus.

1.5 ***Negotiating positions of Parties to the Protocol***

(1) General positions

Before the Cartagena meeting in February 1999, delegations involved in the Protocol's inter-governmental negotiation can be roughly divided into two coalitions on a consisting of developing countries and the other of developed countries, and their positions are generally described as follows:

Procedures for transboundary movements of LMOs

Since transboundary movement of LMOs mainly occurs from developed countries to developing countries, most developing countries considered that the Party of export should inform the competent national authority of the Party of import in advance of exporting, and intended transboundary movement should occur only after the Party of import has given its consent. However, some developed countries such as USA, Japan, Canada and Australia proposed that any company, university, research institute or representative agency should be able to apply for

transboundary movement, and the advance informed agreement (AIA) procedure should not hinder international trades.

Risk assessment and risk management

Risk assessment and risk management are often effective means to minimize the potential environmental disasters resulting from LMOs. Most developing countries insisted that standardized risk assessment and practical risk management be the foundation for the Party of import to decide if it would agree to the import of an LMO. These countries argued that it was necessary to list the requirements and standards of risk assessment as an appendix to the Protocol. However, the US and Japan suggested that it was not necessary for the Protocol to involve risk assessment and risk management, nor to principally mention it, if they are involved in.

Non-discrimination principle for import and export of LMOs

Trade discrimination involves a barrier to international trade. It is against the rules of WTO. Some developed countries advocated that LMO imports and exports should be subject to the principle of same treatment for each country and same treatment for foreign and domestic products, and unfair discrimination should not be allowed. On the contrary, most developing countries considered that because LMOs and their products have particular implications for environmental protection and for human health, each country should have the right to decide whether to import a foreign LMO or not.

Socio-economic problems

The transboundary movement of LMOs may give rise to some serious socio-economic problems in importing countries, including damage to traditional agriculture, loss of genetic resources, destruction to ecosystems and adverse impacts on ethics and cultures. Many developing countries insisted on taking into account the socio-economic situation arising from import of LMOs. However, some developed countries believed that the socio-economic problems were so complex, they should not be mentioned in the Protocol.

LMOs Information exchange

Data and information is a necessary basis for the Party of import to make an advance-informed agreement (AIA) and to conduct relevant risk assessment prior to making the agreement. Most developing countries considered that each Contracting Party was under an obligation to provide the Party of import with enough data and information concerning the import of LMOs for the importing countries to make an assessment, and any Contracting Party should not impede the information exchange by using the excuse of confidential data and information. But some developed countries considered that information exchange was one part of technology transfer, and that the Protocol should include sections for the protection of confidential information and intellectual property right.

Liability for damage from LMOs and redress

Some developing countries proposed that specification of liability and redress was necessary to implement the international protocol on biosafety. Exporters of LMOs should, in their view, be liable to pay for the damages to the environment and human health resulting from the exported LMOs in the importing countries. On the other hand, some developed countries were opposed to listing liability and redress as the Protocol's text. They suggested that it would be too complicated for a protocol.

The extent of coverage of LMOs in the global trade

A major argument during the negotiations was whether the Protocol should apply only to trade in living GMOs (e.g. seeds) or also to products made with the help of genetic engineering (e.g. medicines) or containing GM ingredients (e.g. food, animal feed). The GM-exporting countries, fearful of the potential repercussions for the burgeoning trade in GM foods and pharmaceutical products, insisted on a narrow definition of the Protocol's scope. GM-exporting countries would accept only a narrowly defined Protocol that was subject to the WTO's legal code. But most developing countries, as well as EU, wanted to have all biotechnological products covered by the treaty and they argued in favor of a document with more extensive scope and clearly defined exemptions from existing WTO obligations. In the end, the position of US and Miami Group delegations prevailed and the scope of the Protocol is limited to only LMOs (no inclusion of

derived products) as stated in Article 4 and pharmaceutical products are excluded as described in Article 5.

(2) Polarization of positions

Positions polarized around two contentious issues within protocol negotiations leading up to Cartagena (Gupta 2000). The first was disagreement over the categories of LMOs to be covered under the protocol and its AIA procedure. The second was disagreement about the decision-making procedure that should govern LMO transfer.

Disputes about the first set of concerns were largely along North-South lines. Developing countries argued for a broad spectrum of LMOs to fall within the scope of the Protocol and its AIA procedure. But most OECD countries argued for only those LMOs to be included that would come into contact with the environment of the importing country and thereby pose a threat to biodiversity.

Disputes about the second set of concerns were largely an intra-OECD battle between the Miami Group and the European Union. This dispute turned on whether countries had the right to restrict LMO imports in the absence of scientific certainty of harm. This was closely linked to the highly contentious issue of the relationship of the Protocol to WTO obligations.

2. The Content and Potential Effects of Cartagena Protocol on Global Trade in GMOs

As described in the Article 4, the Cartagena Protocol shall apply to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health. According to the Article 3 of the Protocol, the definition of "Living Modified Organisms (LMOs)" refers to any living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology. While "modern biotechnology" means the application of *in vitro* nucleic acid techniques including recombinant deoxyribonucleic acid (DNA) and techniques of fusion of cells beyond the taxonomic family. So, LMOs can be narrowly referred to as

Genetically Modified Organisms (GMOs) or transgenic organisms. Actually, current LMOs transboundary movement is mainly limited in the international trade of products to genetically modified (GM) plants and animals, including GM-crop seeds and other processed GM foods, as well as fish.

The main potential effects of the articles of the Cartagena Protocol on Biosafety concerning international trade of GMOs are probably as follows:

2.1 *Advance informed agreement (AIA) procedure*

Article 7 of the Protocol provides that the advance informed agreement (AIA) procedure shall apply prior to the first intentional transboundary movement of LMOs for international introduction into the environment of the Party of import. The Article 8 states that the Party of export shall notify, or require the exporter to ensure notification in writing to, the competent national authority of the Party of import prior to the intentional transboundary movement of LMOs.

To satisfy the provision of the Cartagena Protocol, import of GMOs should be subject to AIA procedure. This will make the process of approval formality more complicated than before. Currently, in order to import and export GMOs and derived products it is only necessary to sign a contract simply with a commercial institution or trading company in countries of import, or only to have the approval by a public body responsible for the administration of agriculture. However, once the Protocol enters into force, trade in a GMO requires approval by a specified competent national authority in importing country. Generally, the competent national authority is a national administrative agency of environment in central government, or a coordinating unit formed by ministries of environment, agriculture and public health. The international movement of GMOs will be reviewed more strictly than previously, not only from the view of agricultural production, but mainly from the viewpoint of environmental protection, human health and other aspects. Increased cost will be involved in the export and import of GMOs.

2.2 *Decision procedure for GMOs introduction*

Article 9 of the Protocol stipulates that the Party of import will acknowledge receipt of the notification and state whether the country will process the exporting application according to the domestic regulatory framework. The Article 10 states that the Party of import shall notify in writing to the Party of export that they approve of the import with or without conditions, or prohibit the import and or request additional relevant information in accordance with its domestic regulatory framework. Also the Article 10(5) specifies that failure by the Party of import to communicate its decision shall not imply its consent to an international transboundary movement.

The decision procedure provides the Party of import with an opportunity to design green barriers and allows some flexibility for decision-making. As the decision-making procedure is subject to domestic regulatory framework, the Party of import can formulate some concrete strict domestic regulations under the framework of the Protocol to limit the import and export of GMOs in order to protect the country's benefits. Also the Party of import can willfully revise their domestic regulations according to their actual requirements, to make the domestic regulations more subjective, protectionist and political, though Article 9(3) emphasizes that the domestic regulatory framework shall be consistent with the Protocol's objectives.

2.3 *Information requirements*

Article 8 of the Protocol provides that the Party of export shall enclose, at a minimum, the information specified in Annex 1 in its notification and shall ensure that there is a legal requirement to help enforce the accuracy of information provided by the exporter. In light of this Article, information provision is obligatory for exporters, and the information listed in Annex 1 is required to be a detailed description. It must include: name and identity of LMOs of the biosafety level in the State of export; centers of origin and centers of genetic diversity of the recipient organism and/or the parental organisms; taxonomic status and characteristics of the donor organisms related to biosafety; description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMOs; intended use of the LMOs or

products; quantity or volume of the LMO to be transferred; a previous and existing risk assessment report; regulatory status of the LMO within the State of export; and so on.

2.4 *Procedure for LMOs intended for direct use as human food or livestock feed, or for processing*

The Protocol in Article 11(4) provides that a Party may take a decision on the import of LMOs intended for direct use as food or animal feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol. Further, Article 11(8) stipulates that lack of insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on biodiversity shall not prevent the Party of import from taking a decision, in order to avoid or minimize such potential adverse effects.

The Protocol deals with the international movement of LMOs for food and livestock feed in a special article, because import and export of food and feed is very significant in global trade. Indeed, international trade of GMOs' food and animal feed has become more and more important in recent years, and this trade is accelerating. That GMO food and animal feed are subject to both the AIA procedure and domestic regulatory framework implies that the Party of import has opportunities to erect green barrier to protect the country from the large imports of GMO food or animal feed, or GMOs for processing. It will probably give rise to disputes between countries for trading in GMO food and animal feed.

2.5 *Risk assessment*

Article 15(2) demands that the Party of import shall ensure that risk assessments are carried out or may require the exporter to carry out the risk assessment. Article 15(3) adds that the cost of risk assessment shall be borne by the exporter if the Party of import so requires. In particular, the Annex 2 of the Protocol prescribes a series of principles, methodology and points to consider for risk assessment of LMOs. The risk assessment steps mainly include: identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects on biodiversity and human health; an evaluation of the likelihood and consequences of these

adverse effects; an estimation of the overall risk posed by the LMO based on the evaluation of the likelihood and consequences; and a recommendation as to whether or not the risks are acceptable or manageable.

The Protocol provides the Party of import with the right to carry out risk assessment for the proposed import of GMOs. That implies that the Party of import has a right to impose strict conditions for the risk assessment if the country wants to hinder the import of the GMOs. The proposed export may fail the risk assessment test or the exporter could suffer a long period of assessment. Meanwhile, Article 15 does not impose any economic liability for risk assessment on the importer because the Party of import can request exporter to pay the expenses of the risk assessment, and can also directly ask the exporter to conduct the risk assessment if the country has no capacity to do risk assessments.

2.6 *Handling, transport, package and identification*

Article 18(2) of the Protocol provides that each Party shall provide at least minimum documentation,

(a) to clearly identify the LMOs that are intended for direct use as food or feed, or for processing as LMOs and as not for intentional introduction into environment; and specifies their identity and any unique identification;
(b) to clearly identify LMOs that are destined for contained use as LMOs; and specifies any requirements for the safe handling, storage, transport and use of those; and
(c) to clearly identify any other LMOs that are intended to be introduced into the environment of the Party of import as LMOs; and specifies the identity and relevant traits and/or characteristics, and any requirements for the safe handling, storage, transport and use.

Documentation such as labeling is required by this article to identify LMOs for the three situations of direct use (food or animal feed, or for processing), contained use and intended environmental release. Though the LMOs are for different uses, labeling requirements are similar and must identify relevant traits of the GMOs and requirements in handling, storage, transfer and use. Those labeling measures are likely to have an adverse effect on the market for

GMOs and products. Because labeling may increase consumers' concerns, it will probably result in a price penalty for GMOs and GMO-based products.

2.7 *Liability and redress*

Article 27 of the Protocol states that the Conference of the Parties to this Protocol shall, at their 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 LMOs, and shall endeavor to complete this process within four years.

The issue of liability and redress is one of the main issues during the Protocol's inter-governmental negotiation. Negotiators failed to reach agreement on this issue and had to leave it to the first meeting of the Conference of Parties to the Protocol. It is likely that irrespective of whether an agreement or not is reached in the first meeting, the Parties of import will insist on liability and redress. Once the principle of liability and redress is adopted, it will be an another limitation on international movement of GMOs.

3. Trends in the Development of Global Trade in GMOs and Its Effects in China

3.1 *Commercial production of GMOs and economic benefits*

Scientists first obtained transgenic plants by genetic engineering in 1983, but gene transformation technology only become commercially relevant after 10 years. Following the first pilot experiment conducted in the United States and in France in 1986, more than 25,000 pilot experiments had been conducted globally by the end of 1997. Following the approval in the United States by the commercial production of transgenic late-ripening tomatoes in 1994, a total 51 species of transgenic plants had been approved worldwide for industrialized production before the end of 1997. These included transgenic crops (GM crops) of cotton, corn, soybean, oilseed rape and potato that are resistant to insects, diseases and herbicides. These account for a large area of plantings (Liu, 1999).

The global area of GM crop production is estimated to be 1.7 million ha in 1996, but the area increased dramatically to 12.5 million ha in 1997, of which the planted area for GM soybean, corn and oilseed rape had increased 10 times compared with 1996. Furthermore, there were further large increases to 27.8 million ha in 1998 and 39.9 million ha in 1999 (Falkner 2000). GM crops accounted for 54% of the area sown with soybean, 28% for corn, 9% for cotton and 9% for rape seed in 1999. By gene types, 71% of GM crops were for herbicide tolerance, 22% for insect resistance and 7% for both herbicide tolerance and insect resistance[2].

The plantings of GM crops is concentrated in a few countries. For example, of 27.8 million hectares planted to GM crops in 1998, US accounted for 74%, Argentina for 15%, Canada for 10%, and Australian for 1%. Mexico, France, China, and South Africa constituted the remainder, each with less than 1% (Gupta 2000).

GM crops have produced huge economic benefits. In the United States for example, in 1997, more than 1 million ha of insect-resistant GM cotton was planted, which increased average yield by 7%, and net profit by 83 US Dollars per ha. In total, direct benefit from GM cotton for 1997 was estimated to be 100 million USD. In 1998, 5 million ha was planted to insect-resistant GM corn and it increased average yield by 9%, and net profit per ha by 68 USD. It is estimated to have given a total benefit of 340 million USD for the total GM corn crop. Moreover, in 1997, 1.2 million ha was planted to herbicide tolerant (oilseed) rape, resulting in an increase of 9% in yield and a 50 USD per ha increase in profit. The overall farm benefits for 1997 were estimated to be 60 million USD for the total GM rape crop (Liu 1999). It is believed that in 1999 35% of the US corn acreage and 55% of soybean acreage was genetically modified. It is estimated that approximately 60% of the processed foods in a US consumer's shopping cart may contain genetically engineered constituents[3].

The global sales volume of GM crops increased approximately 30-fold in the period 1995-99. Global sales were estimated to be USD 75 million in 1995, USD 235 million in 1996, USD 670 million in 1997, and between USD 1.2 and USD 1.5 billion in 1998 (James, 1998). And the

[2] Data from *Agricultural Biotechnology Information* (in Chinese), 1999(3):1
[3] Bereano P. The politics of genetically engineered foods: the United States versus Europe, *Seattle Times* newspaper, 8 Nov. 1999

global market for GM crops is projected to reach USD 8 billion in 2005, and USD 25 billion in 2010 (Falkner 2000).

The growing large area planted to GM crops will certainly result in major exports of GMOs and their products. Some GM crops such as cotton, corn, soybean, oilseed rape (canola) and tomato have already become important internationally traded commodities, both for their seeds and in processed products. However, the transboundary movement and environmental release of large quantity of GMOs and their products could have adverse effects on biodiversity and human health in the countries of import. At least this is a current fear.

3.2 *The present status of foreign GMOs and GMO-based products exported to China*

China's import of food has increased in recent decades. It imported about 5 million tons of food each year in the 1960s and 1970s. But in the 1990s this quadrupled. Since 1995 China's import of food, cotton, edible oil and sugar, were respectively reached of 20, 0.7, 3.0 and 2.5 million tons (Liu 1999). China's food imports have remained of about 20 million tons in recent years. Its imported food items and edible oil are mainly imported from the United States and Canada, which are the main countries with GMOs crops. These two countries export over 28 million tonnes of oilseeds and 100 million tonnes of cereals each year (Hodgson 2000). In light of China State statistics on import of commodities in 1998 (China Customs, 1999), the quantity of imported food, animal feed and oil only from USA and Canada was more than 40% of China's total imports of food, feed and oil in that year. Of its imports, 75% of corn, 55% of soybean and 65% of animal feed were imported from USA; 67% rape seed was from Canada, and 86% of wheat was from both USA and Canada (Table 1).

GM products accounted for a large proportion of China's imported foods, animal feeds and oils. It was reported that, in the United State in 1999, 57% of the land for soybean production was planted with the GM herbicide-tolerant varieties, 55% of the whole cotton land with GM insect-resistant cotton, and 43% of the whole corn plantation with GM corn[4] (Tribe 2000). For Canadian oil rape, GM varieties also occupied over 50% of the whole planted area in 1999.

[4] http://www.sina.com.cn 2000/04/04, news from *Science and Technology Daily* (China)

Although wheat and barley are not large commercial GM crops yet, GM wheat and GM barley are potentially large exports from the USA and Canada to China. Therefore, GMOs food imports probably pose a significant potential risk to environment and human health in China.

Table 1. The statistics of imports of food and food products by China from USA and Canada in 1998

Names of imported foods and other products	Importing from USA		Importing from Canada		Total importing in China	
	Quantity (ton)	Value (10^3 USD)	Quantity (ton)	Value (10^3 USD)	Quantity (ton)	Value (10^3 USD)
1. Corn						
Corn seeds	188907	23967			250623	31770
Crude corn granule & powder	468	191			490	206
Fine corn powder	135	55			218	97
Other processed corn	316	295			482	459
Corn chaff, bran and residue	11050	4709			11077	4728
Corn starch					1856	1289
Preliminarily extracted corn oil					940	650
Other corn oil & separate goods					596	478
2. Soybean						
Yellow soybean seeds	1265360	313131	10819	3734	2339845	581148
Black soybean seeds			871	282	871	282
Greenish black soybean seeds	30000	8725			30085	8741
Other soybean	454652	124312	843	319	816971	212527
Soybean powder	2410	632	120	31	8847	2659
Preliminarily extracted oil	373080	231009	41	21	753968	470617
Other oil & separate goods	24709	16324	1765	885	77720	52240
Soybean chaff, bran and residue	21615	4624	116	12	340364	67698
Soybean cake(after oil extracted)	255747	69604			825038	199128
Residue (after oil extracted)	591840	146969			2897264	622749
3. Oil rape						
Rape seeds			928990	268160	1386413	402457
Preliminarily extracted rape oil	9721	5374	36971	23734	246290	153020
Other rape oil & separate goods	3234	2096	5821	3765	38415	21933
Residue (after rape oil extracted)			92	19	107246	12737
4. Cotton						
Cotton seeds	39	17			39	17
Cotton seed oil & separate goods	33	45			76	92
Residue (after oil extracted)					121090	16835
5. Potato						
Crude & fine potato powder	142	73			830	531
Potato powder slice & granule	264	284			1681	1459
Potato starch	667	598			24388	9507
6. Feed						
Processed feed additive	16753	11912	1806	1202	49171	39086
Unnamed compound animal feed	103164	12234	264	64	133926	21912
7. Other main foods						
Wheat and mixed wheat	319003	57877	961661	179826	1489403	278570
Barley			446786	79808	1519141	240966
Total	3673309	1035057	2396966	561862	13475364	3456588

Data source: China Customs Statistics Annual Report for 1998

3.3 *China's domestic development of GMOs and commercial production*

Besides significant introduction of GMOs and products from foreign countries to China, China has developed its domestic biotechnology rapidly during the past 10 years. It is reported that 15 crop species have been developed by Chinese domestic scientists in pilot experiments and have been modified for transgenic insect-resistance, virus-resistance and quality improvement. Of these, 6 varieties of GM insect-resistant cotton and virus-resistant tomatoes have been approved for commercial production. China's statistics state that China had the fourth largest increase in the world planted to GM crops by the early 1990s, immediately after USA, Argentina and Canada. In the early 1990s China began to plant GM virus-resistant tobacco. A large area amounting to 1 million ha in 1996 and 1.6 million ha in 1997 was planted. This tobacco planting was then famed as the largest GM plant community. Domestic research in GM insect-resistant cotton has also progressed, and two cases have been approved for pilot experiments of which one case was approved for commercial production with 10000 ha planted in 1998. In addition, insect-resistant rice, disease-resistant potato and insect-resistant corn are undergoing pilot experiments (Liu 1999).

It is reported that 47 plant species have been used in genetic engineering research in China. These include 7 grain crops, 5 economic non-food crops, 4 oil crops and 31 vegetable and fruit crops (Wang 1999) (Table 2).

Table 2 Plant species used in genetic transformation in China

Groups	Number of species	Crop species
Grain crops	7	Rice, wheat, corn, potato, sorghum, millets, sweet potato
Economic and Oil crops	9	Cotton, tobacco, sugar cane, sugar beet, soybean, oilseed rape, peanut, etc.
Fruit and Vegetables	21	Tomato, cabbage, carrot, pepper, sweet pepper, Chinese cabbage, cauliflower, broccoli, etc.
Others	10	Poplar, alfalfa, etc.

Normally the Ministry of Agriculture in China deals with applications for safety assessment of agricultural GMOs twice a year. By 1998, applications had been lodged for 23 agricultural species, including 13 crops including cotton, rice, tobacco, potato, tomato, capsicum, etc.; 7 plant-related micro-organisms such as corn azotobacter, soybean rhizobium and caryogram polyhedral virus; one veterinary micro-organism and two aquatic animals (common carp and golden carp) (Li and Liu 1999).

By the end of 1998, a total of 86 applications have been accepted by the Ministry, including 63 for plants, 19 for plant-related micro-organisms, 2 veterinary micro-organisms and 2 aquatic animals and plants. Among these 86 applications, 72 have passed the review of the Safety Assessment Committee, including 30 for pilot tests, 36 for environmental release and 6 for commercial production (Li and Liu 1999).

4. The Trends in GMOs in International Trade with and by China

4.1 *Foreign biotechnology introduction is accelerating*

Some large biotechnology companies have paid considerable attention to China's extensive market. For example, Monsanto, Dupont and Pioneer of USA, Zeneca of UK and KWS of Germany have invested in research into GMOs and have conducted experiments in China through single-ventures or joint ventures. Some foreign biotechnology companies have already begun to undertake GMO pilot tests, environmental release and commercial production in China. For example, among the 68 GMO applications received by Ministry of Agriculture in 1998, 7 were from Monsanto and 1 from Pioneer[5]. The planting of the GM insect-resistant cotton obtained from Monsanto totalled 110,000 ha in China in 1998, and the area planted showed a large increase in 1999. Pioneer has carried out pilot experiments for GM corn. There were 40 pilot experiments underway in 1999 accounting for 6000m^2 of land distributed in the 5 provinces of Shandong, Henan, Lioning, Jilin and Helongjiang. Besides, it has been found that among the

[5] 1998 annual report of the review results for GMOs safety assessment applications in China, issued by the Office of Genetic Engineering Safety Administration, Ministry of Agriculture, *Biotechnology Information*, 1999 (1): 46-50.

foreign invested enterprises established during 1990-1996 there are more than 100 enterprises involved in GMOs and their products, with a total investment of USD 630 million.

In addition, an Australian biotechnology and horticultural company, Technico, will invest AUD 5.2 million to establish a production facility for its advanced seed potato technology in China and the facility will produce seeds to enable a production of 44 million tonnes of potatoes annually (ABA 2000). Furthermore, Australia's biotech-industry is preparing to collaborate with Taiwan by co-investment in Chinese herbal medicines (Hillyard 1999).

However, when China accedes to WTO in near future, entry conditions to the Chinese market and competition mechanisms will be linked to the global society, and the market mechanism will be also subject to the rules of the WTO. Consequently, the Chinese technological market will be more open and competition will be more intense. This will lead to a substantial introduction of foreign high technology and products, especially biotechnology and its products. It is anticipated that after China accedes to WTO, foreign GMO products and GMO technologies will irresistibly enter Chinese markets at an accelerating rate in the next a few years.

4.2 *Import of agricultural GMOs and their products increasing*

China has a population of almost 1.3 billion. Though great successes have achieved in agricultural production, China still needs to import a huge amount of food to feed so many people; it is currently importing an amount of 20 million tons of food each year. Due to industrialization and urbanization as well as the policy of conserving forests, grasslands and lakes implemented in the proposed large development planned for middle and western China, China’s area of farmland will be continuously reduced. Meanwhile, its population will continue to increase and natural disasters such as flood and drought often happen in China. Therefore, China’s food imports will continue to increase for the foreseeable future. China is considered to be the largest potential export market for food. This is one of the reasons why the American government actively supports China’s entry to the WTO. It is estimated that after China joins WTO, its main imports of food and oil varieties will increase by two to three times current levels, and cotton will increase fourfold (Liu 1999). China’s sources of imported food, cotton, edible oil and sugar are mainly the USA, Canada and Australia, and these countries are also major

countries involved in GMO food production. So, China will unavoidably become a vast GMO food market for these GMO exporting countries.

4.3 *Export potential of China's domestic GMOs*

Actually, there exists competition between domestic developed GMOs and foreign introduced GMOs in applications for approval for environment releases and commercial productions. It is due to this competition and trade protectionism that the speed of the foreign GMO introduction has been limited objectively by China. However, experts estimate that China's own development of GMOs may be used to meet domestic demands, rather than being exported. Currently, the GM product in China with largest export potential is tobacco leaf, but because of China's GM tobacco production all European countries and US resolutely refuse to import tobacco from China. Because of GMO doubts, these countries even canceled contracts of USD 400-700 million for tobacco leaf and have imposed a great economic loss on China. Therefore, for the present and the foreseeable future, China's domestic GMO exports will be very limited in quantity, but its imports of GMO products will be very large.

Moreover, using imported GMO food for livestock will produce a potential effect on China's export of livestock products. Japan, the South Korea and European countries will execute labeling system for GMOs food. This means that exporters of livestock products to these countries must provide with certification indicating non-use of GMOs feeds, otherwise, exports of the livestock products will be refused or prices lowered. In addition, industrial products using GMOs as raw materials, such as cotton, may be faced with the same type of problem also in the future.

5. China's Countermeasures Implement the Cartagena Protocol and Regulate its Import of GMOs

By signing and acceding to Cartagena Protocol, China will be able to more effectively control its imports of the GMOs that may have adverse effects on its environment and human health. China may use the Protocol's stipulations, such as AIA procedure, decision procedure, risk assessment,

identification, and liability and redress provisions, to control introduction of foreign GMOs, and to regulate the environmental release of introduced GMOs, their commercial production and use. If necessary, China could design some green barriers using the framework of international agreements, to prevent introduction of the GMOs that may have significant adverse effects on its environment and human health. But it may also face significant bargaining pressures in that regard from GMO-exporting nations.

As the Protocol enters into effect and is implemented, China also can, according to the articles concerned, take administrative actions to enhance its management of the introduction of GMOs and to monitor introduced GMOs, as well as to regulate domestic research into GMOs and their commercial production. China's possible countermeasures are outlined below. Some are already proposed in China's National Biodiversity Framework, a government document in press (Xue et al., 1999).

5.1 *Institutional enhancement*

The current institutions and duties

Presently, the main sectors involved in GMO safety and trade in Chinese government are as set out below.

(1) The State Environmental Protection Administration (SEPA)

SEPA is the leading ministry for implementing the Convention on Biological Diversity in China, and also is the leading authority of the Chinese Government Delegation for participating in the inter-governmental negotiations for Cartagena Protocol on Biosafety. In 1998, the State Council, in its duty allocation document, provided SEPA with the new duty of environmental safety administration for biotechnology. The Cartagena Protocol, in its Article 19, requires each Contracting Party to designate one national focal point and one or more competent national authorities to be responsible for performing the administrative functions of the Protocol; and a Party may designate a single entity to fulfill the functions of both being a focal point and competent national authority. Certainly, the authority will be responsible on behalf the country to conduct AIA procedures and apply decision procedures for GMO transboundary movement.

According to the current situation, SEPA will act as a sole competent national authority or the leading authority, if there is more than one authority involved in China. Doubtless, SEPA will also act as a watchdog and monitoring authority for biosafety and GMO issues.

(2) Ministry of Agriculture (MOA)

MOA is the most important sector for management of GMO pilot experiments and commercial production. At present, the GMO transboundary, environmental releases and commercial production, as well as GM food for international trade, are focused on GM agricultural crops. MOA has done much work on GMO safety management. In 1996, MOA issued "The Safety Administration Implementation Regulation on Agricultural Genetic Engineering" and established the corresponding organizations of Safety Administration Office and Safety Assessment Commission. The Regulation has been implemented, and the organizations have already operated normally to cope with applications of GMO pilot experiments, environmental releases and commercial production. MOA is definitely a very important institution for biosafety.

(3) Ministry of Public Health(MOH) and State Medicine Monitoring Administration(SMMA)

MOH is responsible for food safety and issued "Regulation of New Resource Food" in 1990. GMOs food can be defined as one kind of new resource food. MOH is in charge of approval for production of new resource foods and monitoring food hygiene. SMMA is responsible to monitoring medicine production and marketing. SMMA issued "Examining and Approving Rules for New Biological Medicines" and "Regulation of Importing Medicines" in 1999. It is in charge of approval of domestic medicine production and medicine imports and exports. As GMO food and GMO medicine may directly produce adverse effects on human health, the two institutions will play a very important function on biosafety. But, as the transboundary movement of GMO medicines is not included in the Protocol, the GMO medicine trade is not at present under the framework of Cartagena Protocol on biosafety.

(4) Ministry of Foreign Trade & Economic Cooperation (MOFTEC), Customs General and the State Inspection and Quarantine Agency (AIQA)

MOFTEC is responsible to international trade including approval of GMO commodity imports and exports. The Customs General is in charge of customs formalities and customs tariffs for

imported and exported commodities including GMO products. AIQA is involved in quality inspection and quarantine of diseases, insects and weeds of imports and exports. These institutions have direct relationship to GMO trade.

The practices of Western countries

In 1986, U.S. issued a "Co-ordinated Framework for Regulation of Biotechnology", and this framework stipulated that the three departments of the US government will be responsible for the management of biotechnology and products, i.e. Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). In terms of this framework, USDA, EPA and FDA all manage GMOs but they deal with different aspects of GMOs, depending on the categories of proposed use of GMOs and their products. Each sector has its own managerial scope and focus.

Under the EU's united codes and principles, each member country can regulate GMOs according to its own frameworks. For example, in UK, the responsible authority for biosafety is the Department of Environment, Traffic and Region (DETR), DETR is in charge of approval of GMO research, environmental release and commercial production. DETR may, sometimes, consult with other sectors involved in agriculture, fishery and food when they deal with the concrete GMO applications.

In Germany, the national authority for biosafety is a combination of the three departments of Environment, Public Health and Agriculture. But arrangements differ from those in the US, because their management is not separate, and if one body disagrees to an application, it will be denied.

In the Netherlands, as in the UK, the national authority is the Ministry of Environment. The Ministry is in charge of all GMO issues in the country, including issuing licenses for any GMO activities.

In Australia, Gm food is regulated by the Australia New Zealand Food Authority (ANZFA). Likewise, therapeutic goods are controlled by the Therapeutic Goods Administration (TGA).

Agricultural and veterinary chemicals are overseen by the National Registration Authority (NRA). Imports and exports are governed by the Australian Quarantine and Inspection Service. These regulatory controls are underpinned by the Interim office of the Gene Technology Regulator (IOGTR), working with its Genetic Manipulation Advisory Committee (GMAC). These two groups advise on the research, production and use of GMOs in Australia. A new permanent institution, the Gene Technology Regulator (GTR) will be operational by January 2001, instead of IOGTR. GTR is created by the new legislation of Gene Technology Bill 2000[6].

In addition, there are two organizations that are responsible to biotechnology management in Australia. One is Biotechnology Australia (BA), a multi-portfolio agency with the members from different departments. BA's principle tasks are to develop a comprehensive national strategy for biotechnology. Another one is Biotechnology Consultative Group (BIOCOG), comprised of leading individuals from industry and research and representatives from relevant Government agencies. BIOCOG's role is to provide advice to BA and the Ministerial Council. The Ministerial Council is consisted by ministers of relevant government sectors of Industry, Science and Resources, Environment and Heritage, Health and Aged Care, and Education, Training and Youth Affairs (ABA 2000).

Recommended institutional measures to be taken by China

In order to regulate biosafety and transboundary movement of GMOs, it is necessary for China to establish a cross-departmental biosafety coordinating commission at the national level headed by a competent national authority involved in the Cartagena Protocol on Biosafety, because many sectors are involved in the issue. The commission should be responsible for policy-making and inter-departmental coordination on biosafety issues in the whole country. SEPA would head the commission as the national authority. The related departments would share out the work and cooperate with one another. For example, the Ministry of Science and Technology would be in charge of biotechnology research and development policy; MOFTEC in charge of international trade in GMOs; MOA, MOH and SMMA in charge of production of GMOs within their own fields; and SEPA in charge of GMO environmental administration in all stages of environmental release, commercial production, handling, transportation, use and marketing.

[6] Australian Biotechnology: progress and achievements, Commonwealth of Australia 2000. P.6

Under the national authority, it is necessary to establish a series of operational institutions, such as the national focal point for the Protocol, technical units of risk assessment and monitoring, and an information clearing-house.

In addition, enhancing capacity-building of scientific research for biosafety is also very important. Due to lack of scientific certainty regarding the extent of the potential adverse effects of GMOs on the biodiversity and human health, there are many uncertainties involved in decision-making to introduce GMOs and GMO-based products. Therefore, it is essential to establish some national biosafety research institutes or laboratories and invest sufficient research funds to deal with these matters. (Liu and Xue 2000).

5.2 *Legislation construction*

Current legislation

The following ministerial regulations concerning biosafety have been promulgated in China:

(1) Safety Administration Regulation on Genetic Engineering

The Regulation was issued by the former State Science and Technology Commission (SSTC) on 24 December 1993. It refers to recombinant DNA technology using the vector system and the direct introduction of heterogenic DNA into organisms by physical or chemical means. The regulation focuses on safety of biotechnology research and laboratory work, including stipulations on safety classification, safety assessment, application and approval, administrative measures, etc.

(2) The Safety Administration Implementation Regulation on Agricultural Genetic Engineering"

The Regulation is also a ministerial regulation based on the SSTC Regulation described above, issued by the Ministry of Agriculture on 10 July 1996. It provides detailed stipulations of the articles in SSTC Regulation concerning agricultural genetic engineering, and prescribes safety classes and corresponding management, especially the procedures for GMO registration and safety assessment.

(3) The Provisional Administration Regulation on Genetic Resources of Human Beings

The regulation was issued by Ministry of Science and Technology (former SSTC) together with Ministry of Public Health on 10 June 1998. It provides the rules for collection, research, development, merchandising and export of human genes and human organs, cells, blood, genetic materials of recombinant DNA and related materials, etc.

(4) Other regulations

In April 1999, the State Medicine Monitoring Administration (SMMA) issued "Examining and Approving Rules for New Biological Medicines", meanwhile SMMA issued the revised "Regulation for Imported Medicines". Besides, Ministry of Public Health issued " Regulation of New Resource Food " in 1990.

The practices in Western countries

The philosophy underlying the US biosafety regulatory structures was set out by the US Office of Science and Technology Policy in 1986 in the "Co-ordinated Framework for Regulation of Biotechnology". To this end, biotechnology is regulated on a product basis rather than on a process basis, i.e. a product from biotechnology is regulated according to its intended use, not because it is produced by recombinant DNA-technology. Therefore, the regulation of GMOs is divided between three agencies of USDA, EPA and FDA. To accomplish their regulatory tasks, each agency was directed to examine its existing statutes for appropriateness to the products of biotechnology, and to expand their applicability, if necessary. Consequently in the US, biotechnology is regulated by several pre-existing laws, instead of by one special biotechnology law. For example, EPA applies "Federal Insecticide, Fungicide and Rodenticide Act" and "Toxic Substances Control Act"; USDA applies "Federal Plant Pest Act" and "Federal Plant Quarantine Act"; and FDA applies "Federal Food, Drug and Cosmetic Act" (Virgin 1999). So biotechnology in US is regulated by existing legislation, rather than new regulations specifically relating to biotechnology or GMOs.

In contrast to the situation in the United States, the European legislation is process-based, and all organisms that originate from genetic modification are subject to specific GMO regulations. All regulations in Europe are more or less based on the two EC directives regulating the contained

use of GMOs (EC Directive 90/219) and the indeliberate release into the environment (EC Directive 90/220). Furthermore, EU issued Directive 258/97 in 1997, specifically aimed at the commercialization of new GMO foods and new food components (Virgin 1999). All EC member countries must comply with EC statutes when they draft their national regulations.

Australian governments are moving to introduce more relevant standards to cover genetically modified foods. A new Australian food standard legislation, the Standard A18 for Food Produced Using Gene Technology, came into effect on 13 May 1999, issued by Australian New Zealand Food Authority (ANZFA). The standard requires safety assessment of all GMO foods entering the market and need to be labeled. Some other guidelines and standards on GMO risk assessment and gene manipulation were issued by GMAC during the past 10 years. Furthermore, some regulations at provincial level are under debate, for example, a Draft Government Code of Ethical Practice for Biotechnology in Queensland (State) was released on 20 March 2000 for public comment. The draft code contains 26 basic commitments applicable to biotechnology organizations in Queensland, which are divided into three broad categories including general principles, agriculture food and environment, and health (DPI 2000).

A new legislation, Gene Technology Bill 2000, is just issued by Commonwealth of Australia. It aims to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology. The regulatory framework established by the Gene Technology Bill 2000 is to operate concurrently with other Commonwealth and State regulatory schemes relevant to GMOs and GM products, including ANZFA, TGA, NRA, AQIS, Environment Australia, etc.[7]

Recommended legislative measures to be taken by China

China has not set up a legislative system for biotechnology development and safety administration, though several regulations have been issued at the ministerial level. In particular, it is short of regulations relating to international trade in GMOs and their domestic marketing. So, now legislation in China to cover the following would be advantageous:

[7] Australian Biotechnology: progress and achievement, Commonwealth of Australia 2000, p.7

(1) Establishing biosafety legislation

The framework of this system should include law, regulations and rules at different levels of government. It would include: 1)a comprehensive law or regulation on biotechnology and safety at the national level promulgated by the People's Congress or the State Council; 2)a series of professional biosafety regulations or rules issued at ministerial level in the fields of agriculture, forestry, food, medicine, etc; and 3)a set of concrete rules, standards, guidelines and methods to be published by ministries or local governments.

(2) Systemic legislation for trade in GMOs and their commercial use

This legislation should cover export and import of GMOs including: approval, customs management, transboundary transportation, quality inspection and quarantine; GMO marketing covering commercial production, merchandising and use; and guidelines for foreign investment on GMO research and development.

(3) GMO risk assessment mechanisms and administration

It is essential to set up a suite of technical standards, including procedures and methods for GMO risk assessment, procedures for GMO introduction, application and approval, a license system for GMO commercial production, and labeling and purchasing requirements.

5.3 *Policy formulation*

Current principles

China does not yet have a systematic policy for biotechnology safety, but some principles have already been proposed.

(1) Supporting biotechnology research and development

Since the 1980s, the Chinese government has been paying great attention to domestic biotechnology research and development. Hundreds of biotechnology research institutions have been established in China since the early 1980s, especially in agricultural sector. The Chinese government is convinced that biotechnology will play a key role in the 21st century in enabling

Chine to feed its large population. So biotechnology is taken as a priority for China's development of science and technology in the 21 century.

(2) Putting safety first

China has displayed caution in introducing foreign GMO crops. Though local officials in the agricultural sector and farmers are keen on the possibility of planting foreign GMOs in order to raise production and increase their benefits, the Ministry of Agriculture of the central government has officially expressed some reservations about the introduction of GMOs and their use in commercial production, and have only cautiously approved a very limited number of foreign GMOs for pilot experiments and for commercial production. Nevertheless, the area planted with foreign GMOs is significant in some provinces.

(3) Participating actively in the Biosafety Protocol negotiations

China has shown its great concern in intergovernmental negotiations for the Cartagena Protocol on Biosafety and attended all international negotiating activities during the past five years. Considerable coordinating work has been done by the ministries concerned. On Aug. 8, 2000, Chinese Government signed the Cartagena Biosafety Protocol in New York, the Headquarters of the United Nations, to be the 70th signatory country to the Protocol.[8]

(4) Studying and learning from experience in Western countries about regulation of GMOs

China is short of national capacity for biosafety administration (it has limited experience) and expertise, while Western countries have a relatively long history of biotechnology safety management, especially in regulation, administration, labeling, etc. China may hope to learn more from the experience of the Western countries. In particular, it may prefer the strict administrative model of most European countries.

The policies of the Western countries

Generally speaking, the United States and some other countries execute a relatively loose administrative model to cope with GMOs. They only regulate the safety of products in the final stage rather than products during the process of GMO research and development. In the United

[8] http://www.sina.com.cn 2000/08/08, news from *People's Daily* (China).

States, no specific GMO labeling is required. Labeling is required only if the quality of the product has changed, but the label is only required to describe the change in quality of the product, not to specify that a GMO as such is present (Virgin 1999).

However, EU countries apply a relatively strict administrative model to GMOs. In EU and some other European countries, the whole process of GMO research, development, release and commercial production is strictly regulated, step by step and case by case. Furthermore, in Europe, the use of genetic engineering in food and agriculture is a highly debated issue. The European Union Novel Food Regulation approved in 1997(EC 258/97), states that "novel foods and their ingredients produced by means of genetic engineering" must be GMO labeled when:

- there is no substantial equivalence between a novel food and its original counterpart;
- when materials present in the novel food are not present in an equivalent non-modified product and may have consequences for the health of certain groups of people;
- when the novel food contains biotechnologically derived material that may present ethical problems; and
- when living GMOs are present in the food.

EU also takes a united stand on GMOs in member countries. A biotechnology guiding commission was founded in 1984, it is responsible to coordinate the national biotechnology polices of member countries. With respect of commercialization of GMOs and novel food, it is necessarily to gain approval by all 15 member-countries, otherwise they will be prohibited within EU countries.

Generally, GMO policy in Australia is close to that of European countries, and there exists a major debate about GMO food safety. So far Australian commercial production of GM crops is limited to GM cotton, and the public is greatly concerned by GM food. This concern will affect the government's GMO policy.

Especially, Australia has developed a national strategy on biotechnology at Commonwealth level.[9] It put forward a series of objectives, strategies and policies on biotechnology management.

[9] Australian Biotechnology: a national strategy, Commonwealth of Australia 2000.

The strategy was drafted by BA, consulted with BIOCOG, and coordinated by the Ministerial Council.

Recommended policy measures to be taken by China in relation to GMOs

(1) Marketing development policies for GMOs and products

Based on the safety classes of GMOs, different policies should be pursued. They are:

- To encourage and support riskless GMOs and products by the detailed policies establishing risk-investment foundation and credit loans, reducing taxes and promoting preferential development;
- To cautiously develop lower-risk GMOs and products with the policies of executing environment impacts assessment, licensing for commercial production and marketing, and risk management;
- To limit development of medium-risk GMOs and products by strictly controlling the commercial production and labeling the marketed products; and
- To prohibit development for high-risk GMOs and products by banning this commercial production.

(2) Policies for importing foreign GMOs and products

According to the stipulations of Cartagena Protocol on Biosafety, the policies should focus on:

- Executing AIA procedure and decision procedure for any exporter's notifications for GMOs transboundary movement;
- Establishing licensing regimes for allowed import of GMOs and products;
- Conducting risk assessment for any foreign GMOs before they are approved for introduction;
- Requiring identification for handling, package, transportation and storage of foreign GMOs and products, and market labeling;
- Identifying exporter's liability and redress when environmental damage occurs as result of happened by imported GMOs or GMO-based products.

(3) Polices for foreign investment in projects for development of GMOs

Besides the existing polices in foreign sole investment and joint ventures, some special attention should be paid to:

- Guiding foreign investment projects in biotechnological development by classifying investment projects as categories of encouragement, permission, limitation and prohibition.
- Managing foreign investment projects properly through information requirements, risk assessment and approval procedures.

5.4 *Technical measures to control import of MGOs*

The legal measures mandated by Cartagena Protocol and WTO agreements.

The Biosafety Protocol requires exporters to apply the AIA procedure to obtain the consent of importing countries before delivering shipment of GMOs. The concern of exporters is that the AIA procedure could be used simply as a non-tariff barrier to trade and result in some trade disputes. Exporters want the relationship between the Protocol and WTO agreements clarified properly.

The Protocol, in its preamble, recognizes that trade and environments should be mutually supportive with a view to achieving sustainable development and emphasizes that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements. But the next paragraph in the preamble adds that the Parties to the Protocol understand that the above provision is not intended to subordinate this Protocol to other international agreements. Article 2(4) requires that the actions taken by Parties should be consistent with the objective and the provisions of this Protocol and are in accordance with its other obligations under international law. It clearly intends that the Protocol's obligations are parallel to countries' duties and obligations under WTO agreements and other international agreements.

However, WTO obligations are not inconsistent with GMO safety regulation. There are already provisions for the protection of the environment and human health under the WTO. It is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). SPS was completed during the Uruguay Round of multilateral trade negotiations, which also culminated in

the establishment of the WTO. SPS is an explicitly science-based agreement. It mandates that countries base their sanitary and phytosanitary measures (relating to human, animal, and plant health and safety) upon sound science and allows for precautionary decision-making only on a provisional basis, until further scientific evidence of harm or lack thereof has been obtained (Wirth 1994, Gupta 2000). So, the AIA procedure, as a green barrier for health protection, does not conflict with SPS under WTO. The Protocol also does not prevent the GMO-exporting countries from using the WTO dispute settlement procedure to clarify existing obligations under the trade regime (Falkner 2000).

Green barriers to importing GMOs

Green barriers can be one kind of technical barrier to trade. They involve countermeasures taken by importing countries to limit the import of some foreign goods in order to protect environment and human health in the importing country. Green barriers are preventive measures mainly based on the existing international conventions, protocols, agreements and standards on environmental protection and quarantine. Green barriers are, more or less, legitimate, but often involve much politicalisation. As more and more non-tariff barriers to trade are demolished in the process of trade globalization, green barriers have gradually increased. They have become important technical barriers to current international trade.

US, EU countries and Japan already have statutes, directives and standards which limit the import of some commodities to their countries on the basis of technical measures, such as chemical residues, quarantine of animals and plants, quality inspection, limiting packing materials, etc. For example, US Department of Agriculture (USDA) presented a proposal in March 2000 for nationwide standards defining organic foods. The proposal specifically prohibits the use of genetic engineering from agricultural products bearing the organic label. A few weeks before the USDA's proposal, US Senator Barbara Boxer (D-CA) introduced legislation, the "Genetically Engineered Food Right-to-Know Act" (S.2080), which would mandate labels specifying whether a product contains or was produced with GM materials (Fox 2000).

On 12 January 2000, the Commission of the European Communities issued its "Food Safety White Paper", which sets out over 80 separate actions that are envisaged over the next few years in order to improve food safety standards[10].

Japan's Ministry of Health and Welfare has announced that all foods containing GM ingredients will undergo mandatory tests for potential health risks and should be labeled accordingly, beginning from April 2001[11]. Japan's Ministry of Agriculture, Forestry and Fisheries also decided in last August to introduce mandatory labeling of 30 food products containing more than 5% GMOs ingredients, including soybeans, potatoes, and corn, beginning from April 2001(Saegusa 1999). Also South Korea will execute a GMO food labeling system.

China is short of experience in relation to green trade barriers and has often suffered foreign discrimination for its exports, involving high economic losses. As a large importer of GMO food, China should learn from foreign experience about the use of green barriers. There is an opportunity for China to impose green barriers on GMO food imports, based on the Cartagena Protocol on Biosafety, GMO properties and domestic legislation, in order to protect the country's economic benefits, environmental safety and the people's health.

6. Concluding Comments

Attitudes towards negotiations for the Cartagena Protocol were shown in this paper to differ between countries depending on whether the countries involved were likely to be major net importers of GMOs or major exporters. It is mainly developing countries that are likely to be net importers of GMOs in the foreseeable future. Less developed countries (with some support from the EU) were especially concerned that there be adequate provision to ensure that a country importing LMOs, or products based on these, be able to prevent their import, where there is the possibility of considerable risk to its conservation and use of biodiversity, or to human health. Furthermore, developing countries wanted to make sure that there was adequate provision in the Protocol for liability and redress should they suffer damage as the result of their import of LMOs

[10] White Paper on Food Safety, Commission of the European Communities, SANCO/3578/99, Brussels, 12 Jan. 2000.
[11] Japan steps up GMO tests, *Nature Biotechnology*, Vol. 18(2): 131, 2000

or products based on these. While agreement was reached on the first issue that was not possible on the second matter, and its resolution has been left to the first meeting of the Conference of Parties to the Protocol.

Globally the cropped area planted to GM crops is expanding rapidly with the USA and Canada being the main producers. China, in recent times, has increased its food and agricultural imports substantially and the USA and Canada are the principle sources of such imports. Consequently, China is already importing large quantities of GM products.

The Chinese Government is also of the view that GM crops will make a large contribution to agricultural productivity in the 21st century. It is expanding its capabilities in genetic engineering and accelerating the introduction of biotechnology to farms. Nevertheless, China appears to have little scope to export GMOs and GM products.

China needs to adopt a range of administrative measures to implement the Cartagena Protocol and to regulate its import of GMOs and GM agricultural products. These were outlined taking into account policies adopted in Western countries. The possibility of China using green barriers to limit the import of GMOs is discussed. Green barriers have become increasingly important barriers to international trade as other technical barriers to international trade have been reduced by the WTO. However, once the Cartagena Protocol is in effect, GMO exporting countries are likely to increasingly use WTO dispute settlement procedures to reduce such barriers. So this could limit China' s scope to use such barriers effectively; as would bilateral negotiations outside the WTO framework. In such negotiations, wealthy countries, such as the USA, may have an advantage in terms of their ability to provide economic incentives e.g. aid, or mount threats e.g. withdrawal of aid.

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