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Report

Biosafety system frameworks for living modified organisms in Japan and Taiwan

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Abstract Recently, the development of techniques for generating living modified organisms (LMOs) has become a vital issue worldwide, in both developing and developed countries. Movement of LMOs across boundaries and the uses of LMOs pose global biosafety issues. Trans-boundary movement is regulated internationally by the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD), which seeks to protect the biological diversity of natural ecosystems from risks posed by the deliberate release of LMOs into the environment. The regulatory frameworks of individual nations also play an important role in biosafety rules and biotechnology development, especially in the process from research and development to commercialization. However, a number of countries have not yet implemented the CPB CBD. In particular, Taiwan has not yet developed a complete and workable regulatory framework. The information presented in this comparative study should be useful for stakeholders in Taiwan, and will illustrate modalities and specific issues that will be useful for countries that are in the process of developing a biosafety regulatory framework. These countries may integrate Japanese primary experiences and feedback for mutually elaborative regional systems.

Key words: Biosafety regulatory framework, living modified organisms, risk communication, public perception.

Recently, the development of techniques for producing living modified organisms (LMOs) has become a vital issue worldwide, in both developing and developed countries. Taiwanese and Japanese researchers have conducted a great deal of basic research in the fields of molecular biology and genetic engineering, constituting the first step in the production and commercialization of genetically modified plants. In 2003, Japanese plant scientist K. N. Watanabe stated: "Although there is high-quality basic research on plant molecular biology and genetics in Japan, these valuable results have remained unexploited because of regulations and the lack of support systems for implementing the environmental release of genetically modified plants or for assessing biosafety (Watanabe 2003)." The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) was enacted on Sept. 11, 2003. This set of international laws regulates the trans-boundary movement of genetically modified (GM) organisms (GMOs) and LMOs to protect the biological diversity of natural ecosystems from the risks posed by deliberate release of LMOs into the environment.

In Japan, the efforts of various ministries and the ratification and enforcement of the CPB have resulted in the establishment of a Japanese national law based on the legal obligations of the CPB, together with supplemental national regulations and guidance. The Cartagena Protocol domestic law of Japan (www.bch.biodic.go.jp/english/law.html) was enacted in 2004. Japan has also made significant advances in developing workable biosafety regulations for GMOs. Currently, Japan is importing LMOs-FFP (LMOs for direct use as food, feed and processing) on the basis of representative threshold and implementing rules. In contrast, the representative regulations developed by European nations may not yet be sufficiently workable for implementation. European countries do not import LMOs from overseas or from within Europe because of the legal limits.

Other international organizations, such as the World Trade Organization (WTO), the International Organization for Standardization, Food, and Agriculture, and the World Health Organization (WHO) Joint Food Standards Programme Codex Alimentarius Commission, also regulate LMOs and biosafety issues. However, many

Abbreviations: CPB: Cartagena Protocol on Biosafety, DOH: Taiwan Department of Health, GM: genetically modified, GMFSAC: Genetically Modified Food Safety Advisory Committee of Taiwan, GMOs: genetically modified organisms, GOs: government organizations, LMOs: living modified organisms, LMO-FFP: living modified organisms for direct use in food, feed, and processing, MAFF: Japanese Ministry of Agriculture, Forestry, and Fisheries, MoE: Japanese Ministry of Environment, MEXT: Japanese Ministry of Education, Culture, Sports, Science, and Technology, NGOs: non-governmental organizations.

This article can be found at http://www.jspcmb.jp/

countries, especially the least-developed countries and small-island developing states, still lack domestic legal frameworks or provisional resources for the implementation of international protocols. For example, Bhutan, Cambodia, Laos, Mongolia, and Myanmar have not yet developed a practical legal framework for domestic implementation of the CPB protocol (Watanabe et al. 2004b), although the United Nations Environment Programs-Global Environmental Facility (www.unep.ch/biosafety/) provides substantial monetary support for this purpose. In Taiwan, lawmakers are still drawing up regulations to complete a framework for LMOs.

The present study is a comparative analysis of the regulatory frameworks of Taiwan and Japan. This analysis may aid the Taiwanese ministries in developing a workable and practical regulatory framework to enhance the application or commercialization of GM plants. It also illustrates modalities and specific issues relevant to countries that are in the process of setting up a biosafety regulatory framework. These countries may choose to integrate the Japanese primary experiences or may provide feedback for mutually collaborative regional systems.

Japan and Taiwan: Background

Japan

Japan is one of the largest importers of U.S. agricultural products, and it relies particularly heavily on imports of U.S. maize and soybeans, two of the major GM crops produced in the U.S.A. Japan is the largest export market for U.S. maize and the third largest market for U.S. soybeans. The U.S.A. supplies about 95% of the 16 million metric tons (MTs) of maize imported annually into Japan. Of this amount, feed maize (including bulk maize, which is not segregated from GM maize) accounts for 12 million MTs, and the remainder is non-GM maize for food use. Japan imports about 4.5 million MTs of soybeans annually, including 3.5 million MTs from the U.S.A.

About 3.5 million MTs of soybeans are crushed annually in Japan for their oil, which is exempt from GM labeling. Almost all of the soybeans imported into Japan for crushing are bulk general shipments, which are not segregated by GM/non-GM status. On the other hand, the food industry demands that soybean importers supply non-GM soybeans to be used as raw ingredients for tofu and other soy-based foods, in addition to the 0.2 million MTs of non-GM soybeans produced domestically (Brooks et al. 2005; Hamilton 2005).

Taiwan

In 2004, the U.S. exported more than $2.2 billion in agricultural products to Taiwan, its sixth largest agricultural export market. Of this amount, $897 million was in the form of GM products (soybeans, $302 million; maize, $594 million). Taiwan is the third largest export market for U.S. maize and the fifth largest market for U.S. soybeans (Brooks 2005; Trachtenberg 2005).

Influence of GM crops from China

The deregulation of GM rice and other products in China will soon influence both the agricultural practices related to food commodities and their movement to surrounding countries in eastern Asia, including Japan and Taiwan. China is poised to commercialize GM rice, possibly within one year, because of its health benefits, and it is already being sold there illegally (Cyranoski 2005). Planting of GM crops in China may result in the unintentional entry of GM feed into neighboring countries that have not yet harnessed GM technology or implemented adequate regulatory systems. Thus, countries in this region must ensure that a border control system is included in their biosafety system framework (Okusu and Watanabe 2005; Watanabe et al. 2005). Although China ratified the CPB in 2005, its less developed neighbors, such as Myanmar and Laos, are not at all prepared to implement regulation of trans-boundary movements of LMOs-FFP (www.unep.ch/biosafety/).

In developing countries, different legal philosophies around the significance of "ratification" mean that ratification of the CPB is not necessarily associated with its implementation. Nonetheless, commodity trading is a day-to-day practice that is the cause of much concern relating to the illicit movement of LMOs-FFP from China to these countries (Cyranoski 2005). Therefore, China's neighboring countries must develop complete regulatory frameworks for biosafety issues.

In addition to these trade and geographical considerations, both Japan and Taiwan must also consider the safety of their own endeavors to develop genetic engineering techniques for LMO research and development (see details in Section 3). As a response to this need, the government of Taiwan has initiated the National Science and Technology Program for Agricultural Biotechnology (www.sinica.edu.tw/~npagrbt/page1.htm). The present comparative study of the biosafety regulatory structures of Japan and Taiwan was conducted in the context of the background information and considerations summarized here.

Living modified organisms in Japan and Taiwan

Japan

Field studies- Japan is a leader in LMO biotechnology. Many scientists at public research institutes and universities in Japan are engaged in LMO research and development. As of Oct 12, 2005, 49 regulations for

Table 1. Genetically modified crops approved for Food uses in Taiwan since 2002.

Crop	Unique Identifier	Trait	Event	Company
Soybean	MON-040-446	Glyphosate tolerant Roundup Ready Soybean	40-3-2 (RRS)	Monsanto Far East Ltd. Taiwan Branch
Corn	MON-00810-6	Insect resistant YeildGard	MON810	Monsanto Far East Ltd. Taiwan Branch
Corn	MON-00021-9	Glyphosate tolerant Roundup Ready Corn	GA21	Monsanto Far East Ltd. Taiwan Branch
Corn	MON-00603-6	Glyphosate tolerant Roundup Ready Corn	NK603	Monsanto Far East Ltd. Taiwan Branch
Corn	SYN-BT011-1	Glufosinate tolerant and insect resistant	Bt11	Syngenta Taiwan Ltd.
Corn	SYN-EV176-9	Glufosinate tolerant and insect resistant	Event 176	Syngenta Taiwan Ltd.
Corn	ACS-ZM003-2	Glufosinate tolerant	T25	Bayer CropScience
Corn	DAS-01507-1	Insect-resistant and glufosinate tolerant	TC1507	Dupont Taiwan
Corn	DKB-89614-9	Insect-resistant and glufosinate tolerant	DBT418	Monsanto Far East Ltd. Taiwan Branch
Corn	DKB-89790-5	Glufosinate tolerant	DLL25	Monsanto Far East Ltd. Taiwan Branch
Corn	MON-00863-5	Insect-resistant, YieldGard Rootworm resistant	MON863	Monsanto Far East Ltd. Taiwan Branch
Corn	DAS-59122-7	Insect resistance and glufosinate tolerant	59122	Dupont Taiwan
Corn	MON-88017-3	YieldGard Rootworm/ Roundup Ready Corn	MON88071	Monsanto Far East Ltd. Taiwan Branch

Source: Global status of approved genetically modified plants. AgBiosafety (www.agbios.com/dbase.php; also 140.112.89.47/jsp/show.jsp?MasterNo=3&SlaveNo=8&NotifyNo=281).

approving LMOs for Type 1 use had been passed, including three for eucalyptus (www.bch.biodic.go.jp/bch_3_10.html). LMO plants with Japanese approval include carnations, maize, cotton, rice, and beets (www.bch.biodic.go.jp/english/lmo.html).

Commercial GM plants for cultivation- Although government-approved GM cultivars can legally be planted and sold to consumers, as yet, no GM plants have been cultivated commercially in Japan, largely due to public concern (Watanabe 2003). In addition, some farmers are concerned about contamination of their non-GM crops by surrounding GM crops. Hokkaido prefecture has already drafted an ordinance that carries penalties for offenders who embark on commercial GM crop production without a permit (www.asahi.com/english/nation/TKY200502250146.html).

Approval of GM crops for food use- The Japanese government has approved 76 GM cultivars for use as food, including corn (25 cultivars), rapeseed (15), cotton (18), potato (8), soybean (4), sugar beet (3), and alfalfa (3) (www.mhlw.go.jp/english/topics/food/pdf/sec01-2.pdf).

Taiwan

Field studies- Techniques for developing GM crops and foods have been a focus of research in Taiwan for more than 20 years. Taiwanese stakeholders, such as governmental organizations (GOs) and educational institutions, remain at the stage of research and development. Several field studies of GM crops were recently conducted. These crops included rice (higher lysine levels or insect resistance), cauliflower (resistance to the diamondback moth or heat tolerance), potato (heat tolerance or higher starch content), and tomato (resistance to Gray leaf-spot diseases) (gmo.doh.gov.tw/Web/life/main4.shtml).

Commercial GM crops for cultivation- GM papaya, which is resistant to papaya ringspot virus, was the first cultivar to undergo complete isolated and specific field studies (www.sinica.edu.tw/~npagrbt/third/page2-1-14.htm). GM papaya is not approved for planting or commercialization, however, and therefore no commercial GM papaya crops are produced by Taiwanese developers, and none are expected to be on the market within the next year. However, several GM fruit and vegetable varieties will enter the market in the next five years in all likelihood (Trachtenberg 2005).

Approval of genetically modified crops- All of the GM crops approved in Taiwan for food, feed, and processing (FFP), but not for planting, are shown in Table 1.

Biosafety regulatory frameworks in Japan and Taiwan

Japan

Japan is a subscribing member of the CPB-CBD. Once a country ratifies the CPB, three additional domestic arrangements must be made: 1) enactment of the CPB into national law, 2) establishment of a national biosafety clearing house, and 3) preparation of national regulations and guidelines to supplement the national law. Six Japanese ministries have made enormous efforts to reach these goals: the Ministries of Finance; Education, Culture, Sports, Science, and Technology (MEXT); Health, Labor, and Welfare; Agriculture, Forestry, and Fisheries (MAFF); Economy, Trade, and Industry; and Environment (MoE). In addition to these cross-ministerial activities, a Food Safety Commission was established in the Cabinet as a mechanism for risk analysis, including risk assessment, risk management, and risk communication. The aims of the commission are to assess the characteristics of recipient organisms and transformed products in relation to human health; these characteristics include their nutritional aspects and the identification of their toxic or allergenic properties.

The CPB was enacted via the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms." In addition, the "Regulations

Related to the Enforcement of the Law" and "Guidance for Implementation of an Assessment of the Adverse Effects on Biological Type 1 [uncontained] Use of LMOs" are also important parts of the step-wise implementation of the CPB. The law, regulations, and guidelines cover all stages, from the laboratory and greenhouse to isolated fields and then to ordinary fields.

Taiwan

Taiwan cannot ratify the CPB because it is not internationally recognized as a sovereign state. Nevertheless, with regard to the regional development of regulatory frameworks and laws concerning biotechnology issues, Taiwan is independent of China. It has its own regulatory system and concepts, which differ from those of many Chinese provinces (Trachtenberg 2005). Taiwan has unilaterally implemented some international agreements, and it is expected to incorporate the CPB into its import-export regulations governing LMO seeds and planting.

The Bureau of Animal and Plant Inspection Quarantine Council of Agriculture is the lead agency for CPB implementation and serves as the Secretariat for the Biotechnology Interagency Task Force under the Cabinet Biotechnology Industry Guidance Committee of Executive Yuan. This committee was established in 2003 and includes six Ministries and twelve academic experts of different backgrounds. The Ministries include Economic Affairs, Environmental Protection of the Administration, the Department of Health (DOH), the Council of Agriculture, the National Science Council, and the Consumer Protection Council. The Council of Agriculture is responsible for assessing environmental risks and for overseeing the use of LMOs in livestock and crop production and aquaculture. The DOH is responsible for assessing food safety risk. To gain food safety approval from the DOH, LMOs must be approved by the Genetically Modified Food Safety Advisory Committee (GMFSAC), which is composed of outside experts who evaluate materials submitted by life-science companies. (Lee 2004; Niu 2004; Ying et al. 2004).

Some laws and regulations concerning GMOs, such as feed safety laws, are currently under development in Taiwan. Completion of these laws and of a management framework for biosafety are necessary to expedite development of LMOs in Taiwan, and will make Taiwan more competitive in this area.

Similarities and differences between the regulatory frameworks of Japan and Taiwan

Similarities

With the rapid global development of biotechnology, biosafety issues concerning GM plants have been steadily increasing. Although different ministries or agencies are responsible for overseeing and regulating these activities in Taiwan and Japan, their objectives are the same: to assess the environmental and food safety of LMOs. These issues are also the primary concerns of consumers and the public (Watanabe et al. 2005). Furthermore, both countries use similar procedures to arrive at conclusions. For example, the Committee on Impact Assessment on Biological Diversity, in Japan, and a similar organization in Taiwan, the Biotechnology Interagency Task Force, both assess the effects of LMOs. They assess the characteristics of the recipient organisms and the transformed products, including comprehensive aspects such as competitive dominance, the production of harmful substances, hybridization, and their constituent elements. The Food Safety Commission of Japan is similar to the GMFSAC of Taiwan. In establishing a biosafety framework and laws, the government of Taiwan referred to international protocols, such as the CPB, and the laws of other countries, including Japan and the European Union. Thus, the legal philosophies of Japan and Taiwan regarding LMOs are similar, although they are different from those of the U.S.

These similarities to international protocols improve the prospect of international trade and research activities in Taiwan and other countries, and enhance the development of biotechnology. However, public attitudes toward GM crops differ in Taiwan and the U.S., and the U.S., as noted previously, is the source of the majority of GM crops imported into Taiwan. The current concern rests on the question of how to balance these different attitudes. For instance, a GM papaya cultivar (with a papaya ringspot virus resistance gene) developed in Hawaii has been commercialized in the U.S., whereas a GM papaya developed by Taiwanese researchers has not yet been approved.

Because the sovereignty of Taiwan is not internationally recognized, it is often excluded from international organizations and committees, even though it boasts many outstanding experts and scientists. This exclusion may prevent Taiwanese stakeholders from sharing information or knowledge with other countries. Therefore, to enhance international activities and lessen the gaps between international protocols, Taiwanese stakeholders must increase their non-governmental activities by participating in academic and research symposiums or committees.

Differences

Despite the similarities discussed above, the regulatory frameworks of Japan and Taiwan differ in several respects. First, Taiwanese lawmakers are still drafting the laws pertaining to LMOs. To establish a satisfactory biosafety regulatory system for Taiwan, lawmakers feel

Table 2. Similarities and differences between the LMO regulatory system frameworks of Taiwan and Japan.

	Japan		Taiwan	
National Law	Law Concerning the Conservation and Sustainable use of Biological Diversity though regulating the use of Living Modified Organisms Cartagena Protocol. (National Law, Regulations and Guidance)		The basic laws managing genetically modified organisms (incomplete)	
Laboratory Experiments	Type 2		National Science Council	Biotechnology safety committees in universities
	MEXT MoE MOF*	MHLW METI MOF*		
	For research & development	For industrial uses	For the National Laboratory	Universities, institutions, or private laboratories
Field studies	Type 1		Council of Agriculture	
	MAFF* MoE* MEXT* (from 2005)			
	Committee on Impact Assessment on Biological Diversity		Biotechnology Interagency Task Force	
Approval of genetically modified food	Food Safety Commission		GMF Safety Advisory Committee*	
	MHLW, MAFF*		Department of Health	
Approval of genetically modified feed	MAFF* & Food Safety Commission		Council of Agriculture	
Labeling	5% tolerance by weight to determine a genetically modified food		5% tolerance by weight to determine a genetically modified food	

* Major differences between Taiwanese and Japanese systems.

Japan: The Ministries of Education, Culture, Sports, Science, and Technology (MEXT), Environment (MoE), and Finance (MoF): Ministerial notification under the ordinance concerning Type-2 uses for research and development (www.bch.biodic.go.jp/english/law.html). The Ministries of Health, Labor, and Welfare (MHLW) and Economy, Trade, and Industry (METI): Ministerial notification under the ordinance concerning industrial applications of Type-2 uses (www.bch.biodic.go.jp/english/law.html). The Ministry of Agriculture, Forestry, and Fisheries (MAFF). Beginning in 2005, Type-1 field experiments for research and development were also supported by MEXT (www.bch.biodic.go.jp/bch_3_10.html). Type-1 use: LMO use (except for Type-2 use); Type-2 use: Contained use of LMOs. For further information, see www.bch.biodic.go.jp/english/law.html.

Taiwan: Only the National Laboratory and programs under the National Science Council are involved in the regulatory framework. Others, such as university researchers, are not involved in this regulatory framework. Both types of field study can be conducted only in the areas administered by the national body; scientific researchers cannot conduct field studies in their own experimental areas. The isolated field areas are located at National Taiwan University, National Chung-Hsing University, and The World Vegetables Center. The specific field areas are located at National Chung-Hsing University, the Agricultural Research Institute, Research and Extension Station, and The Seed Improvement and Propagation Station of the Council of Agriculture.

that they must rely, at least in part, on experiments conducted in other countries, from international protocols. Because the social, political, and economic conditions in Taiwan are unique, its system framework cannot be copied directly from the framework of any single body, such as Japan or the European Union. Rather, they must determine the specific conditions in Taiwan pertaining to LMOs and then make laws based on these conditions, with reference to the laws and conditions of other nations.

Second, the ministries responsible for laboratory experiments and field studies differ between the two countries. In the Japanese framework, the MAFF, MoE, and MEXT Ministries are jointly responsible for field studies. In contrast, in Taiwan, the Council of Agriculture is the only ministry responsible for these activities. MEXT began to guide activities associated with field studies for research and development in October 2005 (www.bch.biodic.go.jp/bch_3_10.html). This development may facilitate the approval process, since experts in MEXT can supply professional information specifically related to LMO research and development to expedite the proceedings.

Third, only two countries, Japan and Switzerland, have met all three requirements of the CPB (Hayashi 2005); Taiwan has not. The Japanese experience may be more useful than that of Switzerland in drafting laws for Taiwan. In addition to a pending system framework that is similar to that of Japan, Taiwan is similar to Japan in its high-quality basic research capabilities and its importation of many GM crops from the U.S.

Fourth, Taiwan's delay in developing a regulatory framework may further delay its progress in biotechnology development. For example, although the GM papaya was the subject of four national isolated- and specific-field studies in Taiwan in 2000 and 2003

(www.sinica.edu.tw/~npagrbt/third/page2-1-14.htm), it still awaits approval. According to its developer, Professor Yen, this delay is the result of an incomplete regulatory framework and the conservative attitude of the Taiwanese government. The regulatory framework is incomplete both in terms of its laws and in the availability of experts who can assess the health and environmental risks of GM crops or food.

In Taiwan, GMFSAC meetings are often postponed, perhaps because its members are academics with many other commitments. Because they are not professional regulators, committee members may lack an understanding of the regulatory process. In addition, the food safety assessment process is further slowed because the committee makes decisions by consensus (Trachtenberg 2005). The slowness of this process threatens to disrupt future trade, and it may delay the introduction of products developed in Taiwan, such as GM rice, fruit, and vegetables (Professor Yen, personal communication).

Finally, in Japan, regulatory frameworks governing environmental and food safety must undergo a public comment period before approval or non-approval (Administrative Procedure Act, 1993). The Taiwanese framework lacks this feature. Since open decision-making increases public support, meetings of committees involved in regulating biotechnology and genetic engineering should be open to the public, rather than closed. Openness would also improve public confidence in the regulators and might result in safety regulations more acceptable to industry, obviating the need for closed-door discussions. Most people are already aware of the benefits of biotechnology, but they remain concerned about hidden decision-making (Macer 1997). The public's attitude toward the development of LMOs is important and will be discussed in detail in the next section.

Importance of positive public attitudes toward LMOs

Techniques for genetic modification have the potential to improve agricultural productivity, increase food supplies, and enhance quality of life, but this potential will be realized only if the public accepts the use of these new technologies in food production. The public must be confident that agricultural biotechnology is safe and effective, as well as ethically and socially acceptable (Macer 1997). Public opinion could have an important influence on the future direction of biotechnology. A lack of public acceptance could prevent use of some technologies, even if they are approved by regulatory agencies. For example, Japanese plant scientists are concerned that negative public sentiment might translate into government actions that will compromise their overall competitiveness and research and development capabilities (Watanabe et al. 2004c; McCluskey et al. 2004).

Scientists will win more public support for biotechnology research by using a process that is open to the public. The public are very suspicious of safety statements made by scientists, especially those statements supporting commercial development decisions (Hoban 1993). Marris concluded that one of the lessons to be learned from studies of public attitudes toward GM crops and foods was that, "Public concerns need to be taken into account by all the operators of the industry, including research and development, marketing, commerce and distribution. Governments and international bodies also need to take these concerns into account when elaborating risk-related regulations and dealing with trade disputes" (Marris 2004).

Public attitudes toward LMOs in Japan and Taiwan

Japan

In 2004, the Japanese Society for Plant Cell and Molecular Biology and the Japanese Society of Breeding began to sponsor discussions with consumer groups, stakeholders, GOs, and scientific societies about transgenic crops. Although this action is just the beginning of a long process, and a sustained effort is needed, it is a step in the right direction (Watanabe et al. 2004a).

In addition, non-governmental organizations (NGOs) in Japan also work to increase consumer and public awareness of issues related to GM crops. Among these NGOs are the "NO! GMO campaign" (www.no-gmo.org/), the Japanese Offspring Fund (tabemono.info/index.html), the Citizens' Biotechnology Information Center (www5d.biglobe.ne.jp/~cbic/english/2003/), and Life BioPlaza 21 (www.life-bio.or.jp/index.html). Public awareness and understanding of biotechnology is increasing in Japan, and environmental risk and food safety are considered to be important issues (Watanabe et al. 2005). In contrast, the general public in Taiwan do not presently have much awareness of issues related to GM crops, and neither do consumer protection or environmental protection groups, or other related groups (Chou 2005).

Taiwan

Telephone surveys conducted in 2003 and 2004 throughout the country indicate that the public in Taiwan are not very knowledgeable about GM foods. Only 49% in 2003 and 56.5% in 2004 had ever heard of GM foods. Roughly half of those interviewed had never heard of the issues involved. In 2003, 82.2% of those Taiwanese that had heard of GM foods said that they did not understand

the relevant principles or production procedures. Thus, the Taiwanese public, in general, are unaware or ignorant of the safety issues associated with GM foods (Chou 2005; Taiwan Genomic Survey, 2006).

With the exception of organic food consumers, who are generally skeptical about GM foods, most consumers are not aware of the existence of GM food. In general, they continue to purchase food in bulk from traditional wet markets and to eat traditional Chinese breakfasts that, unknown to them, are made with GM soymilk (interview with Professor Yen and the American Soybean Association in Taiwan). However, the consumption of processed non-GM foods, such as soymilk and tofu, is gradually increasing because of marketing by local producers and increasing consumer awareness. For example, the Women Consumers' Cooperative in Taiwan announced in 1998 that they would only purchase non-GM soybeans for food use. Although this group is not actively against GM food and does not try to persuade non-member consumers to buy organic food, more people will become aware of the issues as their membership increases. Therefore, the government must supply accurate information to consumers if the consumers are to accept GM foods. Once consumers decide to accept or reject something, changing their minds can be difficult.

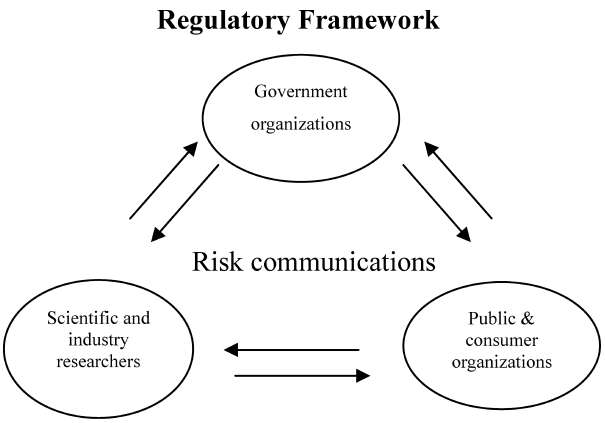

Figure 1. The regulatory framework. A triangular network including government organizations, researchers, and the public, is important to progress in the field of developing and commercializing living modified organisms (LMOs). For the purposes of the Codex Alimentarius Commission, risk communication is defined as "the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors, and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community, and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions" (www.codexalimentarius.net/).

Expectations and recommendations

The issues surrounding GM crops affect all people, including members of governmental and consumer organizations, scientific researchers, investigators, and the public. Each group constitutes a part of the framework system for regulating LMOs. To enhance biosafety regulatory systems, especially in Taiwan, we offer several recommendations.

Governments should make efforts to ratify and enforce laws to protect the public from health and environmental risks associated with biotechnology and to build public confidence in the governments' ability to manage these risks. Governments should also provide unhindered access to basic information about LMOs through educational forums and the media, such as newspapers, television, and public forums.

Scientists should take responsibility for the social consequences of their research. In addition to researching the development of safer and more healthful LMOs, academic researchers should talk to the public about basic scientific concepts and findings to decrease knowledge gaps between scientists and the public or GOs. Consumers and other members of the public should try to understand the basic concepts and issues concerning GM crops, whether or not they themselves accept GM crops. As public awareness increases, researchers and stakeholders are more likely to emphasize safety in the development of GM crops because consumers who are more informed can better monitor developments in biotechnology. Increased public engagement and understanding are goals for the future. Taiwan, in particular, must enact a regulatory framework for the development of GM crops. Its neighboring countries in Asia are already developing GM crops, such as the GM papaya developed in Thailand. If Taiwan continues to wait, it will fall behind other developing countries in Asia in this area of biotechnology.

The major reason behind governments supplying information to the public is not that of persuading consumers to accept LMOs. Rather, because LMO development is a global trend, each government needs an appropriate and practical regulatory framework system to decrease LMO-associated health and environmental risks. Furthermore, risk communication concerning the development of GM crops is another important issue that involves a triangular network. The three components of the triangle (GOs, researchers, and the public) must each play a responsible role in order to balance this triangle. Moreover, the risk communication framework should incorporate knowledge of the natural and social sciences, which is also necessary for the successful development of LMOs.

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