USE AND REGULATION OF GENETICALLY MODIFIED ORGANISMS

Report of the APO Study Meeting on Use and Regulation of Genetically Modified Organisms held in the Republic of China, 18-23 November 2002 (02-AG-GE-STM-04-B)

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INTRODUCTION

The Study Meeting on the Use and Regulation of Genetically Modified Organisms which was organized by the Asian Productivity Organization (APO) and implemented by the Council of Agriculture, Executive Yuan (COA), China Productivity Center (CPC) and Taiwan Agricultural Research Institute (TARI) was held in Taichung from 18 to 23 November 2002. Twelve participants from seven member countries and seven local and overseas resource speakers attended the study meeting.

The objectives of the study meeting were: 1) to review recent developments and achievements in the genetic modification of organisms, particularly, its agricultural applications; 2) to discuss the possible implications of genetically modified organisms (GMOs) in terms of food safety and security, as well as their potential impacts on the environment; and 3) to examine appropriate ways and means of regulating the use of GM products.

The study meeting consisted of the following major activities: 1) presentation of resource papers by invited experts; 2) presentation of country reports; 3) workshop discussions; and 4) conduct of field studies. The resource papers focused specifically on several topics, namely: 1) Recent Developments and Achievements in Agricultural Applications of Biotechnology; 2) Production of GM Foods/Products: Implications on Food Safety; 3) Benefits and Costs of Commercialization of GM Technology; 4) Environmental Impacts of GM Crops: assessing the Risks of Application of Coat-Protein Gene Transgenic Papaya in Taiwan; 5) Regulation and Policy on GM Labeling and Detection in Japan; 6) Public Communication: Consumer's Perspective of GMO/GM Foods; and 7) Developing Appropriate Mechanisms for Regulating the Use of GMOs: Japan's Experience. The country reports, on the other hand, highlighted the recent situation in the use and regulation of GMOs in the respective participating countries. For their field studies, the participants visited the Asian Vegetable Research and Development Center (AVRDC) and the Taiwan Salt Industrial Corporation (TSIC).

The following summary presents the highlights of the study meeting.

RESOURCE PAPERS

Recent Developments and Achievements in Agricultural Applications of Biotechnology
(George B. Fuller, Ph.D.)

Projections for global population growth and food requirements through the year 2020 point towards a need to increase productivity by 76 percent. Both the need and the opportunity to achieve that productivity are primarily in the developing world. Simply by adopting existing technologies and farming practices, a 50-percent increase in productivity in the developing world is possible, but more is needed. Fortunately, the latest developments in plant biotechnology provide a formidable addition to the tools available to and suitable for the developing world as well as the developed world to greatly increase productivity of agriculture.

Plant biotechnology is the term used to describe the latest recombinant DNA techniques which have been used to greatly expand the sources of new genes available to plant breeders to improve their crops. However, it is important to remember that these latest developments are only the latest in a continuum of human intervention in the biological process dating back to bread-and-beer production 8,000 years ago. Since the first introduction of plant biotechnology crops in the U.S. in 1995, global adoption has been more rapid and widespread than for any other agricultural technology in history. Growth in hectares planted with plant biotechnology crops has grown from just over 2 million ha in 1996 to 52.6 million ha in 2001.

Along with this development there has been considerable controversy generated by protest groups who are concerned primarily with the influence of multinational companies in the food production system but who target most of their attacks based on hypothetical risks and questionable laboratory studies in the area of food safety. In spite of this, polls by third parties consistently find that biotechnology is not a major concern among consumers around the world.

Regulation of biotechnology in Asia has been in development since the early 1990s and much of that development has been influenced by the polarization of the political approach to plant biotechnology between the U.S. and the EU. While the scientists on both sides of the Atlantic are in agreement on the need to take a science-based approach to regulation and in agreement with the safety of plant biotechnology products currently on the market, the divergence in political and trade approaches has created a dilemma for governments in Asia. Asian governments are trying to find a middle path which will allow them to reap the benefits of biotechnology while avoiding trade issues with either the U.S. or the EU. This has caused regulatory progress in Asia to be somewhat slower than in the U.S. but definitely faster than in the EU.

Other factors influencing the development of plant biotechnology regulations in Asia include local investment in biotechnology research and the smuggling of seeds by farmers who grow impatient waiting for government approvals.

To date Japan, Korea, China, Australia, Taiwan, India, Indonesia, Thailand, Malaysia and the Philippines have all granted some type of approval for plant biotechnology products. These approvals have taken the form of food safety approvals for imports, approvals for field testing and approvals for commercialization. Japan, China, Australia, India and Indonesia have granted all three types of approvals.

The development of plant biotechnology is gaining momentum due to rapid advances in genomic which allow better understanding of what genes can be added to crops to enhance their productivity or nutritional value. At the same time, genomic advances are being applied to traditional breeding techniques through the use of molecular marker-assisted breeding. New traits have already been demonstrated in the greenhouse which increase yield, resist stress and improve nutrition.

In conclusion, plant biotechnology is an important tool which can have significant impact on the world's ability to produce not only more food but higher quality food. Plant biotechnology products currently on the market have exceeded expectations in the benefits they provide and the future promise of yield enhancements and quality traits is within our grasp. The science is ready and the need is clear.

It is a fact of life that this technology has become a subject of a sometimes highly polarized and emotional debate which in many cases is a symptom of much more significant underlying social concerns such as globalization and the influence of multinational companies.

There are valid areas for debate and concern. Like every other technology, biotechnology is neither inherently good nor inherently bad. The keys to successfully reaping the benefits of biotechnology and avoiding possible pitfalls will be open dialog, transparency of regulatory systems, recognizing the difference between scientific fact and hypothetical risks and recognizing the need to address legitimate socioeconomic concerns.

Production of GM Foods/Products: Implications on Food Safety (Dr. Shu-Kong Chen)

GM foods can be defined as foods containing or derived from organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The process has been referred to as modern biotechnology (or alternatively, gene technology, recombinant DNA technology or genetic engineering). GM foods are produced because of some perceived advantage to the producer or consumer of these foods. The GM crops currently on the market are mainly aimed at an increased level of crop protection through the introduction of resistance against plant diseases or through increased tolerance towards herbicides.

The issue about the safety of GM foods can be seen from the perspective of the UN statement on the use of GM foods as food aid in Southern Africa. Some of these foods donated under the World Food Programme (WFP) contain GMOs and while governments in Southern Africa have accepted them other governments expressed their reservations and have sought advice from the U.N. However, since there are no existing international agreements yet in force with regard to trade in food or food aid relating to GM products the U.N. policy is that the decision to accept or not rests with the recipient countries. In this regard, the WFP position has been that all donated food must meet the food safety standards of the donor and recipient countries and all applicable international standards, guidelines and recommendations. And while FAO and WHO have not undertaken any formal safety assessments of GMO foods themselves, donors to the WFP have fully certified that these foods are safe for human consumption.

As regards trade in food under WTO there are two relevant agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). SPS measures are measures applied to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs. Since such measures, however, must be based on scientific principles the SPS Committee has not discussed GMOs in any detail. Under the TBT Agreement the provision on prevention of deceptive practices for consumer protection means the right of consumers to know the specification of the products they buy or consume. Accordingly, there have been continuing discussions in the TBT Committee on mandatory labeling for GMOs ever since the EU imposed such regulation on its trading partners.

The Cartagena Protocol on Biosafety regulates trans-boundary movements of living modified organisms (LMOs). GM foods, however, are within the scope of the Protocol only if they contain LMOs that are capable of transferring or replicating genetic material.

Three specific cases that have been presented with regard to GM food safety issues are: 1) Brazil nut allergen in GM soybeans; 2) adverse effects of GM potatoes on rats; and 3) allergenicity of GM corn (Star Link). In the case of the first, researchers determined that at least some persons with a hypersensitivity to Brazil nut were also allergic to the GM soybean. Thus, Pioneer which developed the product never marketed it although the variety was developed primarily for animal feed. As to the second case, a review of the Rowett research, which indicated that GM potatoes affected the development of organs and immune system of rats in feed trials, by the Royal Society concluded that the work at Rowett was flawed and that there was no convincing evidence of adverse effects from GM potatoes. It maintained that experiments done on one particular species of animal would not justify drawing general conclusions about whether GM foods are harmful to humans as each GM food must be assessed individually. Regarding the third case, it was reported that 28 people experienced apparent allergic reactions after eating corn products that may have contained Cry9c protein. Food and Drug Administration (FDA) analysis, however, showed that the findings do not provide any evidence that the reactions were associated with hypersensitivity to the Cry9c protein.

The Codex Intergovernmental Task Force on Foods from Biotechnology was established in 1999 and it has developed the principles for the risk analysis of foods derived from modern biotechnology and the guideline for the conduct of safety assessment of foods derived from recombinant DNA plants. The Royal Society in its 2002 report advocated for continued research on GM crop development, broadened public debate about GM food, making explicit and objective the criteria for safety assessments, using profiling techniques and more detailed guidelines of nutritional assessment. The report also stated that there was no evidence that GM foods can cause allergic reactions, that risks to human health from viral DNA in GM plants are negligible and that there was no effect of ingestion of GM plant DNA on human health.

In conclusion, GM foods currently available on the international market have passed risk assessments and are not likely to present risks to human health; no effects on human heath have been shown as a result of consumption of such foods in countries where they have been approved; continuous use of risk assessments based on the Codex principles and, where appropriate, including post-market monitoring, should form the basis for evaluating the safety of GM foods; and modern technologies must be thoroughly evaluated if they are to constitute a true improvement in the way food is produced. The more holistic evaluation of GM products should consider not only safety but also food security, social and ethical aspects, access and capacity building.

Benefits and Costs of Commercialization of GM Technology (Dr. George Kuo)

Genetic engineering is changing the genetic makeup of an organism using molecular techniques. Genetic modification is used interchangeably with genetic engineering although there are many types of genetic modification that do not involve genetic engineering.

Addressing the global malnutrition problems which have been closely associated with poverty has been one of the major tasks of agricultural research. With the world population reaching some eight billion by 2025 many countries, particularly in the developing world will be increasingly challenged to provide a balanced diet for a healthy and productive life. The ability to meet this challenge will be further influenced by rapid urbanization, climate change that would decrease the productivity of marginal lands and economic growth that would disfavor small farmers. Clearly, traditional breeding will not be enough so that there is a need for coming up with alternatives such as those provided by modern biotechnology. GM technology specifically is viewed as contributing to food security and poverty alleviation by helping promote sustainable agriculture centered on small farmers in developing countries.

GM technology has been attractive because one or more beneficial traits are added to already established cultivars without otherwise altering cultivar integrity. But there is a need of information regarding performance of such transgenic plants in the field. The developmental flow of GM products involves proceeding from gene identification and isolation to genetic engineering to field trials and then to commercialization. Global area and value of commercialized GM crops have been estimated at over 50 million ha and US$3 billion, respectively. The major crops include soybean, corn, cotton canola, potato and squash. The main traits involved are herbicide tolerance, insect resistance (*Bacillus thuringiensis* [*Bt*]), *Bt*/herbicide tolerance and virus resistance. The GM crops are mainly produced in the U.S., Argentina, Canada, China, South Africa and Australia. Field trials in the developing countries have resulted in more than 150 releases of cotton, corn, potato, soybean, tomato, banana and sugarcane in 13 Latin American and Caribbean countries; and cotton, corn, potato, soybean and tomato in six countries in Africa and the Arab States, and five countries in Asia.

GM technology is not a silver bullet for achieving food security. In conjunction with other techniques, however, the technology may be a powerful tool in the fight against food insecurity. Its potential benefits for developing countries include: 1) more and better animal and plant based food; 2) clean and safe production of food; 3) improved diet, nutrition and health benefits; 4) more and better animal feed; 5) enhanced market potentials with value-added traits; 6) alternative utilization of agricultural products; 7) lesser environmental impact with clean technologies; and 8) bio-processing for new materials (organic acids, preservatives, enzymes). New agricultural businesses derived from GM technology covers GM research and development (R&D) industries, production of GM products, GM service industries, GM value-added agri-food industries, new food processing companies and GM technology consulting.

An ex-ante study of transgenic *Bt* corn conducted in the Philippines has postulated three kinds of benefits: 1) enhancing competitiveness; 2) increasing farmers' incomes; and 3) reducing pesticide use. An ex-post study (or impact assessment), however, is yet to be produced. An ADB report in 2001 stated that the potential benefits of GM technology will be realized only if the following conditions are met: 1) public institutions need to direct the research toward social and equity goals; 2) complementarity between the public and private sectors needs to be maximized; and 3) governments must commit to developing technologies for the public good. The disadvantages of GM technology application in developing countries are the low public sector investment in R&D, the immature environment of related biotechnology industry; low competitiveness of local agriculture and hence lesser incentive for investment and an R&D system yet to be linked with industry requirements.

The requisites for successful application of GM technology in the tropics include: 1) knowledge on production constraints of crops and animals in the tropics; 3) knowledge on mechanism and source of resistance to/tolerance on biotic and abiotic stress problems; 4) knowledge on quality and value-added traits; 5) knowledge on how to conduct proper field trials; and 6) knowledge on how to integrate and apply acquired GM technology with conventional methods.

The coming of GM technology will be inevitable and it will be a powerful tool for addressing issues of future agricultural systems in developing countries. The technology will likely also create new agri-food-related industries in those countries. However, other issues such as those on biosafety, intellectual property management and regulations will need to be resolved.

Environmental Impacts of GM Crops: Assessing the Risks of Application of Coat-Protein-Gene Transgenic Papaya in Taiwan (Dr. Shyi-Dong Yeh)

Papaya ring-spot virus (PRSV) was first identified in southern Taiwan in 1975. Within a few years it spread to the whole island and destroyed most of the papaya production in commercial orchards. Several control measures have been used to protect papaya seedlings from PRSV infection, including selection of planting time to avoid the peak of winged aphids, intercropping with barrier crops such as corn, application of mild strain for cross-protection and growing papaya under netting. None of these control methods, except netting, provided a long period of effective protection against PRSV. Although raising papaya under a large net house is extremely costly and vulnerable to natural risks such as tropical storms, this method is widely used in Taiwan by papaya growers because of the high economic returns.

During the past decade, the PRSV coat-protein (CP)-transgenic papaya lines have been developed in Taiwan. They provided high levels of resistance to PRSV infection, not only under greenhouse conditions but also in field trials during 1996-2000. In order to investigate the diversity of PRSV and identifying the distinct virus that may break down the transgenic resistance, several viruses collected from orchards of different areas of Taiwan, including the diseased trees in the experimental farms where transgenic papaya lines were tested, were collected and analyzed by host reaction, serology, reverse transcription-polymerase chain reaction (PCR) and heterodulex mobility assay. Several PRSV strains and a distinct poty-virus, papaya leaf-distortion mosaic virus (PLDMV), capable of breaking the transgenic resistance have been identified. These PRSV strains and PLDMV are considered as potential threats to the application of the CP-transgenic papaya in Taiwan.

In conclusion, there should be a regulatory enforcement for the development and utilization of genetically engineered products and an administrative system for biosafety assessment of GMO should be established. The transgenic papaya can be used as a model to hasten the field evaluation and deregulation processes. A model of technology transfer to private sectors can be established also and long-term support provided for the studies and application of transgenic plants, both agriculturally and medicinally. Targeting of horticultural crops of tropical and subtropical areas can also be made.

Regulation and Policy on GM Labeling and Detection in Japan (Dr. Akihiro Hino)

The global area for growing GMOs has increased to over 50 million ha in 2000, most of which are found in the U.S. and Argentina. Crop-wise, the major GMO crops planted are soybean, maize, cotton and canola. In Japan, 44 kinds of GM crops have been commercialized and are available in the market.

The country's food self-sufficiency ratio is only 40 percent so that its import of food items has been sizeable. For example, Japan currently imports 4.9 million mt of soy (76 percent from the U.S.), 4 million mt of which are for edible oil (containing GMOs); 16.6 million mt of maize (85 percent from the U.S.), 11 million mt of which are for feed (containing GMOs); and 2.2 million mt of canola (85 percent from Canada), all for edible oil (containing GMOs). The country has, therefore, set up a regulatory framework for biosafety involving environmental safety, food safety and feed safety.

There is a GMO issue in the country because: 1) the general public is concerned by new technologies); 2) the general public does not take into account biological principles when considering agriculture and food safety; 3) mass media are inclined to give alarming news while disliking riskless news; 4) the general public distrusts bureaucrats' statements; and 5) the general public does not really feel the necessity of a new technology for food production. To resolve and suggest some ways to relieve the anxieties of the general public about GM foods, Japan and some other countries have established a new labeling system for these foods. This new system has been enforced by the Ministry of Agriculture, Forestry and Fisheries (MAFF) from 1 April 2001. The purpose of the system is to provide information regarding the use of GM technologies and promote consumers' right to select GM foods. The Ministry of Health, Labor and Welfare (MHLW) has also set up a labeling system for GM foods as part of its function to protect public health under the Food Sanitation Law. Thus, the labeling system for GMOs in Japan is regulated by two standards. The subject and contents in the regulations, however, are almost the same. Under the system, the foods are classified into three groups: those using GMOs, those using non-GMOs and those for which GMO use is not segregated during their production/distribution. Labeling is compulsory for those using GMOs and not segregated foods while it is optional for those using non-GMOs. Those foods requiring labeling referred to as designated foods cover five main crops used as food materials (soybean, corn, potato, rapeseed and cotton) and 30 processed foods made from soy, maize and potato where DNA has remained in the food. Agricultural products are regarded as "non-genetically modified" when it is confirmed that they are treated under "identity preserved handling" in their production/distribution processes. Because unintentional mixing is inevitable, however, a threshold level of 5 percent has been mandated in the case of soy and maize.

Most food industries in Japan are now obliged to switch to non-GMO food materials largely to meet demand from retailers and GMOs are excluded from the market because the general public is anxious about the foods they eat. It is unavoidable, however, that a certain amount of GMOs is mixed into even farm crops separately distributed and the scientific detection sensitivity of GMOs is very high. Because of this, it is considered difficult to label GM foods without scientific verification. Food processors cannot avoid mixing some GMOs when they import materials from the U.S. and Canada. Accordingly, they need to test the ratio of mixed GMOs and confirm that the figure is below the predetermined level before making a non-GM labeling.

There are controversial points concerning GM detection such as: 1) many kinds of varieties for a GM line are bred; 2) it is hard to obtain genuine seeds of GM line and non-GM line (almost all seeds were contaminated with other varieties); 3) there are many analytical methods for detection (different results could be reached by different methods); and 4) applicability of detection method for processed foods. In this regard, the National Food Research Institute has developed a new quantitative detection method for GM crops and processed foods which provide reliable and practical techniques to quantifying GMO by use of real time PCR method including detection method and reference materials.

It was suggested that: 1) standardization of detection methods for GM crops be considered at the national and international levels; 2) validated methods should be used; 3) proficiency of laboratories should be controlled by some authority; 4) any crops unknown about the DNA or amino acid sequences cannot be detected; and 5) it is very difficult to trace GM grains by only detection and documentation. To alleviate the anxieties and confusion of the general public, scientists should positively make opportunities to talk to the public. Government and NPO should provide many kinds of information materials and schools should consider the importance of science programs for young people. The media people should also have greater consideration for the views of the scientific community vis-à-vis those of consumer activists.

Public Communication: Consumer's Perspective of GMO/GM Foods (Dr. Fu-Sung Frank Chiang)

Consumer acceptance plays a key role in the marketing of GM products. Several surveys have been conducted in Taiwan to measure this and to analyze the effects of GM information on consumer behavior. Some analyses have also been conducted to determine differences among four countries by comparing their survey results with respect to consumer knowledge about GMOs/GM foods, perception of health risk, willingness to purchase GM foods, ethical and religious concerns, and GM labeling issue.

Specifically a pilot telephone survey was conducted on 9-11 September 2002 involving a total of 257 completed interview samples. The survey was part of a research project attempting to provide a global perspective about GM foods using a multi-country survey in Japan, Taiwan, Norway and the U.S. The questionnaire used in the pilot survey was similar to those used in other countries except for some differences in the exact wording in respect of language. There were five parts in the questionnaire, namely: 1) perception of GM foods, 2) knowledge of GM foods, 3) GM foods labeling, 4) purchasing preference of three food items (soybean oil, *tofu*, and salmon), and 5) household demographic information.

The pilot survey results showed that 38.5 percent of the respondents considered themselves "not informed" and another 34.2 percent, "somewhat informed" about GM foods or organisms. Only 1.6 percent claimed to be "very well informed". In general, the results from the public surveys indicated more favorable attitudes toward GMOs/GM foods in the U.S. than in Norway and Taiwan. The degree of accepting GMOs/GM foods varied significantly from country to country. In addition, opinions about GMOs/GM foods were quite mixed due to the uncertainty and unfamiliarity about biotechnology.

In conclusion it was suggested that: 1) consumer perception and behavior toward GMOs/GM foods be assessed continuously; 2) the public be educated about the GM technology with accurate scientific information; and 3) a communication/linkage among scientists, industries and consumers be established.

Developing Appropriate Mechanisms for Regulating the Use of GMOs: Japan's Experience
(Dr. Keiji Kainuma)

With world population projected to reach some of 8.9 billion in 2050 there will be an increasing pressure, particularly on developing countries where most of the population growth will occur, to provide safe and healthy foods. In this regard historical figures show that an average increase in world crop productivity dropped from 2.3 percent during 1950-84 to 0.5 percent since the 1990s, a rate that is equivalent to just one-third of the global population growth. The difficulties of increasing productivity in developing countries can be attributed to: 1) limitation on further agricultural land expansion; 2) environmental degradation; 3) destruction of tropical forests; 4) movement towards more sustainable food production; and 5) shortage of water for agricultural use.

To enhance food security in developing countries the Consultative Group on International Research (CGIAR) was established under the auspices of the World Bank, FAO, UNDP and UNEP. The research activities of CGIAR have since focused on: 1) increasing the basic food supply in developing countries; 2) global conservation of plant genetic resources; and 3) improving food policy and strengthening the research basis in developing countries. The CGIAR centers (16 worldwide) were responsible to a large extent for the Green Revolution that occurred in the 1960s and 1970s. Presently, the centers are in the forefront of realizing the so-called "Double Green Revolution" or "Evergreen Revolution" which emphasizes sustainable production using environmentally friendly technologies. Two of the key technologies are Integrated Pest Management (IPM) and biotechnology.

The first generation of transgenic crops involved virus resistant crops, fruits and flowers, herbicide-resistant crops, insect-resistant crops, transgenic tomato with late maturation phenotype and transgenic flowers with a variety of color. The second and third generation of transgenic plants and crops included abiotic stress-tolerant transgenic crops, transgenic crops with high productivity and improved quality and transgenic plants for the production of useful compounds and medicine.

The import of GMO crops in Japan reached some US$1.5 billion in 2001 mainly involving soybean, corn, canola and cotton. The system for safety assessment of GM crops are based on there guidelines, namely: 1) Guideline for Laboratory Safety Assessment (Ministry of Education, Culture, Sports, and Science and Technology); 2) Guideline for Environment Safety Assessment (MAFF); and 3) Guideline for Food Safety Assessment (MHLW). The country has so far approved 43 cases for food uses under the system.

GM foods in Japan are classified into three categories. Category 1 covers GM products or processed foods – not equivalent to non-GM foods in components, nutrients and uses. These products involve mandatory labeling. For GM products in processed foods – equivalent to non-GM foods in components, nutrients and uses, there are two categories, namely: Category 2 – exist transferred DNA or protein; and Category 3 – not exist transferred DNA or protein. Category 2 products may involve mandatory or voluntary labeling. For example, GM soybean or soybean (not segregated) requires labeling while soybean (segregated, not GM) involves voluntary or no labeling. Category 3 products (e.g., not GM canola) need no labeling or only optional labeling.

In summary, Japan's labeling system can be described as follows: mandatory GM labeling is required for a list of "covered products" (rDNA derived), that are detectable (contain DNA/protein) and when they are one of the top three ingredients, each 5 percent or more of the total weight of the food. In the U.S. case, voluntary guideline for labeling applies for "bio-engineered" foods under development; voluntary labeling may be used for foods containing or not containing new DNA/protein; and no thresholds have been established. For South Africa, the mandatory labeling of GM foodstuffs derived from plants with human or animal DNA/RNA or animals with DNA/RNA from animals of different family has been proposed; labeling must indicate origin of nuclear acids (DNA/RNA); and up to 1 percent adventitious presence is allowed for negative claims. In Australia and New Zealand, there is mandatory labeling of foods derived through gene technology and where DNA or protein is present in the final product; and up to 1 percent unintentional presence is allowed. Brazil has mandatory labeling of "genetically modified foods and ingredients", or if foods contain, consist of, or are derived from GMOs; and has adopted a 4 percent threshold (by weight or volume) for GM material.

For better understanding of GMOs there is a need for defining more clearly the roles of the various stakeholders: scientists, governments, consumers, industries and mass media.

COUNTRY REPORTS

Overview

In very recent times, modern biotechnology or more specifically, genetic modification of organisms has created a great deal of controversy not only among policymakers but also among the general public in many developing countries, including those in Asia and the Pacific region. It is because the technology or GMOs in particular has been perceived by many to hold potential risks to human health and to environmental safety in the long term. Scientists, however, have more or less reached a broad consensus not only about the safety of GM technology but also about its benefits to society as a whole. In particular, the important role that it can play in meeting the food security objectives of developing countries is now increasingly being recognized by many governments. Accordingly, greater emphasis on biotechnology is being given by those governments in their R&D agenda. It has been viewed as a particularly promising tool for improving productivity in a sustainable manner. But just like conventional techniques of breeding/propagation, and perhaps more so because of the controversy it has created, regulatory systems have been or are being put in place to control the use/application of the technology in agriculture.

Thus, the country reports have indicated that within Asia many of the countries have at least drafted regulations to cover the import, distribution, sale, utilization, field trials or commercial planting of GM crops/ products. To date, the concern about GMOs for most of the countries has to do more with their importation of agricultural/food products/materials such as soybean and corn which contain GMOs, particularly, those imported from the U.S., the largest producer and exporter of GM products in the world. Application of GM technology has not gone beyond field trials in Asia and thus, so far, no GM products have been produced or commercialized in the participating countries. Most of the research also has been focused on enhancing the protection of crops from biotic and abiotic stresses and improved quality. Such kinds of manipulation are expected not only to increase yields but also significantly reduce the use of chemical pesticides and fertilizers which would benefit the environment.

The regulatory framework has generally involved concerned sectoral ministries/departments (agriculture, health, commerce, environment) depending on their particular responsibilities. In some cases an independent/separate entity/committee has been created to oversee or provide overall management/control over the system and, in general, to promote the judicious use/application of biotechnology techniques. The framework or system has been based on recently drafted country-specific biosafety laws/protocols that have been worked out following the experiences of the more advanced countries.

One major concern that has been expressed by the participating countries was the need to promote greater public awareness about GMOs among the general public and specific groups of stakeholders. In this regard, various methods have been used including mass media and education, particularly, targeted at the younger population. Constant dialogue between government and consumer groups has also been pursued and in this regard scientists have been pressured increasingly to provide a more meaningful and clear message that can be easily understood/accepted.

Republic of China

Biotechnology is one of the most important high-tech sectors in Taiwan. In recent years, strong government commitment has led to several national programs in R&D. However, at the national level, agricultural biotechnology has taken a relatively smaller share among the entire activities. At the same time, public acceptance towards GMOs remains overall uncommitted. Currently, almost all the GMOs appearing in Taiwan’s market are from foreign import. Native R&D and regulatory infrastructure are still at a very young stage, and so is the science for risk assessment.

The regulation of transgenic plants in Taiwan is based on the amended Plant Seed Law promulgated in 2001, while those for transgenic animals and aquatic organisms are based on the amended Animal Husbandry Law and amended Fisheries Law, respectively, both promulgated also in 2001. A reviewing board consisting of representatives from the three major agencies concerned with GMOs was established for examining the applications and experimental results from field trials of transgenic plants. Four isolated field trial stations for transgenic crops have also been designated, namely: Taiwan Agricultural Research Institute, AVRDC, National Taiwan University and National Chung Hsing University. Taiwan plans to enlarge the scale of these designated stations and build new greenhouses, as well as to formulate inspection methods for GMOs and establish a set of biosafety assessment criteria for the ecological environment.

With its recent accession to WTO, Taiwan is beginning to learn how to play an ample role in the international community by abiding by the rules. For instance, the current Department of Health (DOH) guideline for risk assessment of GM foods will need to be revised in accordance with the Codex. Also in the spirit of WTO, GM crops developed domestically will be treated with the same stringent regulations as the foreign-sourced GM crops.

In Taiwan consumers, industry people and other stakeholders demand a reasonable degree of choice between GM and non-GM products. The adventitious presence of GM and non-GM crops will create legal and economic costs which will eventually be borne by the general public. The reality of coexistence among GM and non-GM, as well as organic, products will, however, be accepted ultimately as the norm so that the controversy about biotechnology will be minimized as its role in and contribution to the betterment of human civilization is increasingly recognized.

India

Recognizing the importance of biotechnology for bringing economic benefits to the farming community and for improved human health, the Indian Government has placed high priority on the development of not only skilled human resources in this area but also on the establishment of strong centers of plant molecular biology in the country. Specifically, the government has established a separate Department of Biotechnology which has since propelled much of the developments with respect to infrastructure and capabilities in harnessing cutting edge technology for human health.

Specifically, many promising achievements have been made in biotechnology with the development of *Bt* cotton, *Bt* rice, *Bt* vegetables, chitinase rice, barnase-barstar mustard, potato with balanced protein, etc. But various works in the country are yet to progress to field trials.

The major issues in the use of GM foods/crops in India include: 1) uptake of genes via the food chain; 2) antibiotic-resistant genes in GM food; 3) biosafety; 4) labeling of GM and non-GM food; 5) environmental concerns; 6) effect on biodiversity; 7) public awareness; and 8) regulation of GMOs. The introduction of GMOs has thus been perceived both in the negative and positive dimensions. The general view, however, is that the country should be able to enjoy the benefits of GMOs, if the positive points outweigh the negative points.

The use of GMOs in India is regulated by the biosafety laws entitled "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells" contained under the Environmental (Protection) Act, 1956. The Department of Biotechnology has a compendium of guidelines for doing r-DNA research. There are three important statutory bodies dealing with GMOs, namely: 1) Institutional Bio Safety Committee (IBSC), which is the mediating body between the Project Investigator and Review Committee of Genetic Manipulation (RCGM) constituted within an institution; 2) RCGM which approves and monitors all biotechnological research activities in the country, besides giving permission for the import of transgenic materials for research purpose only; and 3) Genetic Engineering Approval Committee, which gives approval for any import and large-scale field release of GMOs.

In India, a special monitoring-cum-evaluation committee has been set up by RCGM to monitor the projects involving transgenic plants. The committee also advises the RCGM on the risks and the benefits involved in the use of transgenic plants. A registration document containing all biosafety aspects (viz., the characteristics of the donor organisms providing the target nuclei acid, characteristics of the vectors used, characteristics of the transgenic inserts and characteristics of the transgenic plants) should be submitted for approval of any genetically engineered organism. The import and shipment of transgenics for research purpose should be routed through the National Bureau of Plant Genetic Resources (NBPGR) with phytosanitary certificate. RCGM will issue an import certificate based on safety and national need.

India's rich biodiversity is congenial for producing a number of crops and thus the use of GMOs will be useful for expanding the Indian economy and also for alleviating problems of feeding the growing population. The GMOs must be used wherever it is most economic, viable, safe and usable so as to derive maximum benefits.

Indonesia

Indonesia has been accommodating and supportive in regard to the development and utilization of GMOs. This particular stance is important from the viewpoint of the future agricultural development of the country since Indonesia is now one of the biggest food-importing countries in the world. The main crops imported by the country are soybean, corn, wheat, rice and cotton. These are the common crops subjected to genetic modification through transgenic technology in the producing and exporting countries. Transgenic corn, peanut, cacao, cotton, soybean, rice, papaya, sugarcane, tobacco, potato, and sweet potato have already been available from limited field trials in Indonesia. These transgenic crops come as results of biotechnology research conducted by Indonesian research institutes and universities, and also in collaboration with foreign research counterparts. Most of these transgenic crops have agronomic traits of resistance to insects and diseases, and also to glyphosate herbicide.

The Government of Indonesia has established strict regulations in order to anticipate the negative impacts of these transgenic products. In relation to biosafety aspects of GMOs, for instance, the Minister of Agriculture has signed a decree (No. 856/Kpts/HK.330/9/1997) in September 1997 containing provisions on biosafety of genetically engineered agricultural biotechnology products. This decree was then amended in

1999 to cover both biosafety and food safety aspects through a decree which was signed jointly by the Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister of Food and Horticulture. This regulatory provisions of the decree applies to all GMOs and its products used in Indonesia including animal, fish, microorganisms and plants.

For its implementation, a National Biosafety and Food Safety Commission has been formed. This Commission is assisted by a Technical Team for Biosafety and Food Safety whose duty is to help the Commission study, evaluate, assess and test a GMO application in biosafety containment or in a confined field. All transgenic crops must pass through the assessment and evaluation in the laboratory of biosafety containment and confined field testing. The Technical Team in that laboratory has already evaluated some transgenic crops including *Bt* corn resistant to stem borer, *Bt* cotton resistant to boll worm, and Roundup Ready corn, cotton, and soybean resistant to glyphosate herbicide.

Republic of Korea

Since the early 1980s, Korea has made great efforts to promote biotechnology through R&D investment. Given the rapid changes in international environment, the government has committed itself to foster biotechnology as a strategic industry in the 21st century, proclaiming 2001 as "the year of biotechnology". The Ministry of Agriculture and Forestry (MAF) initiated the "Plan for Promoting Agricultural Biotechnology" in early 2001 and set out 20 strategic projects in five core areas by which Korea was able to account for 5 percent of the world market in crops and livestock. In 2001, the government invested about ₩28 billion (about US$23 million) through MAF, Rural Development Administration (RDA), Korea Forest Service and Korea Food Research Institute and it plans to increase this amount to ₩45 billion (about US$37 million) in 2002.

Korea is currently developing 16 transgenic crops and animals with 40 varieties/species. The transgenic crops account for 14 products with 35 varieties, including cereal grains, fruits and vegetables, and tuber and roots. Most transgenic crops are under experimental stage in laboratories but rice and potatoes have advanced to the level of open-field tests. There are, on the other hand, two transgenic animals with five species. Transgenic pigs are basically under development stage of verification and examination while the transgenic chickens are being explored in laboratories. As yet to be commercialized, it is likely that the transgenic crops and animals under greenhouse and field-level experiments such as rice, wheat, cabbage, potatoes and pigs could be diffused and marketed in five years.

The regulatory framework for GMOs can be divided into two areas. One refers to health and environmental safety and the other addresses consumer information. Currently, the estimated import of GM soybeans amounted to 888,600 mt (32 percent of total soybean imports), up from the 20,900 mt (0.9 percent) imported over the 1997-2000 period. As for GM corn, it also rose from 39,400 mt (0.5 percent) to 773,500 mt (9 percent) in the same period. Having nothing to do with health or environmental safety concern, the labeling system aims at ensuring that consumers are able to exercise their 'right-to-know' and 'right-to-choose' in the market.

The GMO labeling scheme was introduced for food crops (soybean, corn and soy-sprout) in March 2001 and that for potatoes was added in 2002. A threshold level of unintended mingling of GMOs into non-GM crops was set at 3 percent. As for processed GM food, the scheme encompasses 27 processed food based upon soybean, corn and soy-sprouts. The risk assessment of GMOs are independently managed by the Ministry of Science and Technology (management of GMOs for research purpose), MAF (management of GMOs as raw materials), Ministry of Commerce, Industry and Energy (management of GMOs for industrial use), Ministry of Health and Welfare (management of GM foods), Ministry of Environment (biohazard management of GMOs in the ecosystem), and Ministry of Maritime Affairs and Fisheries (management of GMOs in the marine environment). Recently (in October 2002), the Korean Agency for Technology and Standards (KATS) established seven Korean standards related to the safety management of GMOs such as guideline for monitoring strategies for unintentional release into the environment during production, transport and sale.

Malaysia

Improving food production has been and will continue to be one of the top priorities and commitment of government agencies involved in biotechnology. To accelerate biotechnology development in Malaysia, the Ministry of Science, Technology and the Environment (MOSTE) has set up the National Biotechnology

Directorate (BIOTEK) in May 1995. BIOTEK is entrusted with the task of spearheading and coordinating biotechnology research in the country. To streamline biotechnology research, seven Biotechnology Cooperative Centers (BCCs) in the areas of plant, food, animal, molecular biology, medical, environment/ industry and bio-pharmacy have been established.

Biotechnology in Malaysia had recently received a further boost with the announcement of the BioValley and the Malaysia-MIT Biotechnology Partnership Programme (MMBPP) initiative. BioValley will include three new research institutions conducting research in genomic and molecular biology, nutraceuticals and pharmaceuticals, and agricultural biotechnology. The MMBPP is a collaborative effort of Malaysian academic, industrial and government research organizations.

At present MOSTE is the focal point and is responsible for coordinating all matters pertaining to biological diversity including biosafety under the Convention on Biodiversity (CBD). A Genetic Modification Advisory Committee (GMAC) was established in March 1996 under the ambit of the National Committee on Biodiversity (NCB), with the objective of carrying out risk assessment and making recommendation to the competent authority for final consideration and approval.

Any research agencies involved in carrying out research on genetic modification must establish an Institutional Biosafety Committee (IBC) to ensure that experiments relating to genetic modification and release undertaken by the institution conform to the provisions of the National Guidelines for the Release of Genetically Modified Organisms into the Environment. Currently, the importation of GMOs is regulated by sectoral legislation. For GM plants, permission to import must be obtained from the Department of Agriculture; and for GM animals, fish and food from the Department of Veterinary Services, Department of Fisheries and Ministry of Health, respectively.

Regulations pertaining to GMOs in Malaysia need to be strengthened through legislative means. Realizing this fact, the government in June 1997 has directed the GMAC to draft a Biosafety Bill which is expected to be tabled in the Parliament in 2003 for approval. Similarly, a Bill on the regulation of GM foods has been drafted and is expected to be tabled in the Parliament in the same year.

To date, two GMOs crops, namely; transgenic papaya modified to delay ripening, and transgenic oil palm that is tolerant to herbicide glufosinate ammonium (phosphinothricin, Basta 15) have been submitted for their confined release. So far, the transgenic papaya has been approved for confined field release under a netted house. Application for the importation of transgenic soybeans (*Glycine max*) for food and feed has been approved by the GMAC. The basis for the approval was the fact that the "Roundup Ready Soybean" has been deregulated in the U.S. since May 1994 based on the assessment that there was no difference from the conventional soybeans and therefore is safe for import into the country for food and feed.

Views concerning the future of GMOs plants and plant products in Malaysia indicate firstly that the use of GMO plants and foods will be further encouraged. However, research on the long- and short-term risk posed by GMOs needs to be urgently established to avoid creating any fears and skepticism about GMOs by the general public. Secondly, GM products or foods in the market may require labeling to ensure transparency and to allow consumers to make a choice. Finally, GMO plants which have undergone assessments to demonstrate that there is no long- and short-term potential affects on human health and environment and which at the same time can benefit the country in the long run will be encouraged for the purpose of commercialization.

Thailand

Thailand has been involved in R&D on plant genetic engineering since the mid-1980s. Progress has been made in some locally grown plants and vegetables although none has reached the commercial market. Work on the ring spot virus resistant papaya is probably the closest to commercial development, and food safety assessment is being conducted. R&D has been undertaken at universities, governmental research institutes and the National Center for Genetic Engineering and Biotechnology, which also perform risk assessments following several biosafety guidelines. The National Biosafety Committee (NBC) was set up to take charge of technical assessments and to provide advice on the safety issues of GMOs to competent authorities.

Specifically, experiments on the development of desirable characters of selected crops have been conducted, mainly in tomato, cotton, papaya, chili pepper, yard-long bean, and orchid. Disease- and insect-resistant genes are the major genes selected for the plant transformation, except in orchid, where the gene controlling color expression has been selected. Some greenhouse experiments have already been set up for papaya, chili pepper, cotton and tomato but none for the yard-long bean and orchid. For the imported GM plants, 43 cases have been approved but only three cases thereof, namely; *Flavr Savr* tomato, *Bt* cotton and *Bt* maize have made it to the field trials under the strict guidance of the NBC. Due to the importation of certain foods and raw materials, the labeling of the packaging/containers of products containing GMOs has been discussed and issued recently. Detection and evaluation criteria for GMO contamination of raw materials and food products have been set. However, public awareness and education are still needed for the majority of the population in order to enhance their bio-ethical maturity and ability to balance the benefits and risks of GMOs in their everyday life.

When the public and the international trade market became skeptical of the safety of GM foods in the late 1990s, laboratories have been immediately set up to provide GMO detection services mainly to the private sector. Several policy bodies were also authorized to decide on such issues as import regulations, labeling and safety assessment. Decisions have been made to prohibit the importation of GM plants according to the existing law, but to exempt soybean and corn grains. The Cabinet has later acknowledged a request to impose a moratorium on all field tests by the Ministry of Agriculture and Cooperatives until a national biosafety law is in place. The labeling of GM food that has higher than 5 percent content has also been announced in mid-2002.

The Plant Quarantine Act 1964 (amended 1999) that prohibits the importation of GM plants except those intended for research purpose, has limitations in itself as it does not cover finished food products. The 'Biosafety Law' concept has been proposed and it is hoped that it will achieve more effective control of research and utilization of all GMOs in Thailand, preferably under the forthcoming Biodiversity Framework Law. At present educational programs are being conducted to provide more information to the public about GM foods and genetic engineering. In many occasions the public including many stakeholders have been invited to share their views and provide suggestions to decision-makers.

Vietnam

Vietnam's agriculture has performed extremely well with its sustained growth of 4.5 percent per year. The new policies and the important roles performed by science and technology are two main factors contributing to such achievement. In the coming years, however, the country will face and have to overcome challenges in agriculture and rural development such as the high frequency of natural disasters, high incidence of poverty, high production cost and low product quality and severe competition in the world market. Specific issues will concern efficiency and the role of biotechnology and its long-term implications in terms of food security, public health and environmental safety.

The main crops under study for application of biotechnology include rice, maize, rubber, coffee, vegetable and some major fruits. At present, GMOs in food crops and medicinal plants have been limited to laboratory and greenhouse testing. Field testing is not allowed for such GMOs. Vietnamese scientists have been successful in producing transgenic plants for rice, maize, potato, soybean, cotton and some forest plants. Until now the country has not established a regulatory framework for GMOs and their products. Based on the International Convention on Biological Diversity and the Biosafety Protocol including exchange and transport of GMOs at international level, the draft biosafety regulation for GMOs and their products in Vietnam has been prepared by many senior experts of involved ministries led by the Ministry of Science and Technology and Environment (MOSTE) and the Ministry of Agriculture and Rural Development (MARD).

The formulating and implementation of the biosafety regulation for GMOs and their products in Vietnam are based on sound science and the local situation and biosafety reviews are conducted on the basis of scientific principles and experiences gained from other developing countries.

WORKSHOP

A workshop was conducted to provide an opportunity for further discussion and sharing of views and experiences among the participants. Specifically, three discussion areas were taken up, namely: 1) promoting greater public awareness through education, mass media and other schemes; 2) harmonization of regulatory systems: information sharing and networking among countries in the region; and 3) mechanisms for consumer protection from illegal GMOs that may not be safe.

To facilitate the discussions the participants were divided into two small groups. The outputs of the two groups were presented in a plenary session and are briefly outlined below:

Group I Dr. Wei-Ping Hung (ROC), Dr. Kirpa Ram Koundal (India), Dr. Song-Soo Lim (ROK), Mr. Mazlan Saadon (Malaysia), Dr. Nares Damrongchai (Thailand), Mr. Do Khac Thinh (Vietnam) and Dr. George B. Fuller

1. ***Promoting Public Awareness***

* Any public awareness promotion program should make clear what GM technology means.
* It should include education/demonstration aspects that involve all stakeholders such as policymakers, business, scientists, media, school/students, etc.
* Awareness may not always lead to acceptance.
* In raising public awareness people with credibility and supportive of biotechnology (such as Norman Borlog and Prof. M. S. Swaminathan) can be enlisted for their support.
* Some lessons we have learned from our six-year experience include as follows:
  – We might not have done anything seriously wrong, but some people are doing better than us.
  – There is a need for a balanced message (i.e., mentioning/referring to not just the benefits).
  – Reassurance of effective regulatory protection: the industry says biotechnology is good. But the important message is that biotechnology can be good or bad, but that there are regulatory systems in place to take care of it.
  – Information to the public should be broader in scope beyond science (ethical, legal and social issues [ELSI]).
  – Broaden stakeholders/communicators beyond scientists.
  – Although so far there has been no evidence about GM food being unsafe, we should be conservative.
  – Use non-food crops as lead examples.
  – Compromise with NGOs.
  – Urgent response unit should be set up: the case of Thailand (local) and Monsanto's service (global).
  – Awareness is not enough – there should also be understanding. In this regard, education should involve young people for long-term Human Resource Development (HRD) and understanding (Singapore is starting this kind of education at a very early stage). We should create a list or guideline (best practice) that fellow countries can refer to.
  – Consumer preference is still paramount – will it be enough for the consumer to choose benefit over risk?
  – A national biosafety framework should be set up.
  – Stakeholder groups should include scientists, governments, consumers, industries, food processors, food retailers, mass media and growers.

2. ***Harmonization of Regulatory Systems***

* All systems do not have to be the same.
* Have everybody talk about the same information: data requirements, data review and regulatory decision.
* Focal points in each country should share their information (database) over the web.
* Capacity building should be promoted and there are international organizations (e.g., UNEP-GEF [Global Environment Facility] and CGIAR) that support capacity building.
* On networking: all country representatives should provide APO with personal e-mail address and country web sites for compilation and circulation.

3. ***Mechanisms for Consumer Protection***

* Protection may be from: i) illegal GMOs that may be unsafe; ii) from illegal GMOs, even though they may be safe, including illegal cultivation and distribution of known events (e.g., Star Link); or iii) illegal development and distribution of unknown events.

* How to design a mechanism to find out illegal GMOs:
  - Certain (post-market) monitoring systems that are cheap and effective.
  - International bodies like International Office of Epizootics (OIE) in the case of foot-and-mouth disease.
  - Biosafety Protocol pertaining to LMO/FFPs (living modified organisms intended for direct use as food, or feed, or for processing.
  - Monitoring and controlling should be done at the growing stage, before it enters the consumer's market.
  - International bodies like Codex should get to the point that it approves a list of GMOs that are safety assessed.

Group II Dr. Wen-Yen Kao (ROC), Dr. Thirugnanam Senguttuvan (India), Dr. Soeranto Human (Indonesia), Dr. Weon-sun Shin (ROK), Dr. Prasartporn Smitamana (Thailand), Dr. Tran Duy Quy (Vietnam) and Dr. Keiji Kainuma

1. ***Promoting Public Awareness***
* Focus is made on the primary school and program for off-campus training with different techniques to promote the benefits such as mass education programs for the public and country-wide radio programs (India).
* Young people are targeted through cybernet/networking for knowledge-based communication. Radio program is also employed. Use of right terminology is important to make the people think properly. Key person in the family should be educated on the subject (ROC).
* Middle school is targeted as medium for simple education about biotechnology; high-school for more specific education; and university for specialized knowledge. Strong family link is supportive of proper, effective and positive GMO information. Local government handles independently promotion programs. At national level each government agency contributes to provision of correct information. Distribution of booklets and brochures and frequent articles/items in newspapers are encouraged; and cartoons for small children are produced. These measures are taken to counteract strong opposition of NGOs to GMOs which has created negative impact on the public (Thailand).
* TV, radio, workshop programs are aired/conducted for 30 minutes a day by MOSTE to enhance limited knowledge of general public including farmers about GMOs. Information is provided also about national program on GMOs by MARD including limitation of detection methods. Consumer group surveys on public awareness are conducted (Vietnam).
* Biotechnology is promoted by national-level/related workshops which are conducted frequently. Strong NGO activity/program on TV and radio has created country-wide impact. Heterogeneity in language and dominance of Muslim religion which does not favor GMOs are big constraints (Indonesia).
* There are no labeled products in the market. There is consumer preference for non-GM *tofu* and industries voluntarily change towards non-GMO/science-based communication guideline for mutual understanding (Japan).
* Booklets and brochures are produced and information networking is promoted to address consumer's need to get the correct information. Some religious problem associated with GMOs (ROK).

2. ***Harmonization of Regulatory Systems***
* Although there were differences of opinion regarding the issue of harmonization, many recommended personal networking through APO activities/cyber-networking through APO. APO activities can support APEC work. Networking with transnational government bodies for crisis management will be desirable.

3. ***Mechanisms for Consumer Protection***
* Proper terminology should be used. Although the products may be the same the situation may be different among the countries in terms of regulation. There is a lack of correct information beyond the scientific circles. A surveillance system is recommended (ROC).
* There is difficulty in managing unidentified GMOs with multi-borderline characteristics. There is lack of documents/need for clearing house for information/plan for logos for uneducated people (Thailand).
* Logo for uneducated people is desirable (Indonesia).

*	Guideline approved for food use is available (Japan).
*	Regular surveillance for post-market monitoring is recommended (ROK).

FIELD STUDIES

Asian Vegetable Research and Development Center

The AVRDC located in Tainan is the principal international agricultural research center dedicated to vegetable R&D. Established in 1993 it has since been improving nutrition and raising incomes in the developing world by increasing the yield and quality of vegetables, and by training agricultural researchers and extensionists. The center's R&D programs are led by professionals from 12 countries and supported by some 250 national researchers and technical and administrative staff.

The center through its training courses, internships, fellowships and international joint research efforts has increased the number of capable vegetable scientists in the developing countries. At the same time, it has greatly increased international cooperation in vegetable R&D by helping to establish and administer five research networks in Africa, Asia and Central America.

The facilities of the center include laboratories, greenhouses, a gene bank, an insectary, an experiment farm and meeting/training rooms. It has outreach programs in Thailand and Tanzania and Project Offices in Bangladesh, Philippines and Costa Rica. More than 230 AVRDC improved vegetable varieties have been released to farmers in 90 countries. Aside from increasing the performance of plant materials, the Center also develops improved cultural practices and management systems making use of grafting, hydroponics, slow-release fertilizers, protective culture and growth regulators to alleviate constraints to vegetable production and reduce the risk of environmental pollution from leaching of nitrogen and pesticide residues.

The Center maintains more than 49,000 germ plasm accessions and ships more that 20,000 packets of seeds of improved varieties to more than 190 countries each year. The participants had an opportunity to visit the Genetic Resources and Seed Unit of the Center where the germ plasms were kept and maintained. They also had a tour of the greenhouse facility for transgenic plants.

Taiwan Salt Industrial Corporation

The TSIC was established in 1952 as the Taiwan Salt Works initially under the jurisdiction of the Ministry of Economic Affairs and later the Ministry of Finance. It was reorganized into its present setup in 1995. In order to survive the economic difficulties during that time, the corporation had to diversify its core business into other production activities. Thus, in June 1999 it established its biotechnology department and established a branch factory in the Tainan Science Park. The Taiwan Salt Biotech Factory (TSBF) which cost some NT$250 million to set up introduced collagen-related production technology from the U.S. and since then it has been actively involved in the development, manufacturing and marketing of collagen-based medical/surgical products.

In July 2001, the Corporation invested some NT$245 million in a second factory in Tainan which started producing microbial products. With the deterioration of the agricultural production environment due to the global expansion in population, overuse of chemical fertilizers and pesticides and industrial pollution, the urgent need to protect the environment and the general public motivated the Corporation to develop new substitutes for these chemicals. These substitutes included fungicides, bio-fertilizers, aquaculture products and animal feed additives.

Its *Bacillus subtilis* (BS) product is a mycorrhizal fungi that promotes crop growth and disease resistance. It enhances the symbiosis of N_2-fixing bacteria with legumes, reduces the application of chemical pesticides, changes microbial flora in soil and reduces the loss from continuous cropping. Its *Streptomyces saraceticus* (SS) product, among others, decreases root knot nematodes of melons, tomatoes and vegetables, prevents root rots from papaya and bitter gourd and enhances fruiting and decreases occurrence of stem rot and the application of chemical pesticides of *Anoectochilus formosanus*.

The factory produces about 300 mt of these products annually. It is so far exporting only to China but has some field trials currently ongoing in Australia. It plans to build a new automated line costing some NT$33 million in the near future to take better advantage of export opportunities.

CONCLUSION

In recent years, biotechnology has become an increasingly important tool for meeting the food needs of many developing countries, particularly, in Asia and the Pacific where food security has remained and will continue to remain a major challenge. Given the urgent task of finding alternative means of raising productivity in a sustainable manner, many governments in the region are looking at modern biotechnology and specifically, genetic modification as a safe and viable approach to enhanced food security and sustainable agriculture.

The study meeting recognized that GM products that have been properly assessed are safe and beneficial to consumers. However, it agreed that the consumers' negative perception about such products was a legitimate issue that needs to be more adequately addressed by respective governments if the technology was to advance at all, particularly, in the developing countries. In this regard, the study meeting suggested a number of ways on how public awareness and acceptance could be enhanced. Some concern was also expressed about the need to strengthen the regulatory framework, both in terms of transparency and in regard to unauthorized GMOs/unknown events that may prove to be unsafe.

The study meeting provided the participants an opportunity to learn about recent developments and achievements with regard to genetic modification of organisms in the respective participating countries. The active exchange of views and sharing of experiences, in particular, added much insight about the subject. It was hoped that such kind of meetings be continued in the future and that information sharing among the participants be maintained through some form of networking.

1. RECENT DEVELOPMENTS AND ACHIEVEMENTS IN AGRICULTURAL APPLICATIONS OF BIOTECHNOLOGY

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INTRODUCTION

I think we have all seen the global projections for population growth throughout the world and the fact that this growth is projected to occur disproportionately in developing countries.[1] Those of us concerned with food production and availability wonder how we can provide the food necessary to meet the nutritional needs of this expanding population.

The good news is that there is significant room for improvement in agricultural productivity, and that the developing countries which have the most need for a greater food supply have the most room for improvement. Using corn as an example, it is estimated that improvements in technology adoption, farming practices, training and infrastructure could increase productivity in developing countries by up to 50 percent. The developing world will need all of that 50 percent and more as a combination of population and income growth places demands not only on the total calories required for consumption but also on the quality of those calories. As income shifts, demand for meat as a source of calories can be expected to increase as well. It is estimated that by 2020 the population growth will result in a 45-percent increase in food demand and that the shift to increased meat consumption will add another 30 percent on top of that.[2]

Fortunately for all of us there is a revolution in agriculture which, in addition to the improvements outlined above, can be an enormously useful tool to provide the food productivity increases needed in Asia. This revolution, of course, is the rapidly evolving availability and adoption of biotechnology in agriculture. In the developed world, this has already resulted in higher yields, a value shift from chemicals to seeds, an integration of participants and new relationships with growers. The revolution is just getting underway in Asia but already there is clear evidence of dramatically improved productivity for cotton in China and South Africa along with improvements in grower health and the environment.[3, 4] It is anticipated that similar gains will be seen in India once commercialization of insect-protected cotton is more widely adopted.

Biotechnology, for the purposes of this discussion can be seen as a relatively recent development in a continuum of human intervention into the biology of food production dating back to beverage fermentation and bread making in 6000 BC. In its broadest sense, biotechnology can be seen as a collection of scientific tools used to enhance plants, animals and microorganisms for the benefit of humans. Historically, this has involved techniques used to intermix genes from one variety of plant to another through crossbreeding techniques. More recently, these crossbreeding techniques have been stretched with protoplast fusion technology to allow the combination of genes from plants which are more and more distantly related. In addition, mutagens have been used to create novel combinations of genes within a plant variety. Within the past 20 years, recombinant DNA techniques have been developed which allow plant breeders to dramatically expand the genes available for use in a given plant species. It is this most recent application of biotechnology

1 United Nations Population Division and Population Reference Bureau, 1993.
2 International Food Policy Research Institute (IFPRI), FAO, Monsanto estimates.
3 J. Huang, S. Rozelle, C. Pray, and Q. Wang, *Science*, 25 January 2002, p. 674.
4 R. Stewart, K. Vermaak, R. Pharoah, and S. Stavrous, “Makhatini Flats Cotton, Final Report”, DRA Development CC, 14 December 2001.

that has created the new revolution in agriculture and it is this application which I will refer to as plant biotechnology.

Products of plant biotechnology in the United States have been available since 1995 and have included herbicide-tolerant soybeans, corn and canola and insect-protected cotton and corn. These products have already provided increased grain and fiber yield, decreased operating costs, enhanced water conservation and reduced soil erosion. Additional net return per hectare has been estimated to be: US$29.64 for Roundup Ready soybeans; US$67.30 for Yieldgard corn; $133.00 for Bollgard cotton; and US$39.19 for Roundup Ready canola.[5, 6]

STATE OF DEVELOPMENT

Since its first large-scale commercialization in the United States in 1995, plant biotechnology has demonstrated the most rapid growth and adoption of any technology in the history of agriculture. In 1996, plant biotechnology was used on just over 2 million ha worldwide. In 2001, the global usage was estimated at 52.6 million ha.[7]

Although scientists around the world have reached broad consensus on the value and safety of plant biotechnology products on the market today,[8] there has been no small amount of debate in the media and among consumer organizations, usually involving hypothetical risks or extrapolation from questionable laboratory studies. In spite of the controversy reflected in, and perhaps fueled by the media, surveys of actual consumers have shown that attitudes towards biotechnology and the regulatory oversight of food safety related to biotechnology are improving. In Asia, a recent survey by the Asia Food Information Centre (AFIC) has determined that "... contrary to the views reported in other parts of the world, most Asian consumers are not strongly opposed to genetically modified foods. In fact the majority of consumers surveyed were positive, and wanted to know more about the technology, and how it could improve the quality of their everyday foods, such as rice, fruit, vegetables, soybeans and corn".[9]

REGULATION OF PLANT BIOTECHNOLOGY IN ASIA

Worldwide the pace of regulatory acceptance has been proceeding rapidly. Regulatory approvals have been granted by 33 countries in the world including the EU and the four most populous countries in the world. This means that today more than half the world's population is living in countries which make the benefits of biotechnology available to their citizens. This growth is driven by the tremendous benefits offered by plant biotechnology. The regulatory approvals required for this growth are made possible because of the growing body of scientific evidence that plant biotechnology products currently on the market are safe and offer significant socioeconomic and environmental benefits. At the same time, there is no scientifically sound evidence of any adverse effects resulting from the plant biotechnology products currently on the market.

Within Asia most countries have at least draft regulations to cover the import and/or commercialization of plant biotechnology products. The state of regulatory systems in each country is their individual response to a number of factors which are at play in the region.

First and foremost among these factors is the polarization of the political approaches to biotechnology in North America versus Europe. To be clear, the scientists on both sides of the Atlantic are in agreement on the safety of plant biotechnology products, as evidenced by the safety approvals of 13 different products by the EU Scientific Committee on Plants. In October 2001 the EU Commission released a biosafety report[10] summarizing 81 research projects financed by the EU over the last 15 years, at a cost of US$64 million, on

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5 C. James, *Global Review of Commercialized Transgenic Crops*, International Service for Acquisition of Agri-biotechnology Applications (ISAAA).

6 Moschini, *et al.*, Iowa Agriculture and Home Economics Experiment Station, September 1999.

7 C. James, *Global Review of Commercialized Transgenic Crops: 2001*, ISAAA Briefs No. 24, 2001.

8 "Safety Aspects of Genetically Modified Foods of Plant Origin", Report of a Joint WHO/FAO Expert Consultation on Foods Derived from Biotechnology, 29 May-2 June 2000.

9 "What Citizens in Asia Really Think About Genetically Modified Foods" presented by AFIC at the International Rice Congress in Beijing, 19 October 2002.

10 http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/01/1391|0|RAPID&Ig=EN

genetically modified crops and products made from them. “The research has not found any new risks to human health or the environment, beyond the usual uncertainties of conventional plant breeding," according to the European Commission. ”Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods. No unforeseen environmental effects have yet shown up, but even if they do, these should be rapidly detected by existing monitoring systems”,' the Commission added. It should be noted that this scientific agreement is also reflected in the science base for the regulatory systems being developed in the EU. The differences between the U.S. and the EU on plant biotechnology are therefore due to differences in politics and trade rather than differences in science.

Politically, North America and the EU are at opposite ends of a polarized debate which is nominally about biotechnology but more realistically about trade. Countries in Asia see themselves as caught in the middle. On the one hand, there is an interest in maintaining access to the lowest cost agricultural commodities in international trade as well as a need (and in some cases an imperative) to ensure that local farmers have access to the tools they need to be competitive in the global market place. On the other hand, there is the widespread influence of European-based activist groups, in some cases working independently and in others working through local consumer organizations, which create fear and uncertainty around biotechnology in the local media. In addition, there is a fear that ability to trade with the EU can be impaired if they adopt biotechnology. This fear is encouraged by EU traders who increasingly insist on certification that foods exported to the EU is GMO (genetically modified organism)-free even though in many cases (such as soy-derived products) the import of products derived from plant biotechnology is perfectly legal in the EU.

Those countries with a well established science base and regulatory infrastructure enacted and implemented comprehensive regulatory systems relatively early on (Japan, Australia, China, India) while other countries have proceeded more slowly as they try to find a way which will best preserve their options and interests. One interesting manifestation of this dilemma is the phenomenon where India, Taiwan, Malaysia, Australia, China, Japan, Thailand and New Zealand have all announced within the last year that they are investing heavily in biotechnology as an important step in their future growth while at the same time establishing regulatory regimes which will make the realization of benefits from those investments relatively complex.

Another factor which is becoming important in Asia is that farmers are getting tired of waiting for governments to act and are starting to take matters in their own hands by illegally importing plant biotechnology seeds. This phenomenon was first observed in Brazil, where it is estimated that 30 percent of the soybean crop is biotechnology derived even though such use is not yet legal in Brazil. In Asia, similar cases of smuggled seed being planted illegally have been reported in India, Pakistan and Thailand.

While there may be some value in this phenomenon creating a sense of urgency in regulatory bodies, it can still be counterproductive in a number of ways. Naturally the technology inventors lose because their technology is being used illegally without giving them the opportunity to share in the value they have created. It is bad for governments because it creates the impression that they are irrelevant to the farmers and have limited ability to regulate their agricultural production systems. Finally, it is bad for the farmer because without the assurance of quality control and product stewardship that would be available through legal marketing of biotechnology products, there is a real danger of lack of poor performance caused by low quality seeds and lack of understanding on how to use the product to get the most value from the biotechnology trait.

By country, the current state of regulation in the region today is as follows.

Australia

Australia also has extensive experience in regulation of plant biotechnology both for import and for commercial release. Originally, food approvals were the responsibility of the Australia/New Zealand Food Authority (ANZFA) while environmental approvals were the responsibility of the Genetic Modification Advisory Committee (GMAC).

The GMAC system was nominally voluntary, although there is no known instance of environmental release of plant biotechnology products without first seeking GMAC approval. In anticipation of a mandatory system being enacted, an Interim Office of the Gene Technology Regulator (IOGTR) was established in 1999. Legislation in 2000 created the mandatory scheme under which the present Office of the Gene Technology Regulator (OGTR) was established in 2002. ANZFA has undergone minor reorganizations since its establishment but still exists today under the name of Food Standards Australia New Zealand (FSANZ). ANZFA/FSANZ have approved 18 different events for food use either from import or domestic production.

Currently in Australia domestic production is permitted for three types of biotechnology-derived cotton. It is noteworthy that when ANZFA first required mandatory food approval for plant biotechnology products in 1999, they recognized that there would be a serious backlog and were anxious to avoid a disruption in trade which might occur if products were imported prior to the completion of the approval process. Since they recognized that there was no health risk posed by these products, they set up a system whereby products for which applications were submitted by 30 April 1999 AND which were lawfully on the market and considered safe by an overseas regulatory agency AND for which ANZFA had no evidence to indicate lack of safety would receive an interim approval pending completion of ANZFA's review.[11]

China

China was the first nation in the world to adopt biotechnology when they commercialized virus-resistant tobacco in 1992. Since that time, China has approved the commercialization of *Bt* (*Bacillus thuringiensis*) cotton and some locally-derived vegetables with biotechnology traits. In 2001, China enacted a series of rules which created serious disruptions to both the trade in agricultural commodities with biotechnology traits and into the development and commercialization of new traits. Under these new rules, the Minister of Agriculture established a new regulatory system under which imports would require certificates of safety, food products would require labeling and new rules were established for commercialization approvals.

Since the new rules were established, considerable energy has been devoted to obtaining the approvals necessary for continued import of soybeans, canola and corn from the U.S., Canada and Latin America. As a result, China has committed to the U.S. Government that they would not allow the implementation of these rules to inhibit trade and certificates of safety have been issued for all three commodities valid through 20 September 2003.

India

India regulates biotechnology at three different levels. Each technology developer is required to have their own Institutional Bio Safety Committee (IBSC) which must include at least one member appointed by the Department of Biotechnology (DBT). The IBSC's formulate requests for approval for testing which go to the Research Committee on Genetic Modification (RCGM) which is the responsibility of DBT and includes representatives from the Ministries of Health, Science and Technology (the parent Ministry for DBT) and Agriculture. The RCGM can approve field trials and other tests and reviews reports on these tests for further action. Approvals for commercial releases must come from the Genetic Engineering Approval Committee (GEAC) which is chaired by the Ministry of the Environment and includes representatives from the Ministries of Health, Science and Technology and Agriculture.

To date India has approved *Bt* cotton for commercial use in India (March 2002). There is still some discussion within India on how to treat applications for food approvals for imported commodities. Since this happens only rarely in India, the system has not yet been completely defined.

Indonesia

Indonesia was the first country in Southeast Asia to grant approval for commercial production of a biotechnology crop, *Bt* cotton. Since that time, the government has been focused on collecting the various regulations from different departments and creating an umbrella regulatory policy and system with funding assistance from the United Nations Environment Program Global Environment Fund.

Japan

Japan has the most experience in evaluating products of plant biotechnology for food and feed safety assessment as well as for environmental impact. Japan's law providing for food and feed approval of plant biotechnology products was passed in 1995 and the first approvals were granted for imported commodities

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[11] ANZFA User Guide to Standard A18/1.5.2 – Food Produced Using Gene Technology.

in 1996. Since then food safety approvals have been granted for 44 different events.[12] In Japan food approvals are granted by the Ministry of Health, Labor and Welfare (MHLW) while feed and environmental approvals are granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). MAFF has granted environmental approvals for 66 events.[13] At the present time, driven primarily by concerns about BSE (bovine spongiform encephalopathy), there is a proposal to establish an additional oversight body for food safety which will be composed of respected scientists and will be independent of both MAFF and MHLW but it is not yet clear how that body will operate and what its effect on biotechnology approvals will be.

Korea

Korea has been operating a voluntary approval system for imported plant biotechnology products since 1999. The first product to be approved under that system was Roundup Ready soybeans. More recently, approvals have also been granted for Yieldgard corn and Roundup Ready corn. On 27 August, Korea's Ministry of Health and Welfare (MHW) issued a revised food sanitation law to implement a mandatory approval system and established an 18-month period to complete the process for events currently on the market. It is likely that Korea will need to adopt an interim approval system similar to the ones used in Australia and Taiwan in order to avoid disruptions in trade in the event that all the approvals can not be processed in the 18-month time frame.

Malaysia

Malaysia was the first country in Southeast Asia to approve a plant biotechnology product for import, Roundup Ready soybeans in 1997. Since that time, Malaysia has been drafting a comprehensive revision of their regulations for commercialization and labeling of plant biotechnology products. This process is expected to be complete within the next year. At the same time, Malaysia has embarked on an ambitious research program in biotechnology, including the launching of a "bio-valley" analogous to silicon valley. Malaysia has an advanced program of research in plant biotechnology already underway for papaya and oil palm.

Philippines

The Philippines was one of the first Southeast Asian countries to have a system in place to regulate field trials but the complexity of implementing that system meant that the first trials were underway only in 1999. In March of 2002, the Philippines enacted an Administrative Order under the Secretary of Agriculture which constitutes a comprehensive framework for regulation and approval of biotechnology products imported for food use as well as commercialization of biotechnology crops in the Philippines. The first application for approval under that Order was submitted in August 2002 and culminated in December 2003 with the approval for propagation of Yieldgard corn by Monsanto.

Taiwan

Taiwan has permitted field trials for papaya and vegetable crops but has not yet permitted commercialization of plant biotechnology crops, although there is an active ongoing research effort for virus-resistant papaya. Recently, Taiwan has announced a significant investment in biotechnology, including plant biotechnology, indicating a recognition of the importance of this technology to Taiwan's agriculture.

Taiwan is currently in the process of implementing their law requiring food safety approvals for imported plant biotechnology products. This law currently is limited to corn and soybeans and any events not approved by the end of 2002 will not be allowed to be imported. The deadline for submission of events specified by the government was the end of March 2002 at which time eight submissions were on hand. To date, three approval certificates have been granted. Since that time three more submissions have been required and it appears less likely that the approval review process will be complete in time for the 31 December deadline. A likely solution will be for the government to issue interim approval certificates which will be valid until the approval process is complete. This would be similar to the approach used by Australia.

12 www.mhlw.go.jp/english/topics/food/sec01.html

13 www.s.affrc.go.jp/docs/sentan/guide/edevelp.htm

Thailand

Thailand was the first country in Southeast Asia to allow field trials to be conducted but in 2000 a *de facto* moratorium on field trials was imposed. More recently, there are reports that the government is prepared to allow field trials to be conducted again. At the same time, Thailand has an established policy that import of agricultural commodities with biotechnology traits for food or feed use is permitted unless the trait is on their "negative" list. To date, only the Starlink trait is on their negative list.

Thailand has an extensive domestic investment in the development of plant biotechnology and is in the advanced stages of developing virus-resistant papaya.

THE FUTURE

Industry has invested heavily in genomic research to identify important structures and functions of genes in plants and other sources. The result of this research will be manifested in two different development pathways. In one pathway, there is continued work using recombinant DNA technology to either transfer important genes from other sources to the plant system of interest or to enhance or silence genes which already exist in the plant of interest. On the other pathway, increased understanding of the structure and function of genes in plants will allow the use of molecular markers to greatly enhance the capabilities of conventional plant breeding so that desired traits which already exist in plants can be enhanced much more efficiently without using recombinant DNA techniques.

Monsanto estimates that combining genomic and breeding can increase yields in corn, soy and cotton by 15 percent above current yield improvement trends. Areas being covered by genomic research in Monsanto related to yield include photosynthesis, seed development, plant morphology, nutrient utilization and harvestability. In the area of quality traits, research targets include starch and carbohydrate content, lipids and oils, and protein content and distribution. In the area of plant stress, targets include heat tolerance, drought tolerance, cold tolerance and nutrient conversion. Research on disease and insect tolerance is also advancing.

This investment in research for the future is already starting to show exciting promise at Monsanto. Monsanto has already demonstrated improvements in photosynthesis in *Arabidopsis* and in soybeans, improved nutrient utilization in *Arabidopsis* and stress tolerance in *Arabidopsis* and rice. In the area of insect tolerance a new product, Yieldgard root worm, is scheduled to be launched in the United States in 2003 and will create enormous benefits for farmers and the environment.

In the area of quality traits, corn has been developed with high levels of lysine, with a potential for lower costs and increased efficiency of animal feeds. Work is ongoing both at Monsanto and in Renessen, a joint venture between Monsanto and Cargill, for products with better food oils, improved protein and other nutritional enhancements. A major target of this effort is the development of crops with enhanced levels of omega 3 fatty acids, a trait which has been demonstrated to dramatically reduce cardiovascular risk.

CONCLUSION

In conclusion, it is clear that plant biotechnology is an important tool which can have significant impact on our ability to produce not only more food but higher quality food. Plant biotechnology products currently on the market have exceeded expectations in the benefits they provide and the future promise of yield enhancements and quality traits is within our grasp. The science is ready and the need is clear.

It is a fact of life that this technology has become a subject of a sometimes highly polarized and emotional debate which in many cases is a symptom of much more significant underlying social concerns such as globalization and the influence of multinational companies.

I would like to leave you with the thought that there are valid areas for debate and concern and that, like every other technology, biotechnology is neither inherently good nor inherently bad. The keys to successfully reaping the benefits of biotechnology and avoiding possible pitfalls will be open dialog, transparency of regulatory systems, recognizing the difference between scientific fact and hypothetical risks and recognizing the need to address legitimate socioeconomic concerns.

2. PRODUCTION OF GM FOODS/PRODUCTS: IMPLICATION ON FOOD SAFETY

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INTRODUCTION

What Are GM Foods

Genetically modified (GM) foods can be defined as foods containing or derived from organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". The technology allows selected individual genes to be transferred from one organism into another, also between non-related species. Such methods are used to create GM plants, which are then used to grow GM food crops, from which GM foods are produced or derived. There are no GM food crops currently marketed that were developed using genetic material from animal sources. Currently available GM food crops were developed using genetic material from plants, bacteria and plant-specific viruses.

Why Are GM Foods Produced

There are several kinds of reasons for developing and for producing GM foods. One proposed is to solve the divined food crisis. The global population was only approximately 1.6 billion in 1900. At the beginning of this century, this number has surged to six billion and the United Nations estimates that it will reach 10 billion in 2030. Farmers and plant breeders have relied for centuries on crossbreeding, hybridization and other genetic modification techniques to improve the yield and quality of the crops that produce our food and to provide crops with built-in protection against insect pests, plant viruses and other disease-causing organisms. Unfortunately, these processes are often costly, time-consuming, inefficient and subject to significant practical limitations. The tools of modern biotechnology allow plant breeders to select single genes that produce desired traits and move them from one plant to another. The process is far more precise and selective than traditional breeding in which thousands of genes of unknown function are moved into our crops. Modern biotechnology also removes the technical obstacles to moving genetic traits between plants and other organisms. This opens up a world of genetic traits to benefit food production.

What Are the GM Foods Produced

The global area of transgenic or GM crops for 2001 is 52.6 million ha, grown by 5.5 million farmers. 2001 is the first year when the global area of GM crops has exceeded the historical milestone of 50 million ha. During the six-year period, 1996-2001, global area of transgenic crops increased more than 30-fold, from 1.7 million ha in 1996 to 52.6 million ha in 2001.

In 2001, four principal countries grew 99 percent of the global transgenic crop area. The U.S.A. grew 35.7 million ha (68 percent of the global total), followed by Argentina with 11.8 million ha (22 percent); Canada, 3.2 million ha (6 percent); and China, 1.5 million ha (3 percent). China had the highest year-on-year growth with a tripling of its *Bacillus thuringiensis* (*Bt*) cotton area from 0.5 million ha in 2000 to 1.5 million ha in 2001. A growth rate of 18 percent applied to both the U.S.A. (equivalent 5.4 million ha) and Argentina (1.8 million ha) with Canada at 6 percent or 0.2 million ha.

Globally, the principal GM crops in 2001 were GM soybean occupying 33.3 million ha (63 percent of global area), followed by GM corn at 9.8 million ha (19 percent), transgenic cotton at 6.8 million ha (13 percent), and GM canola at 2.7 million ha (5 percent). During the six-year period (1996-2001), herbicide tolerance has consistently been the dominant trait with insect resistance second. In 2001, herbicide tolerance, deployed in soybean, corn, and cotton, occupied 77 percent or 40.6 million ha of the global GM 52.6 million ha, with 7.8 million ha (15 percent) planted to *Bt* crops, and stacked genes for herbicide-tolerance and insect resistance deployed in both cotton and corn occupying 8 percent or 4.2 million ha. The global adoption rates for the four principal GM crops (soybean, cotton, canola, and corn) are important indices of modern biotechnology application in agriculture and food production. In 2001 on a percentage basis, 46 percent of the 72-million ha of soybean and 20 percent of the 34-million ha of cotton planted globally were transgenic. The areas planted to transgenic canola were 11 percent of the 25-million ha, and that of corn, 7 percent of the 140-million ha.

ISSUE ON GM FOOD SAFETY

UN Statement on the Use of GM Foods As Food Aid in Southern Africa

Although GM crops have been planted and consumed for several years, a statement on 27 August 2002 made by the FAO on behalf of the UN urging governments to think carefully before rejecting food aid containing Genetically Modified Organisms (GMOs) in southern Africa where 13 million people may well be seriously damaged as a result of the current food crisis came to worldwide attention. Although some asserted this issue of GM food aid is a concern of food safety, in fact, it relates to food trade other than food safety. The major concern of receiving governments in southern Africa is that if the donated corn kernels are planted by farmers accidentally or intentionally, the corn may pollinated local corn plants. This could lead to the new genetic material being introduced into the local corn varieties, including any crops grown for export or used in animal feed for livestock intended for export. These governments are concerned that once the current food deficit is overcome, and trade might resume, that the exporting market may unilaterally bar their corn or corn-fed animal exports. The UN statement advised those governments in the issue consider carefully the severe and immediate consequences of limiting the food aid available for millions so desperately in need. Finally, the Governments of Malawi, Mozambique and Zimbabwe have agreed to accept UN food aid of corn on the condition that it is milled prior to distribution, but Zambia continues to reject any food aid donations containing GMOs. The followings are some excerptions of the UN statement:

1. The UN is extremely concerned about the unfolding humanitarian crisis in southern Africa. The FAO and the World Food Programme (WFP) estimate that 13 million people will need food assistance in the coming months to avoid widespread starvation and a dramatic deterioration in health and nutritional status of the population in the affected countries.
2. WFP has received donations of foods for use in southern Africa, some of which contain GMOs. Several governments in southern Africa have accepted these donated foods without reservation and GM maize varieties are grown in the region. However, other governments have expressed reservations on receiving food aid containing GMOs and have sought advice from the UN.
3. There are no existing international agreements yet in force with regard to trade in food or food aid that deal specifically with food containing GMOs. It is UN policy that the decision with regard to the acceptance of GM commodities as part of food aid transactions rests with the recipient countries and that is the case in southern Africa. It is WFP policy that all donated food meet the food safety standards of both the donor and recipient countries and all applicable international standards, guidelines and recommendations.
4. With respect to GM maize, soy flour and other commodities containing GMOs, FAO and WHO are confident that the principal country of origin has applied its established national food safety risk assessment procedures. FAO and WHO have not undertaken any formal safety assessments of GM foods themselves. Donors to the WFP have fully certified that these foods are safe for human consumption.
5. Based on national information from a variety of sources and current scientific knowledge, FAO, WHO and WFP hold the view that the consumption of foods containing GMOs now being provided as food aid in southern Africa is not likely to present human health risk. Therefore, these foods may be eaten.

The organizations confirm that to date they are not aware of scientifically documented cases in which the consumption of these foods has had negative human health effects.

Brazil Nut Allergen in GM Soybeans

Soybeans and other legumes are an important source of protein in human and animal diets, but are deficient in the essential amino acid methionine. To improve the nutritional quality of soybeans, researchers at Pioneer Hi-Bred International developed a line of GM soybeans that produces a methionine-rich protein from Brazil nuts.

Because Brazil nut is a known food allergen, Pioneer investigated the potential of increased allergenicity in the new soybean, as recommended by the U.S. Food and Drug Administration (FDA). Using blood and skin-prick tests, the researchers determined that at least some persons with a hypersensitivity to Brazil nut were also allergic to the genetically engineered soybean.

Although this variety was developed primarily for animal feed, Pioneer felt that it could not adequately prevent these soybeans from entering the human food supply, and as a result of these tests, Pioneer never marketed this line of soybeans.

This case clearly shows that although the technique of modern biotechnology is powerful, the safety of a GM food should be carefully assessed before put it onto the market. Especially, the company or institution which conducts the research and product development bears the primary responsibility to ensure the engineered GM food is safe for consumption, and the responsible government agencies should set prudent regulations for the industry to comply.

Adverse Effects of GM Potatoes on Rats

In 1998, result of a research work at the Rowett Research Institute went to public after a TV interview of the researcher who pointed out that GM potatoes containing a lectin gene from the plant snowdrop affected the development of organs or metabolism, as well as the immune system of rats in the feeding trials. That news immediately caused concerns of the public and controversy among scientists. Later in 1999, the Royal Society reviewed all available data related to work at the Rowett Research Institute on the possible toxicity of GM potatoes and concluded that it was not the case and no meaningful conclusion should be drawn from that study. Four points were indicated by the Royal Society regarding the GM potato issue as follows:

1. The safety of GM plants is an important and complex area of scientific research and demands rigorous standards. However, on the basis of the information available to us, it appears that the reported work from the Rowett is flawed in many aspects of design, execution and analysis and that no conclusions should be drawn from it.
2. We found no convincing evidence of adverse effects from GM potatoes. Where the data seemed to show slight differences between rats fed predominantly on GM and on non-GM potatoes, the differences were uninterpretable because of the technical limitations of the experiments and the incorrect use of statistical tests.
3. The work concerned one particular species of animal, when fed with one particular product modified by the insertion of one particular gene by one particular method. However skillfully the experiments were done, it would be unjustifiable to draw from them general conclusions about whether GM foods are harmful to human beings or not. Each GM food must be assessed individually.
4. The whole episode underlines how important it is that research scientists should expose new research results to others able to offer informed criticism before releasing them into the public arena.

Allergenicity of GM Corn (StarLink)

StarLink^{TM} corn contains the new protein Cry9c, genetically modified from the *Bt* sub-species *tolworthi* bacteria. This protein has pesticidal properties and was genetically inserted into StarLink^{TM} corn to protect the crop against several insects, including the European corn borer, the cornstalk borer, and the corn earworm. In May 1998, the U.S. Environmental Protection Agency (EPA) granted a limited license for the production of StarLink^{TM} corn. The license proscribed that this corn variety was to be grown only for animal feed, industrial non-food uses, and seed increase. EPA did not license StarLink^{TM} corn for use in food intended for human consumption because the Cry9c protein shared several molecular properties with proteins that are known food allergens. Despite the EPA ruling, Cry9c-DNA was detected in taco shells in September 2000. This discovery caused several food distributors to recall implicated product lines. Following the media coverage of the food product recalls, FDA began receiving reports of adverse health events from consumers who had eaten food products containing corn. As a result, the U.S. Centers for Disease Control and Prevention (CDC) was requested by the FDA to conduct an epidemiological investigation and a research study to assess potential public health hazards from the inadvertent release of GM corn into the human food supply. The focus of the study was to evaluate the potential for allergic reactions among consumers of corn-containing food products.

In 11 June 2001 CDC published a report titled "*Investigation of Human Health Effect Associated with Potential Exposure to Genetically Modified Corn*". Included in the investigation were: (1) reviewing the adverse event reports (AERs); (2) administering questionnaires to all people who experienced adverse health effects and manifested signs and symptoms consistent with allergic reaction; (3) obtaining relevant medical records; and (4) collecting serum samples for temporary banking. The report concluded that 28 people had experienced apparent allergic reactions. These people had also reported eating corn products that may have contained Cry9c protein. However, after laboratory assay using an Enzyme-linked Immunosorbent Assay (ELISA) method developed by an FDA laboratory to detect antibodies to the Cry9c protein, none of the CDC-submitted samples including serum samples (17) from the affected people, historically banked serum samples (21) collected before Cry9c entered the food supply and serum samples (6) from people identified as being highly sensitive to a variety of allergens reacted in a manner consistent with an allergic response to the Cry9c protein.

CDC finally concluded in the report that these findings do not provide any evidence that the reactions those the affected people experienced were associated with hypersensitivity to the Cry9c protein. The difficulties of this investigation highlight the importance of evaluating the allergic potential of GM foods before they become available for human consumption.

INTERNATIONAL REGULATIONS

Codex Alimentarius Commission (CAC)

The CAC is an intergovernmental body established in 1962 by FAO and WHO to implement the Joint FAO/WHO Food Standards Programme. The purposes of the Programme are: (1) to protect the health of consumers; and (2) to ensure fair practices in the food trade. It currently has 165 member governments, representing over 98 percent of the world's consumers.

In the past, the documents prepared by the CAC whether in the form of "standards", "guidelines" or "recommendations" are only suggestive because it possesses no legal authority over national governments. Greater importance was conferred on the Codex texts since 1995 with the establishment of the World Trade Organization (WTO). The WTO uses the standards, guidelines and recommendations of the Codex as reference points.

World Trade Organization

The WTO was established in 1995. It is the most important international organization dealing with the rules of trade between nations. It has 144 member economies at the time of 1 January 2002. The WTO's functions are: (1) administering WTO trade agreements; (2) forum for trade negotiations; (3) handling trading disputes; (4) monitoring national trade policies; (5) technical assistance and training for developing countries; and (6) cooperation with other international organizations. At its heart are the WTO Agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments.

Two important WTO Agreements mostly related to GM foods and products are discussed in this paper. They are: (1) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures; and (2) Agreement on Technical Barriers to Trade (TBT).

The SPS, which concerns food safety and animal and plant health, spells that WTO members have the right to take SPS measures necessary for the protection of human, animal or plant life or health. But those measures must be applied only to the extent necessary and must be based on scientific principles. The Agreement also states that SPS measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of the SPS. In addition, the SPS explicitly mentioned the CAC is the international organization for developing food standards, guidelines and recommendations. Since regulation on GMOs should conform to the provisions of scientific basis, there have no disputes discussed in the SPS Committee on this regard. However, the situation in TBT Committee is different.

According to the TBT, members of the WTO shall ensure that technical regulations are not prepared, adopted or applied with the effect of creating unnecessary obstacles to international trade, and also that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective. Further, it states that such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; and protection of human health or safety, animal or plant life or health, or the environment. The key point often interpreted differently is the legitimate objective of preventing deceptive practices. Some argued that the prevention of deceptive practices based on consumer protection means the right of the consumers to know the specification and method of production of the products they buy or consume. Consequently, there have been in the TBT Committee continued discussions on the mandatory labeling requirements for GMOs ever since the EU imposed such regulation on its trading partners.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The Cartagena Protocol on Biosafety, basically an environmental treaty that regulates trans-boundary movements of Living Modified Organisms (LMOs), was adopted on 29 January 2000. It has not entered into force yet. GM foods are within the scope of the Protocol only if they contain LMOs that are capable of transferring or replicating genetic material. The cornerstone of the Cartagena Protocol on Biosafety is a requirement that exporters seed consent from importers before the first shipment of LMOs intended for release into the environment. However, the decision of the importing country to reject the shipment does not need scientific certainty based on a precautionary approach. Besides, there are conflicting statements in the preamble of the Protocol, such as: (1) this Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreements; and (2) the above recital is not intended to subordinate this Protocol to other international agreements. Based on the example of rejecting GM food aid in the southern Africa mentioned earlier, the effect of this Protocol on the production and trade of GM foods needs deliberatively watched.

RISK ANALYSIS AND SAFETY ASSESSMENT IN FOOD DERIVED FROM MODERN BIOTECHNOLOGY

Codex Intergovernmental Task Force on Foods from Biotechnology (CCFBT)

The CCFBT was established by a decision of the CAC at its 23rd session in 1999 and Japan is the hosting government. It has held meetings in 2000, 2001 and 2002 to discuss and draft the "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" (Principles) and the "Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants" (Guideline). Both drafts are at step 8 of the elaboration procedure and expected to be adopted at CAC's 25th session in 2003. This work has resulted in an improved and harmonized framework for the risk assessment of GM foods. Some key points of the Principles and the Guideline are extracted as follows:

1. ***Principles***

The purpose of these Principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. These Principles, however, do not address environmental, ethical, moral and socioeconomic aspects of the research, development, production and marketing of these foods. The risk analysis process should follow a structured approach comprising the three distinct but closely linked components, i.e., risk assessment, risk management and risk communication, which are briefly described below:

a. *Risk Assessment*

Risk assessment includes a safety assessment which compares between the food (a whole food or a component thereof) derived from modern biotechnology and its conventional counterpart regarding: (1) intended and unintended effects; (2) new or altered hazards; and (3) changes in key nutrients. If a new or altered hazard, nutritional or other safety concern is identified, the risk associated with it should be characterized to determine its relevance to human health.

b. *Risk Management*

Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, taking into account other legitimate factors and the uncertainties identified in the risk assessment. Risk management measures may include, as appropriate, food labeling, conditions for marketing approvals and post-market monitoring. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring.

c. *Risk Communication*

Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers. The processes of risk communication should be fully documented at all stages and responsive consultation should be included.

2. ***Guideline***

This Guideline supports the Principles. The safety assessment of a food derived from a recombinant-DNA plant follows a stepwise process of addressing relevant factors that include: (1) description of the recombinant-DNA plant; (2) description of the host plant and its use as food; (3) description of the donor organism(s); (4) description of the genetic modification(s); (5) characterization of the genetic modifica-tion(s); (6) safety assessment; and (7) other considerations.

The safety assessment listed above should contain: (1) the possible toxicity of expressed substances (non-nucleic acid substances); (2) the possible allergenicity of expressed substances; (3) compositional analyses of key components; (4) evaluations of metabolites; (5) effects of food processing; and (6) nutritional modifications. As to other considerations in the Guideline, they are: (1) the potential accumulation of substance significant to human health; (2) the use of antibiotic resistant marker genes; and (3) review of safety assessment.

CONCLUSIONS

As the U.K. national academy of science, the Royal Society published a report in 1998 entitled "*Genetically Modified Plants for Food Use*", which concluded that the use of GM plants had the potential to offer benefits in agricultural practice, food quality, nutrition and health, but that there were several aspects of GM technology that required further consideration. In 2002, the Royal Society published an updated report focusing on the effects that GM foods might have on human health.

This new policy document, "*Genetically Modified Plants for Food Use and Human Health – An Update*", beside some suggestions on continued research and broadened public debate, stated that there is at present no evidence that GM foods cause allergic reactions, that the risks to human health associated with the use specific viral DNA sequences in GM plants are negligible, and also that the ingestion of GM DNA has no effect on human health.

In October 2002, the WHO also published a document named "*20 Questions on Genetically Modified (GM) Foods*". To the question of "are GM food safe?", it clearly stated that GM foods currently available on the international market have passed risk assessments and are not likely to present risks for human health. It indicated further that no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved. In spite of this, it also suggested that continuous use of risk assessments based on the Codex principles, including post-market monitoring, is indispensable and important for assuring the safety of GM foods. At last, regarding the improvement of evaluating GM foods, the document stated that modern technologies must be thoroughly evaluated and such evaluations must be holistic and all-inclusive, which should consider not only safety but also food security, social and ethical aspects, access and capacity building.

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3. ENVIRONMENTAL IMPACTS OF GM CROPS: ASSESSING THE RISKS OF APPLICATION OF COAT-PROTEIN GENE TRANSGENIC PAPAYA IN TAIWAN

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INTRODUCTION

Papaya (*Carica papaya* L.) is widely planted in tropical and subtropical areas. The fruit can be harvested 8-10 months after transplanting plants in the field, and fruits can be harvested continually year-round under normal conditions. A destructive disease caused by *papaya ring spot virus* (PRSV) (Purcifull, *et al*., 1984) is a major obstacle to large-scale commercial production of papaya (Yeh and Gonsalves, 1994). PRSV is a member of the genus "*potyvirus*", the largest and economically most important plant virus genus and is naturally transmitted by aphids in a nonpersistent manner. PRSV was first recorded in southern Taiwan in 1975 and it has destroyed most of the papaya production in commercial orchards since then (Wang, *et al*., 1978; and Yeh and Gonsalves, 1994). Several control measures have been used to protect papaya seedlings from PRSV infection, including selection of planting time to avoid the peak of winged aphids, intercropping with barrier crops such as corn, application of mild strain for cross-protection, and growing papaya under netting. None of these control methods, except netting, provided a long period of effective protection against PRSV. Raising papaya under a large net house is extremely costly and it is very vulnerable to natural risks such as tropical storms. However, because of the high economic returns, this method is widely used in Taiwan by papaya growers.

Genetic resistance to PRSV has not been found within *C. papaya* (Conover and Litz ,1978; and Mekako and Nakasone, 1975). Although tolerant selections of papaya have been described, they are not commercially desirable (Conover, 1976; and Conover and Litz, 1978). Two mild strains, HA 5-1 and HA 6-1, of PRSV (Yeh and Gonsalves, 1984), derived from nitrous-acid induction of a Hawaii severe strain HA (Gonsalves and Ishii, 1980), provided a high degree of cross-protection in papaya against infection of PRSV HA under greenhouse and field conditions (Wang, *et al*., 1987; and Yeh and Gonsalves, 1984). The use of cross-protection as a control measure has become a routine practice in Taiwan since 1985 (Wang, *et al*., 1987; and Yeh, *et al*., 1988). However, under greenhouse conditions, high degrees of protection (90-100 percent) against HA were observed (Yeh and Gonsalves, 1984), but relatively lower protection rates (50-60 percent) were obtained when these mild strains were used to protect papaya against the severe strains from Taiwan (Wang, *et al*., 1987). This strain-specific protection restricts the usefulness of the mild strains in Taiwan and other areas of the world outside of Hawaii (Yeh and Gonsalves, 1994).

The concept of parasite-derived resistance (PDR) proposed by Sanford and Johnson (Sanford and Johnson, 1985) suggests that expressing genetic materials of a pathogen in a host would disrupt the essential pathogenic processes and hence result in resistance to the pathogen. Powell-Abel, *et al*. (1986) demonstrated that the transgenic tobacco plants expressing the coat protein (CP) gene of *tobacco mosaic virus* (TMV) conferred the resistance to TMV infection. Using this approach, the CP gene of the mild strain, PRSV HA 5-1, was engineered and transferred to tobacco plants, which showed delay and attenuation in symptom development when challenged with other unrelated potyviruses (Ling, *et al*., 1991). Fitch, *et al*. (1992) successfully incorporated the CP gene of HA 5-1 into papaya via microprojectile bombardment and obtained plants that were resistant to infection by the severe Hawaii HA strain (Fitch, *et al*., 1992). Among their transgenic papaya lines, the line 55-1 was virtually immune to infection by HA (Fitch, *et al*., 1992). In addition, when the R1 plants of the line 55-1 were tested against 12 isolates of PRSV from different areas of the world, they were essentially effective against only the local Hawaii strain (Tennant, *et al*., 1994). As observed for classical cross-protection, the strain-specific resistance of transgenic line 55-1 suggests that it can provide a promising way for the control of PRSV in Hawaii, but may not be effective in many regions outside of Hawaii.

GENERATION OF BROAD-SPECTRUM RESISTANCE TO DIFFERENT GEOGRAPHIC STRAINS OF PRSV IN CP GENE TRANSGENIC PAPAYA

Recently, we have developed an efficient method for generating transgenic papaya carrying the CP gene of a severe PRSV strain from Taiwan, by liquid-phase wounding of embryogenic tissues with carborundum (Cheng, *et al*., 1996) followed with *Agrobacterium*-mediated transformation. With this method, the CP gene of a local strain isolated from Taiwan, designated PRSV YK, was transferred into papaya. A total of 45 putative transgenic lines were obtained and the presence of the transgene in papaya was confirmed by polymerase chain reaction (PCR) amplification. When the plants of transgenic lines were challenged with PRSV YK by mechanical inoculation, they showed different levels of resistance ranging from delay of symptom development to complete immunity. Molecular analysis of nine selected lines that exhibited different levels of resistance revealed that the expression level of the transgene is negatively correlated with the degree of resistance, suggesting that the resistance is manifested by a RNA-mediated mechanism. The segregation analysis showed that the transgene in the immune line 18-0-9 has an inheritance of two dominant loci and the other four highly resistant lines have a single dominant locus. Seven selected lines were further tested for resistance to three PRSV heterologous strains that originated in Hawaii, Thailand and Mexico. Six of the seven lines showed varying degrees of resistance to the heterologous strains, and one line 19-0-1 was immune not only to the homologous YK strain but also to the three heterologous strains. Thus, these CP-transgenic papaya lines with broad-spectrum resistance are considered having a great potential to be applied in Taiwan and other geographic areas for control of PRSV.

FIELD EVALUATION OF THE CP GENE TRANSGENIC PAPAYA LINES

Four transgenic papaya lines expressing the CP gene of PRSV were evaluated under field conditions for their reactions to infection by PRSV and for fruit production. Test plants were exposed to natural inoculation by aphids in two different locations and planting periods. The first trial started from September 1996 and the second from November 1996. In the first trial, the control plants were 100 percent infected with PRSV five months after planting, while all plants of test lines 16-0-1, 17-0-1 and 17-0-5 displayed a high level of resistance without any severe symptoms 18 months after planting. In the second trial, which was under a severe challenge pressure, the controls were completely infected with PRSV three months after planting, while the transgenic lines 16-0-1, 17-0-5 and 18-2-4 showed a similar result as the first trial. In the third trial, under the unfavorable conditions, 70-80 percent of transgenic papaya revealed severe mottling on leaves and stunting in plant growth. Therefore, we ceased the trial six months after planting. However, in the fourth trial, under a good field condition including supplement fertile and fungicide protection, transgenic plants exhibited a high level resistance to PRSV the same as in the first and second trials. In the first and second trials, 20-30 percent plants of each transgenic line were found infected with PRSV and they exhibited mild symptoms of confined mottling or chlorotic spots on leaves, however, no apparent adverse effects on fruit production and fruit quality were noticed. The numbers of plants with the mild symptoms fluctuated according to season and weather conditions, with a tendency to increase in winter or in rainy season and decrease in summer. In the first trial, total fruit yields of each line harvested for nine months showed a 2.5- to 2.8-fold increase as compared to controls and the commercially valuable fruits a 10.8- to 11.6-fold increase. Total fruit yields in the second trial of each line harvested for six months showed a 3.0- to 3.2-fold increase, and the commercially valuable fruits a 54.3- to 56.7-fold increase. These results indicated that the CP-transgenic papaya lines have a great potential for control of PRSV in Taiwan.

IDENTIFICATION OF PRSV STRAINS CAPABLE OF BREAKING TRANSGENIC RESISTANCE

To investigate the divergence of viruses infecting papaya, 18 virus isolates were collected from different areas of Taiwan and analyzed by host reactions, serology, and heteroduplex mobility assay. When tested by enzyme-linked immunosorbent assay (ELISA) using the antiserum to PRSV, all isolates were strongly positive except the DL1 isolate collected from Dalee, which was negative. When analyzed by reverse transcription (RT)-PCR using a specific primer pair designed from the CP gene of PRSV, a 0.82-kbp fragment was amplified from all isolates except the DL1 isolate. The divergence of the 0.82 fragments amplified from the 17 isolates was further analyzed by heteroduplex mobility assay by reannealing them with that amplified from the strain YK, a prevalent mosaic type of PRSV in Taiwan. The heteroduplexes of 5-19 and TD2 migrated significantly slower than the homoduplexes, indicating that they are PRSV strains diversified from YK. Among the 18 isolates, four (5-19, CY4, TD2, and DL1) were able to break down the transgenic resistance of papaya lines carrying the CP gene of PRSV and caused symptoms on the non-transformed papaya plants different from those induced by the strain YK. The DL1 isolate was further identified as *papaya leaf distortion mosaic virus* (PLDMV) for it reacted strongly with the antiserum to the Okinawa isolate of PLDMV in ELISA. The potential threats of the transgenic resistance-breaking PRSV strains and PLDMV to the application of PRSV CP-transgenic papaya lines in Taiwan are discussed.

IDENTIFICATION OF A NEW *PAPAYA LEAF DISTORTION MOSAIC VIRUS* CAPABLE OF BREAKING TRANSGENIC RESISTANCE

The virus isolate was collected from an open papaya orchard located at DaLee, Taichung county, in the central area of Taiwan. This isolate, designated as DL isolate, did not react with the antiserum of PRSV CP in ELISA. Papaya plants infected with the DL isolate displayed severe distortion on fully expanded leaves, shoestringing on newly emerged leaves, stunting in apex, and water-soaking on petioles and stems. Because no local-lesion hosts were available, the pure line of the isolate was obtained by limiting dilution. Electron microscopy analysis revealed that filamentous particle of about 800 nm and cytoplasmic inclusions including pinwheels, scrolls, and laminated aggregates were present in infected cells. In the host range tests, the virus only infected *Carica papaya* L., but did not infect other 18 species inoculated. Using RT-PCR with the primers specific to potyviruses, a DNA fragment of 2.0-kb which contained the terminal region of this isolate was amplified, cloned, and sequenced. A long open reading frame (ORF) encoding a polypeptide of 572 amino acids was found present in the amplified fragment of 1927 nucleotides. The determined 1927-nucleotide fragment reflected the C-terminal part of the NIb (viral replicase) gene, the complete CP gene, and the 3'n non-coding regions of a potyvirus. The results of sequence analyses showed that the DL isolate shares 94.9 percent amino acid identity in the CP gene and 96.2 percent nucleotide identity in 3' non-coding region with those of papaya leaf distortion mosaic potyvirus (Kawano and Yonaha, 1992). Since the DL isolate did not infect cucurbits, it was concluded that the DL isolate is a new pathotype of PLDMV. The DL isolate was further proved to be serological unrelated to PRSV by ELISA with reciprocal tests using antisera produced against each CP of the two viruses. When PRSV CP-transgenic papaya lines were challenged with the DL isolate, it was found that they provide no resistance. This virus is considered as a potential threat to the application of PRSV CP-transgenic papaya in Taiwan.

CONCLUDING REMARKS

The transgenic papaya lines carrying the CP gene derived from the Hawaii isolate demonstrated immunity to HA strains but were susceptible to strains from other areas of the world (Fitch, *et al*., 1992; Tennant, *et al*., 1994, and Gonsalves 1998). Our CP transgenic papaya plants have been tested under greenhouse conditions and in an isolated field in Taiwan Agricultural Research Institute (Yeh, *et al*., 1997). The CP transgenic plants grew well without any other protection measures, but the degree of resistance varied with some factors, such as the stage of the plants, the temperature, and the nutrients, etc. (Yeh, *et al*., 1998). Under greenhouse conditions, the CP-transgenic plants showed different degrees of resistance in different lines, and the different stages of the plants exhibited different degrees of resistance. Owing to the strain-specific resistance, the younger transgenic plants were less resistant to heterologous PRSV strains than older transgenic plants (Bau, 2000).

The virus isolates that were able to break down the CP-transgenic resistance were collected and identified by host reactions and serology, and variation with PRSV YK were analyzed. The results of positive reactions in ELISA indicated that most of the isolates collected were related to PRSV YK strain. However, there existed an apparent diversity in some isolates, because they (5-19, CY4, DT2, and DL1) could infect the CP-transgenic plants. Surprisingly, there was an isolate collected from Dalee (DL1) that showed no serological relationship with PRSV. Thus, our results clearly indicated that the viruses infecting papaya in Taiwan exist in a quite complex situation.

In order to compare the relationships of PRSV isolates with YK strain, Heteroduplex Mobility Assay (HMA) was used for rapid detection of the sequence divergence of the CP genes of quasi species. The heteroduplexes of the isolates 5-19 and TD2 formed with YK strain migrated much slower than the other isolates, therefore the CP gene of the isolate 5-19 was further cloned and sequenced. However, the heteroduplexes formed from the other isolates did not migrate clearly slower, indicating that their CP homology with YK strain was less diverse. The HMA patterns of isolates 4-20, 5-12, and 7-8 were similar and small divergence to YK strain was expected. However, these isolates could break down the CP-transgenic resistance. Thus, it seems that the breakdown in CP-transgenic resistance was not merely dependent on CP sequence homology. Recent reports suggest that the helper component-proteinase (HC-Pro) gene may act as a general pathogenicity enhancer to mediate synergism (Pruss, *et al*., 1997; and Shi, *et al*., 1997) and may also have the capacity to suppress post-transcriptional gene silencing (PTGS) (Anandalakshmi, *et al*., 1998; Brigneti, *et al*., 1998; and Kasschau and Carrington, 1998). Whether the HC-Pro gene of these isolates are responsible for the breakdown of the transgenic resistance remains to be further investigated. Previous studies conducted by our laboratory to illustrate what factors may influence the resistance of the CP-transgenic papaya plants revealed that when the young plants were planted in the test field adjacent to an old diseased orchard, the frequencies of breakdown increased. Other conditions of growth process might also be important, for example, the rainfall, the temperature, the type of soil, the effect of root rot fungi, and the source of nutrient, etc., which may increase the susceptibility to these PRSV isolates.

The DL isolate collected from the central region of Taiwan was found to be serologically unrelated to the antiserum against PRSV CP in ELISA tests. The electron microscopy showed that the DL isolate has the traits of a potyvirus. The DL isolate was also proved to be transmitted by aphids in a non-persistent manner. Host reactions revealed that this isolate infects only papaya, but does not infect *Cucumis metuliferus*, *Chenopodium amaranticolor* and *C. quinoa*. These coupled with the result that the virus could be detected by potyviral specific primer pair Pot1/Pot/2 indicate that the DL isolate is a possible member of potyvirus distinct from PRSV. When DL isolate was tested against the antiserum against PLDMV that was first isolated from Okinawa (Kawano and Yonaha, 1992; and Maoka, *et al*., 1995 and 1996), strong reactions similar to the homologous virus were observed (data not shown). Thus, it was concluded that the DL isolate is a strain of PLDMV, a first record in Taiwan. In the host range test, 19 species of indicator plants except *C. papaya* were not infected by the DL isolate. However, Maoka, *et al*. (1995) reported that the P56 isolate of PLDMV originated from Okinawa not only infects *C. papaya* but also infects several species of cucurbit including *C. metuliferus, C. sativus, C. melo*, and *Cucurbita pepo*, and induced mosaic symptoms on infected plants. Although the DL isolate induced similar symptoms on papaya as those induced by the P56 isolate, the inability of the DL isolate to infect cucurbits that were tested, indicated that the DL isolate is a different pathotype from the P56 isolate of Okinawa.

Kiritani and Su (1999) mentioned that PLDMV had been observed in Taiwan in the mid-1980s, but no details have been described. In this investigation, a PLDMV isolate was identified from central Taiwan and we have shown that our CP-transgenic papaya lines did not provide resistance to PLDMV infection. We speculate that PLDMV has been present in Taiwan for a long time but was neglected under the dominance of PRSV. Therefore, in order to avoid another crisis in papaya production caused by PLDMV, when PRSV CP-transgenic papaya plants are widely used to control the disease caused by PRSV in Taiwan, the establishment of a broad and precise surveillance system to realize the importance and the distribution of PLDMV in Taiwan is currently most crucial.

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4. REGULATION AND POLICY ON GM LABELING AND DETECTION IN JAPAN

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Japan

LABELING SYSTEM

Crops developed by using recombinant DNA (r-DNA) technology are grown in the U.S.A., Canada and some other countries and are widely consumed worldwide in foods. In this circumstance, there has been increasing interest in this technology among consumers. Many in the general public consider the term "genetically modified (GM)" to be a mysterious one and feel worried about the introduction of GM technology. This article attempts to find the reasons for this anxiety and confusion and to suggest some ways to relieve and resolve them (Hino, 2002). Municipal assemblies have gathered more than 1,200 demands to the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) on the necessity for public information and appropriate labeling of GMO (genetically modified organism) foods. Japan, as well as some other countries and international organizations, are studying the possibility of establishing a new labeling system for these foods.

In Japan, MAFF organized discussions among consumers, food industries, cooperative societies, mass media and scientists, who presented a report on the distribution of GMO foods taking account the possibility of scientific verification of GMOs in commercialized GMO crops and processed foods using them and the segregated distribution of non-GMO foods. MAFF's discussion on labeling requirements for GMO foods was continued for two and half years and culminated in a report. Based on this report, MAFF issued a notification of the standards for a new labeling system for GMO foods on 31 March 2000 and mandatory labeling has been in force from 1 April 2001 (MAFF). The purpose of the system is to provide information regarding the use of GM technologies and foster consumers' right to select GMO foods. On the other hand, MHLW has also issued a labeling system for GMO foods in view of public health under the Food Sanitation Law. Japanese labeling system for GMO are therefore regulated by two standards, although the subject and contents in the regulations are almost same (MHLW). Labeling is required for any varieties derived from GMO crops that have been assessed for safety by the government, as well as processed foods, which reach general consumers. In this system, foods are classified into three groups: those using GMOs; those using non-GMOs; and those for which GMO use is not segregated during their production/distribution. Labeling is compulsory for foods using GMOs and foods for which GMO use is not segregated, while it is optional for non-GMOs. The foods requiring compulsory labeling are defined as designated foods. Five main crops used as food materials (soybean, corn, potato, rapeseed and cotton) and 30 processed foods, in which DNA remains after processing from soy, maize and potato, have been specified in the Quality Labeling Standards. Agricultural products can be regarded as "non-genetically modified" when it is confirmed that they are treated under "Identity Preserved Handling" in their production/distribution processes. Even if such measures are adopted, unintentional mixing is inevitable. MAFF and MHLW announced that the threshold level of unintended mixing of GMO is 5 percent in case of soy and maize. Therefore, it should not be deemed as false labeling just because some unintended mixing occurs, when proper confirmation has been done. This means that the non-GM designation requires no scientific verification.

Policies for labeling GMO foods differ from country to country. No moves toward compulsory labeling have been made in the U.S.A. and Canada. EU decided to make labeling obligatory but since it has adopted no rules for implementing the labeling system, no voluntary labeling is carried out except in some member countries. The Codex Committee has decided to establish an international food standard system and is now discussing international standards for labeling GMO foods.

The monitoring of GM foods has already been started from 1 April 2001 at Japanese Quarantine Station and Quality Control.

OUTLINES OF JAPANESE LABELING SYSTEM

Purpose of Labeling

To provide information regarding the use of GM technologies and foster consumers' right to select GMO products.

Extent of Labeling

Any varieties derived from GMO crops that have been assessed for safety by the government as well as processed foods which reach general consumers.

Content of Labeling and Implementation

1. ***Classification of Foods Subject to Labeling Regulations***

Foods labeled on genetically modification are classified into three categories, and practical labeling methods are developed for each of them.

- i) For foods intentionally made from agricultural materials which are GM crops, such as "soybean [GM soybean]", etc. ...
- ii) For foods made from agricultural materials which are not segregated from GM varieties, such as "soybean [GM soybean not segregated]", etc. ...
- iii) For foods made from agricultural materials which is segregated from GM varieties, such as "soybean [non-GM soybean]", etc. ...

2. ***Use of the Term "Not Segregated"***

Taking into account that information relevant to consumers' right to choose should be provided effectively and that GM agricultural products are not currently segregated from unmodified products during their production/distribution, indication that the food is not segregated (between transformed product and un-transformed), such as "soybean [GM soybean not segregated], etc. ...", is required as a basic fact.

3. ***Definition of Non-GM Agricultural Product***

Agricultural products can be regarded as "non-GM" when it is confirmed that they are treated under "Identity Preserved Handling" in their production/distribution processes. Even if such measures are adopted, unintentional mixing is inevitable. Therefore, it should not be deemed as false labeling just because some unintended mixing occurs, when proper confirmation has been done.

(*Note*: Identity Preserved Handling is a control method where non-GM agricultural products are treated under segmental control throughout their production/distribution processes, and the proper segmental control is clarified by certificates.)

DETECTION METHODS FOR GMOs

New labeling standards have been in force from 1 April 2001. Most food industries in Japan are now obliged to switch to non-GMO food materials largely to meet demand from retailers and GMOs are excluded from the market because of the general public anxiety about the foods. But it is unavoidable that a certain ratio of GMOs is mixed into farm crops even when they are separately distributed and the ability to detect GMOs at very low levels of mixture is well developed. Because of this, it is considered difficult to label GMO foods without scientific verification and food industries are now embarrassed. Most Japanese food processors are trying hard to secure non-GMO materials, but even if they want to label their products as "non-GM", they cannot avoid mixing of some GMOs when they import materials from the U.S.A. and Canada. Thus they need to test the ratio of mixed GMOs and confirm that the figure is below the predetermined level, which is unintended and inevitable before making such labeling.

Two methods are available to measure the quantity of GMOs in foods and their materials: one of them is to detect the sequence of the DNA used for gene modification by amplifying a specific sequence in the trait genes using the polymerase chain reaction (PCR) method, and the other is the enzyme-linked immunosorbant assay (ELISA) by which the quantity of protein is measured using the antibody of the protein produced by the introduced trait gene. In some cases the same gene, such as cryIA(b) is introduced into different GM maize lines, and the numbers of their copies (number of genes per cell) are different and so the expression level of proteins are different. Then, quantification is extremely difficult and in the case of maize, it is scientifically impossible. Thus there has been an increasing need for a standard analysis method for quantifying GMOs and provision of reference materials. Further, a large number of varieties are bred from a GM event with conventional varieties to produce appropriate varieties in many locations. Consequently, many GM varieties are produced in the U.S.A. and other countries and can be used as positive controls for GM detection. Therefore, it is difficult to prepare appropriate reference materials by mixing of the GM seeds in non-GM seeds. Thus quantification of GMOs is very difficult and there has been an increasing necessity for standardization of quantitative analyses of GMOs and provision of standard GM samples.

Japanese Standard Methods

The National Food Research Institute has developed, as a joint study project with the National Institute of Health Sciences and private sectors, new quantitative detection methods for GM crops and their processed foods which are reliable and practical techniques to quantify GMOs by using real time PCR methods including detection methods and reference materials. The specificity of each primer was compared using PCR to other GM lines and other major crops, such as rice, wheat, barley, maize and soy as template DNA. We newly designed plasmids for reference molecules to quantify a GM soy and five lines of GM maize (Kuribara, *et al*., 2002). The standard molecules include DNA sequences of universal regions, such as CaMV35S promoter and NOS terminator, and the specific regions introduced in each GM lines, which are same as the regions amplified by PCR using above specific primers. Reference materials produced from agricultural products with the major GM line were not necessary and we could obtain stable standard curves to quantify GMOs in samples. Further, the reference molecules have other benefits compared to reference materials prepared from the seeds of maize and soy, since their production is not affected by agricultural factors, such as cultivated area, climate and year, and they are easily amplified in *Escherichia coli* and could be provided indefinitely.

The coefficient values (Cv) which are used to measure the ratio of GMO in samples by the TaqMan-Chemistry, were calculated from the ratio of target and endogenous gene molecules found in the genuine GM seeds (Shindo, *et al*., 2002). The Cv of each GM line was calculated from the standard curve drawn by using of the reference molecule. The GMO amount could be calculated by using the Cv and the ratio of r-DNA and endogenous senquences in unknown samples. We investigated the detection limit, accuracy and precision by using the standard plasmid and Cv. Inter-laboratory tests have also been proceeding in 15 laboratories in Japan and Korea to validate the performance of our quantitative method (Kuribara, *et al*., 2002) for the real-time PCR instruments ABI PRISM 7700 and 5700. The results of these tests showed that the methods are applicable to the specific quantification of five lines of GM maize and one line of GM soy. After statistical treatment for the removal of outliers, the repeatability and reproducibility of these methods at a level of 5.0 percent were less than 13.7 percent and 15.9 percent, respectively. The quantification limits of the methods were 0.5 percent for Bt11, T25, and MON810, and 0.1 percent for GA21, Event176, and Roundup Ready soy. The results of blind tests show that the numerical information obtained from these methods will contribute to practical analyses for labeling systems of GM crops.

We are now developing some analytical methods by application studies of our technology as follows:

1. Applications for other real-time PCR equipments, including the ABI PRISM 7000, 7900 and Roche Light Cycler.
2. Detection methods for GM potato, such as NewLeaf, NewLeaf phis and for GM maize, such as MON863, NK603 and Dow1507.
3. Detection methods for processed foods made from soy and maize.
4. Simple methods for detection of GM crops by using of DNA extraction and a one-tip PCR device.

Other Detection Methods

Methods of detection for GM herbicide tolerant soy (Roundup Ready soy) (Matsuoka, *et al*., 1999), virus-resistant GM papaya, StarLink maize (Matsuoka, *et al*., 2000), and multiplex PCR methods to qualitatively distinguish the five lines of GM maize were developed (Matsuoka, *et al*., 2001; and Goda, *et al*., 2001). By the multiplex method, the *Zel* and the r-DNAs from the five lines of GM maize were qualitatively detected in one tube. The specific PCR bands were distinguishable from each other on the basis of their expected length. The r-DNA could be detected from the maize sample containing 0.5 percent of each of the five lines of GM maize. Furthermore, we developed many PCR primer pairs for the detection of the segments such as promoter and terminator regions, and construct genes, which are used in many GM crops (Matsuoka, *et al*., 2002). EU researchers also report many kinds of detection methods (Koppel, *et al*., 1997; Ehlers, *et al*., 1997; Remund, *et al*., 2001; Hupfer, *et al*., 2000; and Lipp, *et al*., 2000). Since the presence of the corresponding DNA segments were specifically detected in GM crops by the designed primer pairs, we can conclude that this method is useful for fast and easy screening of GM crops including unauthorized ones.

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5. PUBLIC COMMUNICATION: CONSUMER'S PERSPECTIVE OF GMO/GM FOODS

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INTRODUCTION

Nowadays the uses of biotechnology are applied not only in the context of medicine and pharmaceutical developments but also in the field of food production. The latter includes foods produced through bioengineering, such as genetically engineered, genetically modified (GM) or genetically modified organism (GMO) or food derived through recombinant DNA techniques. In general, advanced technology should be able to bring benefits and welfare to people. Goods produced with a more advanced technology are more desirable to the consumer. However, GM foods appear to be not in this category. Increasing debates and uncertainties about the consumption of GMO/GM foods have been raised in many parts of the world. Thus, consumer acceptance plays a key role in marketing GM foods globally.

In order to better understand how consumers think about the GMO/GM foods, both consumer focus groups and public surveys are useful tools. In particular, the information available on consumer perception and knowledge of GMO/GM foods is very limited in comparison to the progress of biotechnology itself. There have been several consumer surveys conducted in Asia (Macer and Ng, 2000 for Japan; Ng, *et al*., 2000 for Japan; Department of Health [DOH], 2000 and 2002 for Taiwan; Chiang and Tsai, 2002 for Taiwan; Chern 2002 for Japan and Taiwan; and Chiang, *et al*., 2002 for Taiwan), the U.S.A. (Hoban, 1999; Hallman and Metcalfe, 2001; Moon and Balasubramanian, 2001; and Mendenhall and Evenson, 2002), and Europe (Boccaletti and Moro, 2000 for Italy; Burton, *et al*., 2001 for UK; Spetsidis and Schamel, 2001 for Germany; and Verdurme, *et al*., 2001 for Belgium).

A multi-country survey project has been conducted in Japan, Norway, Taiwan, and the United States to understand the factors affecting the consumer acceptance of GM foods and to estimate the willingness to pay (WTP) for selected non-GM products (Chern, 2002). In this joint research project, several consumer surveys have been conducted during 2000-02. There were a uniform student survey in the four countries during December 2000 and March 2001 (Chern, 2002), a mail survey of residents in Columbus, Ohio, U.S.A., in March 2001 (Chen and Chern, 2002), a pilot national telephone survey in Norway and the United States in April-May 2002 (Chern and Rickertsen, 2002a), and a pilot notional telephone survey using a revised uniform questionnaire in Taiwan in September 2002 (Chiang, *et al*., 2002 for Taiwan). In this paper, we focus only the results from Taiwan and the United States.

This paper consists of two major sections. The first section provides a comparison of public surveys conducted in Taiwan during the last three years. The second section describes a comparison among public surveys to address the issues and differences of consumer perception and acceptance toward GMO/GM foods between Taiwan and the United States. The specific issues include consumer knowledge about GMO/GM foods, perception of health risk, willingness to purchase GM foods, ethical and religious concerns, and GM labeling issue. A concluding remark section is also included.

COMPARISON OF PUBLIC SURVEYS IN TAIWAN

There were several consumer surveys conducted in Taiwan during the last three years. Two of them were funded by the DOH, ROC and conducted by the Gallup Market Survey Corp., Taiwan in September 2000 and August 2002 (DOH, 2000 and 2002). A total of 1,083 respondents for each survey were interviewed. The objective of these two surveys was to attempt to understand the public perception and attitude toward the GM foods. In addition, the opinion on the mandatory labeling regulation applying to the GM foods was another main issue in the survey. The findings from these two national telephone surveys certainly provided valuable information to the policymakers to develop appropriate policy on the use and regulation of GM foods in Taiwan.

Chiang and Tsai (2002) conducted an interview survey in March 2001 in Keelung city, which is located in the northeastern part of Taiwan and has a population of 0.4 million. The sample included 200 households. In September 2002, a national telephone pilot survey, which is part of a multi-country survey project, was conducted to explore the consumer acceptance and perception of GM foods in Taiwan (Chiang, *et al*., 2002). Three and a half percent of the respondents were vegetarians. The details of questionnaire used in the multi-country survey will be described in the next section. This presentation only covers the above four surveys due to the availability of data and the compatibility of questionnaires.

Table 1 shows the basic information and major demographic questions of the four surveys in Taiwan. The percentage distributions across age, sex, and education are similar in the four surveys although the sizes of the sample are different. The descriptive statistics (in percent) for selected questions from four surveys are shown in Table 2. Results show that 56-75 percent of the respondent had heard of GMO or GM foods before the survey. On average, a quarter of respondents expressed that they are not familiar with the term of GMO/GM foods. In all four surveys, a majority of respondents support a mandatory labeling system. Taiwanese consumer perception of the health risk of GMO/GM foods varies from survey to survey. Over two-fifths of respondents view GMO/GM foods as "risky" and less than 25 percent of respondents rank GMO/GM foods as "very safe", the percentages are higher in DOH's surveys (28.2 and 27.8 percent). In asking the willingness to purchase GMO/GM food items, 50 percent of respondents are at least "somewhat willing" to purchase GMO/GM foods. By comparison, at least 30 percent of respondents are not willing to purchase non-GMO/non-GM foods. Thus, the acceptance level of GM foods varies greatly among consumer surveys in Taiwan. In the last two questions in Table 2 are related to specific knowledge on GMOs. About one-third of respondents answered "false" in both questions and about one-half of respondents indicated "don't know/refused" to the two true-false questions.

It is interesting to examine whether or not the knowledge about GMOs has any effect on the attitude and perception toward GM foods. Figures 1 and 2 present the distributions of the responses to the following questions in the Taiwan public survey: 1) how risky would you say GM foods are in terms of human health?; and 2) how willing are you to consume foods produced with GM ingredients? by answer of "true, false, or don't know", to the following "false" statement: "non-GM soybeans do not contain genes while GM soybeans do".

These figures show that the knowledge has a mixed effect. Those who evaluated the statement correctly are more likely to consider GM foods risky to human health than those who did not answer correctly. However, those who were more knowledgeable about GMOs would be more willing to consume GM foods than those less knowledgeable.

Table 1. Sample Mean Statistics in terms of Percentage Distribution for Selected Demographics from Four Surveys in Taiwan during 2000-02

(Unit: Percent)

Item	Alternative	DOH 2000[a]	Chiang and Tsai[b]	DOH 2002[c]	Chiang, *et al.*[d]
Year/month		2000/1	2001/3	2002/8	2002/9
Survey method		Telephone	Personal interview	Telephone	Telephone
Sample size:		1,083	200	1,083	257
Age	<20	0	2.5	0	0
	20-29	25.2	17.5	23.5	13.6
	30-39	28.6	26.5	24.9	25.3
	40-49	20.6	32.0	21.9	34.6
	>50	25.6	21.5	29.7	24.1
	Refused	0	0	0	2.3
Sex	Male	50.4	43.0	48.5	44.0
	Female	49.6	57.0	51.5	56.0
Education	Elementary	7.1	20.5	14.8	19.5
	Junior high	8.8	14.5	10.4	13.6
	Senior high	29.4	40.5	33.8	35.0
	Junior college	16.7	14.5	18.4	13.2
	College	16.8	8.0	18.7	16.0
	Graduate	3.0	2.0	3.1	2.0
	Refused	18.3	0	0.8	0.8

Sources: [a] Department of Health, 2000, "2000 Surveillance of Public Opinion about GMO in Taiwan", Project Report, conducted by the Gallup Market Survey Corp., 30 September 2000; [b] Fu-Sung Chiang and Chai-Rung Tsai, 2002, "An Analysis of the Effects of Genetically Modified Foods Labeling on Consumer Perception and Behavior", paper presented at the 3rd Empirical Economics Conference, 20-21 April 2002, Nan-Tou, Taiwan (in Chinese); [c] Department of Health, 2002, "2002 Surveillance of Public Opinion about GMO in Taiwan", Project Report, conducted by the Gallup Market Survey Corp., 22 August 2002; and [d] Fu-Sung Chiang, Tsu-Tan Fu and Lee-Jung Lu, 2002, "Analysis of Consumer Perception and Acceptance of Genetically Modified Food in Taiwan", paper prepared for presentation at the 2002 Annual Conference of the Taiwanese Economic Association, December 2002, Taipei, Taiwan (in Chinese).

Table 2. Sample Mean Statistics in terms of Percentage Distribution for Selected Questions from Four Surveys Conducted in Taiwan during 2000-02

(Unit: Percent)

Question	Alternative	DOH 2000	Chiang and Tsai	DOH 2002	Chiang, *et al.*
Before this survey, have you ever heard of the term of GMO?	Yes	68.1	71.0	56.2	74.3
	No	29.6	29.0	41.9	25.7
	Don't know and refused	2.2	0	1.9	0
What type of labeling would you support?	Mandatory	73.5	89.5	88.2	82.9
	Voluntary	8.4	2.0	3.0	5.1
	Don't know and refused	18.1	8.5	8.8	12.0
How safe or risky of GMO or GM foods to human health?	Very risky	20.9	6.3	11.3	7.4
	Somewhat risky	40.7	39.2	46.8	32.7
	Very safe	28.2	18.9	27.8	14.8
	Don't know and refused	10.2	35.7	14.1	45.1*
How willing would you be to purchase GMO or GM foods?	Extremely willing	-	-	-	27.7
	Somewhat willing	-	-	-	22.2
	Unwilling	-	-	-	26.5
	Don't know and refused	-	-	-	23.3
How willing would you be to purchase non-GMO or non-GM foods?	Extremely willing	19.0	27.3	21.1	-
	Somewhat willing	14.9	44.8	21.8	-
	Unwilling	42.7	28.0	42.0	-
	Don't know and refused	23.4	0	15.1	-
Non-GM soybeans do not contain genes while GM soybeans do.	True	-	-	11.0	21.4
	False	-	-	36.3	32.3
	Don't know and refused	-	-	52.7	46.3
By eating GM foods, a person's genes could be altered.	True	-	27	-	49.0
	False	-	29	-	25.3
	Don't know and refused	-	44	-	25.7

Note: * Includes "neither risky or safe".

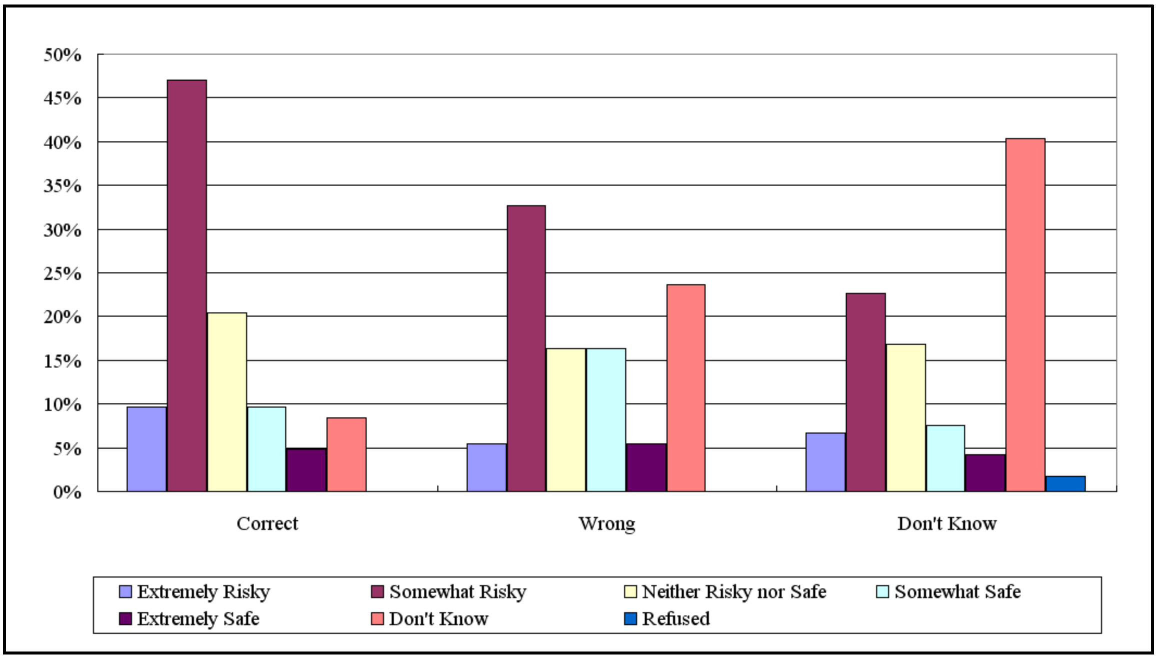

Figure 1. Distribution of Responses to the Question "How Risky Would You Say GM Foods Are in terms of Risk for Human Health? by Answer (True, False or Don't Know) to the Statement "Non-GM Soybeans do not Contain Genes while GM Soybeans Do" from the Taiwan Survey, 2002

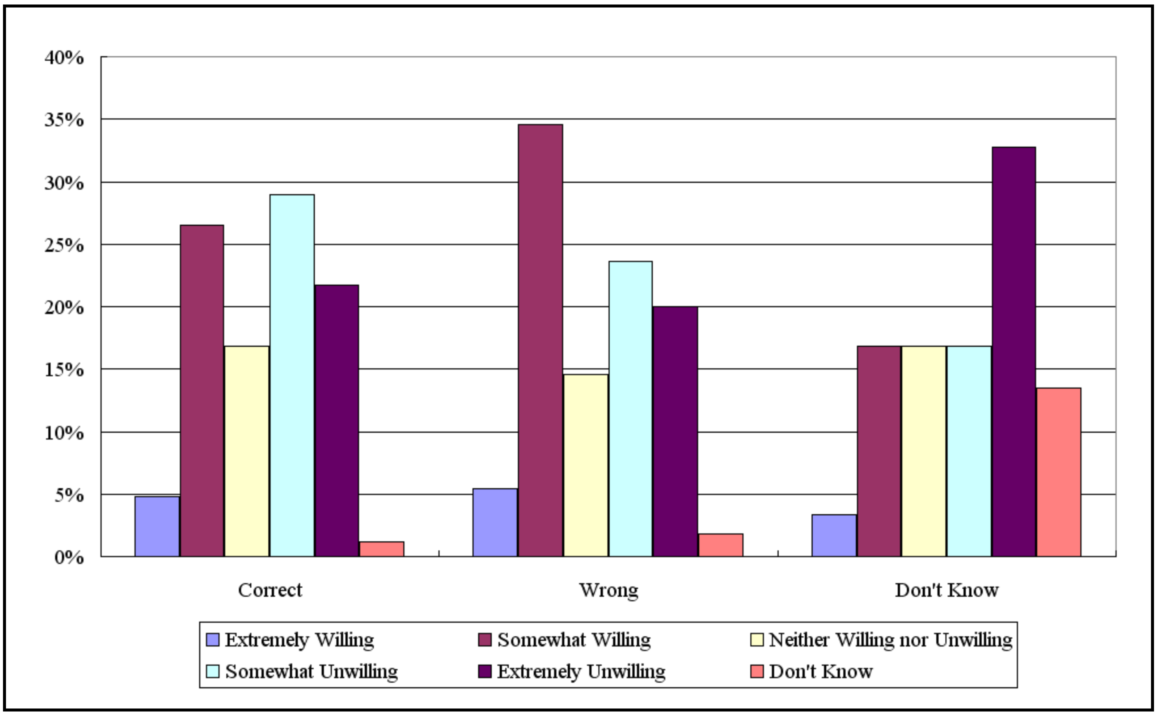

Figure 2. Distribution of Responses to the Question "How Willing Are You to Consume Foods Produced with GM Ingredients?" by Answer (True, False or Don't Know) to the Statement "Non-GM Soybeans Do Not Contain Genes while GM Soybeans Do" from the Taiwan Public Survey, 2002

COMPARISON OF PUBLIC SURVEYS FROM NORWAY, TAIWAN, AND THE United States

Background of the Public Surveys

As mentioned earlier, a joint research project on the consumer acceptance of GM foods has been conducted in Norway, Japan, Taiwan and the United States, in 2002. The project included a pilot national telephone survey in Norway and the United States in April-May 2002 (Chern and Rickertsen, 2002a) and a pilot notional telephone survey using a revised uniform questionnaire in Taiwan in September 2002 (Chiang, *et al*., 2002). The telephone survey questionnaire was developed by the GMO research group at the Ohio State University, U.S.A. The questionnaire used in the national pilot survey in Taiwan was similar to those used in other countries except that some differences in the exact wording in the respective language.

There are five parts in the questionnaire: 1) awareness of GMO/GM foods; 2) perception of GMO/GM foods; 3) GMO/GM food labeling; 4) purchasing preference of three food items (soybean oil, tofu, and salmon); and 5) household demographic information. In the first part, respondent's awareness and knowledge of GMO/GM foods were investigated to obtain information on degree of knowledge about GMO/GM foods. Next, we explored respondent's perceptions and attitudes of GMO/GM foods, such as willingness to consume, reasons not to consume, concerns of environmental impacts and ethical and religious concerns associated with GMO/GM foods. Then several questions related to the labeling of GMO/GM food were asked to probe the respondent's attitude toward the importance of labeling and types of GMO/GM food labeling. Further, a set of price scenarios was given to elicit the respondent's willingness to consume three selected GM food products versus their traditional counterparts. The design of the set of price scenario was based on the market prices of the respective GM and non-GM products. The last part of the survey contained the respondent's demographic and economic information.

Chiang, *et al*. (2002) conducted a pilot telephone survey, which is part of a multi-country survey project, to explore the consumer acceptance and perception of GM foods in Taiwan during 9-11 September 2001. This survey was funded by the National Science Council and conducted by the Office of Survey Research, Academia Sinica. A full scale telephone survey of 1,000 people island-wide will be conducted in early 2003. The public survey results from Taiwan, and the United States can be directly compared by using a uniform questionnaire. In this section, a comparison of public surveys from these two countries is given in the following. Note that in Taiwan and the United States survey we required that the respondents identify themselves as a food shopper in the household. The details of the survey results from the United States are available in Chern and Rickertsen (2002b) and Chern (2002).

Consumer Knowledge about GMO/GM Foods

Table 3 shows the consumer information and knowledge, percentage distribution for selected questions from the public surveys in Taiwan and the United States. Results show that about 8 percent of the respondents considered themselves "very well informed", about 40 percent considered themselves "somewhat informed", and about 44 percent considered themselves "not informed" about GMO/GM foods. The figure of the United States (14.1 percent) differs substantially from Taiwan (1.6 percent). In particular, none of the American respondents replied "don't know". However, a quarter of Taiwanese respondents answered "don't know". In addition to the previous question, two true-false questions were asked to explore the consumer knowledge about GMO/GM foods. They are "non-GM soybeans do not contain genes while GM soybeans do" and "by eating GM foods, a person's genes could be altered", respectively.

The proportion of correct answers of these two knowledge statements can be used to compare with the answers from the previous question to the proportions of uninformed respondents to see whether they correspond well. In addition, respondents can be identified as knowledgeable consumers if they answer both true-false questions correctly. About 43.8 percent of the American and 32.3 percent of the Taiwanese respondents thought it was false that "non-GM soybeans do not contain genes while GM soybeans do". At the same time about 61.3 percent, and 25.3 percent of the American, and Taiwanese respondents, respectively thought it was false that "by eating GM foods, a person's genes could be altered".

Perception of Health Risk

Table 4 shows the consumer attitudes toward GMO/GM foods and percentage distribution for selected questions from the public surveys in Taiwan and the United States in 2002. In total there are eight questions. Perception of health risk of GMO/GM foods varies between the two countries. About 48.9 percent of Americans believed that GMO/GM foods are risky to human health while 40.1 percent of Taiwanese respondents considered they are risky. Among them, 9.4 percent of the Americans thought them extremely risky as compared to only 2.4 percent of Taiwanese respondents. And 20.7 percent of Americans, and 14.8 percent of Taiwanese respondents believed that GMO/GM foods are safe to human health while 17 percent of respondents from two countries answered "don't know". A quarter of the Taiwanese respondents answered "don't know" which is consistent with a higher percentage of unawareness about GMO/GM foods.

Table 3. Consumer Information and Knowledge, Percentage Distribution for Selected Questions from the Public Surveys in Taiwan and the United States, 2002

(Unit: Percent)

Question	Alternative	U.S.A.[a]	Taiwan[b]
Year/month		2002/5	2002/9
Survey method		Telephone	Telephone
Sample size:		250	257
Before this survey, how well were you informed about GM foods or organisms?	Very well	14.1	1.6
	Somewhat	41.0	34.2
	Not informed	44.9	38.5
	Don't know	0	25.7
Non-GM soybeans do not contain genes while GM soybeans do.	True	23.4	21.4
	False	43.8	32.3
	Don't know	32.8	46.3
By eating GM foods, a person's genes could be altered	True	22.3	49.0
	False	61.3	25.3
	Don't know	16.4	25.7

Sources: [a] Chern and Rickertsen, 2002a, Table 3, p. 23; and Chiang, *et al*., 2002, Table 1, p. 19.

Willingness to Purchase GM Foods

Again, the acceptance level of GMO/GM foods differs significantly between the two countries. Only 28 percent of Taiwanese respondents claimed that they are willing to consume foods produced with GM ingredients, the percentage is higher in the United States (43 percent). In the meantime, a higher percentage of Taiwanese (26.5 percent) are "extremely unwilling" to consume GM foods than the United States (16.4 percent) respondents.

However, consumers changed their degree of willingness to consume GM foods when some benefits are associated in the questions, such as the reduced use of pesticides, improved nutritional qualities, and lower prices. In other words, the opposition against GM foods is reduced when benefits are explained. For example, Taiwanese respondents increased their willingness to consume GM foods notably when the reduction of the amount of pesticides applied to crops offered in the question, i.e., from 28 percent to 51.5 percent. Similarly in the United States, the percentages increased from 43 percent to 68.4 percent.

A somewhat higher percentage of respondents from the two countries said that they would be "extremely unwilling" to consume GM foods if they posed a risk of causing an allergic reaction for some people. The majority of Americans (41.4 percent) and Taiwanese respondents (54 percent) were extremely unwilling to take such a risk.

Ethical and Religious Concerns

More than 48.3 percent of Taiwanese respondents indicated that ethical and religious concerns were not important to their decision on consuming GM foods. Only 13.6 percent of Taiwanese respondents considered that these concerns were important as compared to 36.3 percent, in the United States.

GM Labeling Issue

All respondents from the two countries viewed the GM food labeling "extremely important" with a large margin. In other words, the majority of Americans (87.1 percent) and Taiwanese (86.8 percent) consumers demand a labeling system. Results indicate that consumers demand the right to choose between GM or non-GM foods.

Table 4. Consumer Attitudes Toward GMO/GM Foods, Percentage Distribution for Selected Questions from the Public Surveys in Taiwan and the United States, 2002

(Unit: Percent)

Question	Country	Alternatives						
		Extremely (1)	Somewhat (2)	Neither (3)	Somewhat (4)	Extremely (5)	Don't Know	Refused
How risky would you say GM foods are in terms of risk to human health? 1, 2 = risky; and 4, 5 = safe	U.S.A.[a]	9.4	39.5	16.0	15.2	5.5	14.5	0
	Taiwan[b]	7.4	32.7	17.9	10.1	4.7	26.5	0.8
How willing are you to consume foods produced with GM ingredients? 1, 2 = willing; and 4, 5 = unwilling	U.S.A.	4.7	38.3	13.7	23.8	16.4	3.1	0
	Taiwan	4.3	23.7	16.3	22.2	26.5	7.0	0
How willing would you be to consume GM foods if they reduced the amount of pesticides applied to crops? 1, 2 = willing; and 4, 5 = unwilling	U.S.A.	13.7	54.7	9.4	11.3	9.0	2.0	0
	Taiwan	26.5	35.0	16.7	6.2	10.5	5.1	0
How willing would you be to purchase GM foods if they were more nutritious than similar foods that are not GM? 1, 2 = willing; and 4, 5 = unwilling	U.S.A.	18.0	53.9	5.1	9.4	10.9	2.7	0
	Taiwan	26.5	30.4	16.0	10.9	12.1	3.9	0.4
How important is the price factor when you decide whether or not to buy GM foods? 1, 2 = important; and 4, 5 = unimportant	U.S.A.	29.7	37.5	7.0	12.1	12.5	1.2	0
	Taiwan	21.0	25.3	13.3	21.4	16.7	2.3	0
How willing would you be to purchase GM foods if it posed a risk of causing allergic reactions for some people? 1, 2 = willing; and 4, 5 = unwilling	U.S.A.	3.5	21.5	5.9	26.2	41.4	1.6	0
	Taiwan	2.3	12.8	10.5	17.9	54.1	2.3	0
How important are ethical or religious concerns when you decide whether or not to consume GM foods? 1, 2 = important; and 4, 5 = unimportant	U.S.A.	12.5	23.8	15.2	18.0	28.9	1.6	0
	Taiwan	5.8	7.8	3.9	30.4	48.3	3.9	0
How important is it to you that food products are specifically labeled as GM or non-GM? 1, 2 = important; and 4, 5 = unimportant	U.S.A.	58.6	28.5	4.3	5.9	1.6	1.2	0
	Taiwan	81.3	5.5	2.0	2.7	4.3	4.3	0

Sources: [a] Chern and Rickertsen, 2002a, Table 4, p. 24; and Chiang, *et al*., 2002, Table 2, p. 20-21.

CONCLUDING REMARKS

This paper reports the consumer's perspective of GMO/GM foods in using public survey results from Taiwan and the United States. The survey results should be able to provide an understanding of public thinking on GM foods, such as awareness and perception, familiarity with terms, views about labeling, and issues and concerns related to GMO/GM foods in these two countries.

A pilot telephone survey was conducted on 9-11 September 2002. A total of 257 completed interview samples were obtained. This survey was part of a research project attempting to provide a global perspective towards GM foods using a multi-country survey in four countries: Japan, Taiwan, Norway and the United States. The pilot survey results show that 38.5 percent of the Taiwanese respondents considered themselves "not informed" and 34.2 percent considered themselves "somewhat informed" about GM foods or organisms. And only 1.6 percent of them claimed to be "very well informed". In general, the results from the surveys indicate more favorable attitudes to GMO/GM foods in the United States than Taiwan. The degrees of accepting GMO/GM foods differ significantly between the two countries. In addition, the opinions about GMO/GM foods are quite mixed due to the uncertainty and unfamiliarity towards biotechnology. Thus, it is very important to educate the public about the GM technology with accurate scientific information and to build up a communication/linkage among scientists, industries, and consumers.

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1. REPUBLIC OF CHINA

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INTRODUCTION

Genetic modification or engineering is a new biological technology that enables direct manipulation of genetic material by inserting, removing or altering genes, and thereby accelerates the development process and shaving years off agricultural Research and Development (R&D) programs. While the use of modern biotechnology to create genetically modified organisms (GMOs) through agricultural research has created exuberance amongst those looking forward to a new 'Green Revolution', GMOs have also attracted strong criticism. Unlike other products of technology, the public perception and acceptance of GMOs plays an important role not only in market acceptance but also in national policy and regulations. Thus, the future of GMO product development is also at stake in the ongoing debate. The contentious views of different national policies and regulations have lead to great friction in international trade and market access, including disagreements on what constitutes an appropriate level of protection (ALOP). While the technology is spreading, the issues are just beginning to be addressed and the results are far from certain. In the Resolution of the 53rd World Health Assembly related to the GM food, it is simply stated that "biotechnology holds a great potential regarding efficiency of food production and public health improvements, such as increase in nutrient content and decrease in allergenicity while at the same time potential effects on human health should be studied"[1].

CURRENT USE OF GMOs IN TAIWAN

Taiwan has no commercialized GM crops or GM animals in production. Of the four major GM crops currently available on the global market, Taiwan imports close to 2.5 million mt of GM corn and 5 million mt of GM soybeans annually, the majority being purchased from the United States. By 2001, it was estimated that at least one-third of corn in the United States and 70 percent of soybeans were GM. The majority of imports are either for animal feed or for vegetable oil industry. Less than 14 percent of soybeans are reportedly channelled to members of the Taiwan Provincial Tofu Union for a variety of food uses. However, several major food manufactures in Taiwan who market packaged soybean milk and tofu products have chosen an alternative by importing non-GM soybeans on their own through "Identity-Preserved" certified sources or from non-GM producing countries at a significantly higher (3-5 times) global market price.

NATIONAL PROGRAMS

At present, investments from the private sector in the area of agricultural biotechnology are few[2] and small in size (Figure 1). Efforts to promote agricultural biotechnology has mainly relied on government funding and initiatives. Under the "Strengthening the Biotechnology Industry Program" of the Executive Yuan the Strategic Review Board, the National Science and Technology Program of Agricultural Biotechnology (NSTPAB) was set up in 1999. Within the NSTPAB, seven major areas of R&D have been

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1 Resolution of the 53rd World Health Assembly (http://www.who.int/fsf/GMfood/105thEB.htm).

2 Industrial Development Bureau, Ministry of Economic Affairs, *Biotechnology Industry in Taiwan, 2002*, September 2002, Taipei (ISBN: 957-01-1282-4).

recently identified and funded for three-year projects (Table 1). The number of projects funded in Phase I were 53 in 1999, 67 in 2000 and 73 in 2002, respectively.[3] Among those studies, virus-resistant GM papaya was the first successful case in Taiwan that has completed the field trial and is ready for environmental release, although the food safety assessment has not been completed yet.

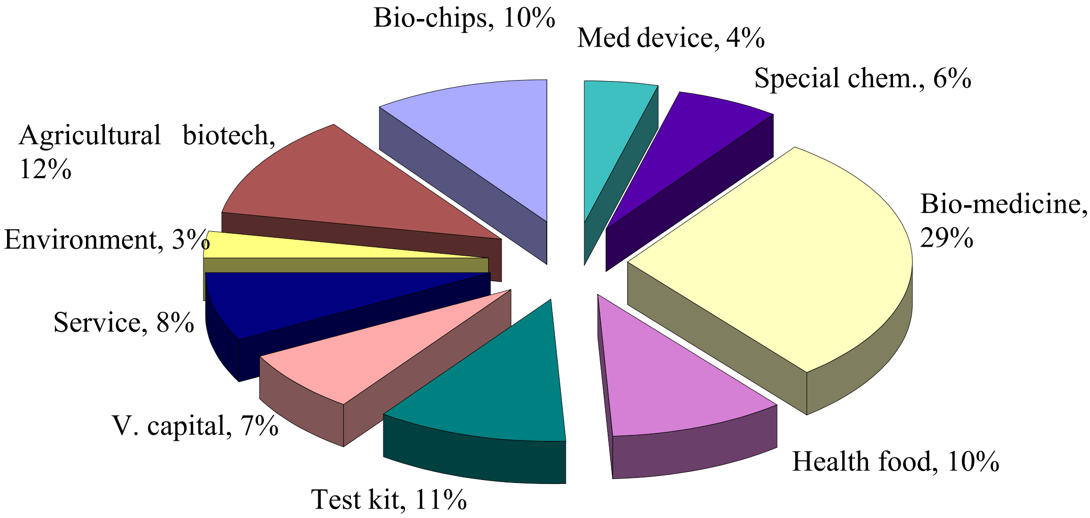

Figure 1. Start-up Biotech Companies in Taiwan
(January 1997-February 2002, N = 108)

Source: Industrial Development Bureau, Ministry of Economic Affairs, *Biotechnology Industry in Taiwan, 2002*, September 2002, Taipei (ISBN: 957-01-1282-4).

Table 1. National Program in Agricultural Biotechnology (NSTPAB)

(Unit: NT$ million)

Funding Source/Year	Phase I			Phase II		
	1999	2000	2001	2002	2003	2004
National Science Council (NSC)	100	127	134.6	160	187.5	207
Council of Agriculture (COA)	4.6	20	9	30	30	30
Academia Sinica	10	29	30	30	30	30
Program Areas:						
Flowers				20	22	24
Plant protection				22	26	30
Aquaculture				30	34	37
Veterinary vaccine				36	43	45
Agricultural utilization				40	43	45
Environmental				32	37	38
Pharmaceutical plant				40	42	48
Total	114.6	176	173.6	220	247.5	267
(US$ million)	(3.3)	(5.1)	(5.0)	(6.4)	(7.2)	(7.7)

Source: NSTPAB Office, the 5th Biotechnology Strategic Review Board Conference, 21 May 2001, Taipei.

[3] NSTPAB Office, Conference of the 5th Biotechnology Strategic Review Board (SRB), 21 May 2001, Taipei.

Other studies of transgenic plants including GM rice and potato are also approved for the first stage of field trials, and these will perhaps be followed by GM banana, broccoli, tomato, mustard greens and bitter melon in the near future.

The GM animal studies in Taiwan include anti-heat stress strains in GM cattle and pig, development of GM fish against infectious pancreatic necrosis virus, fast-growth of triploid oyster and transgenic *Ayu* fish. Among the contenders in this area of research, the Animal Technology Institute Taiwan has taken a leading role in both transgenic and the cloning of large animals.

REGULATORY FRAMEWORK

In Taiwan, three government agencies are currently involved in the regulation of GMOs, namely; the National Science Council (NSC), the Council of Agriculture (COA) and the Department of Health (DOH). The NSC is responsible for laboratory research.

The "NSC Guidance for Experiments Using Recombinant DNA Techniques" was recently revised in 2001. At present, the lack of proper legal status makes the guidance difficult to enforce with the private sector. For the COA, there are the "Highlights in Field Trials of Transgenic Plants" and the "Bio-safety Assessment Principles for Transgenic Plants", both promulgated in 2001 that were based on the Plant Seed Law – also amended earlier in 2001.

The DOH stipulated its first GM food regulations on 22 February 2001: "Labeling Requirements for Food Containing Ingredient of Genetically Modified Soybean or Genetically Modified Corn" (Appendix I); and "Registration Requirement for Genetically Modified Soybean and Genetically Modified Corn" (Appendix II). These were in accordance to the Law Governing Food Sanitation, which was amended in 2000. Prior to the implementation of the administrative orders for GM food regulations, the DOH funded a project in 1998 to begin drafting the first version of the "Guidance for Safety Assessment of Genetically Modified Food". The Guidance dictates the methodology of GM food safety assessment and is now in the process of revision in accordance to the Codex "Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants".[4]

At present, the DOH has received eight submissions for pre-market registration and approval, including one GM soybean and seven GM corn events (Table 2). Based on experiences with soybeans and corn, the DOH plans to expand the scope of crop species to be placed under regulation next year.

PUBLIC ACCEPTANCE

Recognizing the controversial nature of the issue, two nation-wide public surveys were performed by the DOH in 2000 and 2002 to study public perception and acceptance of GMOs. The data of both surveys are available at the DOH website for public access.[5] In brief, 42 percent of those interviewed would prefer non-GM foods while the same number of those interviewed did not care about GM or non-GM products in their food. Younger people (age 20-29) especially showed fewer tendencies to buy non-GM products. Again, 42 percent of those interviewed felt genetic modification may be bad for the food, but 45 percent believed modern technology would bring improvement to food for human consumption. Interestingly enough, 37 percent of those interviewed believed that non-GM products should not be sold at higher prices, and 37 percent of those interviewed believed there should be a price difference. In our survey, the consumer attitude in Taiwan seems generally split in an even tie on many issues. The only clear consensus is the strong support (88 percent) of a mandatory labeling rule on for GM foods.

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4 Report of the Third Session of the Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, 4-8 March 2002, Yokohama, Japan, ALINORM 03/34.

5 DOH Public Surveys on GM Foods, http://food.doh.gov.tw/ (Chinese only).

Table 2. Current Applications and Approvals (latest revision: 28 October 2002)

Product	Name	Event	Applicant	Date of DOH Approval	Note
Soybean	Glyphosate-tolerant Roundup Ready® Soybean	40-3-2 (RRS)	Monsanto Far East Ltd., Taiwan Branch	22 July 2002	Expiration: 22 July 2007
Corn	Insect-resistant YieldGard® Corn	MON810	Monsanto Far East Ltd., Taiwan Branch	15 Oct. 2002	Expiration: 15 Oct. 2007
Corn	Glyphosate-tolerant Roundup Ready® Corn	GA21	Monsanto Far East Ltd., Taiwan Branch	Interim approval	Expiration: 3 June 2002
Corn	Glyphosate-tolerant Roundup Ready® Corn	NK603	Monsanto Far East Ltd., Taiwan Branch	Interim approval	GMFAC* approved: 24 Sept. 2002
Corn	Insect-resistant/ Glufosinate-tolerant Corn	Bt11	Syngenta Taiwan Ltd.	Interim approval	Under GMFAC evaluation
Corn	Insect-resistant/ Glufosinate-tolerant Corn	Event176	Syngenta Taiwan Ltd.	Interim approval	Under GMFAC evaluation
Corn	Glufosinate-tolerant Corn	T25	Bayer Crop Science (formerly Aventis Crop Science Taiwan Ltd.)	16 August 2002	Expiration: 16 Aug. 2007
Corn	Insect-resistant/ Glufosinate-tolerant Corn	TC1507	Du Pont Taiwan	-	Under GMFAC evaluation

Source: http://www.doh.gov.tw/dohenglish/Laws/Laws_Item.asp?No=31&ClassNo=L03
Note: * Genetically Modified Foods Advisory Committee.

INTERNATIONAL STANDARDS

In 1998 the World Health Organization and the Federal Agricultural Agency jointly commissioned a Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology to study the development of international standards. The Task Force commenced its first meeting in 1999, and by the third meeting in 2002 it had achieved two major accomplishments: the "Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" and the "Draft Guideline of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants". In an unusual move, the Task Force also recommended to the Codex adoption of the "Draft Annex on the Assessment of Possible Allergenicity". This demonstrates the urgency of reaching international standards when the GM crops have become so widely accepted by the producers and many varieties are grown on a very large scale. The Codex standards will become the science-based standards of WTO agreements, most notably the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures. This makes Codex standards on biotechnology extremely important to the international trade of commodity grains which have become predominantly GM.

With the accession to the WTO in 2002, Taiwan became obligated by this international forum to abide by these rules. In order to reduce trade barriers, the current DOH "Guidance of Risk Assessment for GM Foods" will be revised in accordance to the Codex guidelines. Also in the spirit of WTO membership, GM crops developed domestically will be treated with the same stringent requirements as foreign GM crops. In the last few years a number of notifications related to GMOs have been sent to the WTO/TBT (Table 3), many of which were labeling requirements.

Table 3. GMO and the WTO/TBT Agreement Notifications concerning GMOs

Year	Notifications
1995	2
1996	0
1997	5
1998	1
1999	12
2000	9
2001 (-August)	8
Total	37

Source: Vivien Liu (WTO/TBT Secretariat), “Workshop of International Standards under WTO/TBT”, 23 November 2001, Taipei, Taiwan.

It is apparent that these days the WTO has become a necessary multilateral forum for nations and regions to negotiate on their regulation and use of GMOs.

CONCLUSION

In Taiwan, consumers, the food and feed industries and retailers demand a reasonable degree of choice between GM and non-GM products and the demand for organic products is also on the rise. But different modes of agricultural production, especially in the United States are not naturally compartmentalized. Commingling or the adventitious presence of GM and non-GM crops creates legal and economic costs which in turn place a burden on the general public. Experience has shown that non-GM products have been gaining a market niche in many regions of the world. Perhaps the reality of the coexistence of GM, non-GM and organic products will eventually be accepted as a norm, so that the controversy will become minimized and biotechnology will play a better role in contributing to the betterment of human civilization.

Appendix I

Labeling Requirements for Food Containing Ingredient of Genetically Modified Soybean or Genetically Modified Corn
(DOH Food No. 0900011746)

- * Promulgated: 22 February 2001
- * Under the Law Governing Food Sanitation, Article 17, Paragraph 1, Sub-paragraph 6.

1. Food products containing ingredient of GM soybean or corn that is more than 5 percent by weight of the finished product, shall be labeled with the words “Genetically Modified” (GM) or “Containing GM Ingredients”.
2. Food products made of non-GM soybean or corn may be labeled with the words “Non-GM” or “Not GM”.
3. Non-GM soybean or corn adventitiously or accidentally commingled with less than 5 percent of GM varieties during harvesting, storage, transporting, or other reasonable causes, may be labeled as “Non-GM”.
4. Soy sauce, soybean oil (salad oil), corn oil, corn syrup, and corn starch, etc. made of GM soybean or corn are exempted from the GM labeling requirement.
5. The text size of the words “Genetically Modified” on a label shall not be smaller than 2×2 mm, and be placed immediately after the name of the product or the ingredients, or other conspicuous places in the labeling.
6. The effective dates for mandatory labelling are:
   (1) on 1 January 2003, mandatory GM food labeling will take effect for soybean and corn products in the raw agricultural form, including soybean meal (flour), corn grit/meal (flour).
   (2) on 1 January 2004, mandatory GM food labeling will take effect for primarily processed soybean and corn products, including tofu, dried tofu, soy milk, soy curd, frozen corn, canned corn, and soy protein products.
   (3) on 1 January 2005, mandatory GM food labeling will take effect for all other processed soybean and corn products with the exception of those highly processed food items including soy sauce, soybean oil (salad oil), corn oil, corn syrup, and corn starch, etc. which do not contain fragment of transgenic or its protein.
7. The effective date for voluntary labelling is 1 January 2001.

Appendix II

Registration Requirement for GM Soybean and GM Corn
(DOH Food No. 0900011745)

* Promulgated: 22 February 2001.
* Under the Law Governing Food Sanitation, Article 14, Paragraph 1.

1. ***Definition***: Genetic modification means techniques that apply genetic engineering or modern biotechnology to transfer or insert genetic material into a living cell or organism resulting in genetic modification of the cell or organism. The technique does not include conventional breeding, cell fusion, protoplast fusion, hybridization, induced mutagenesis, *ex vivo* fertilization, somatic mutation, or polyploidy induction.
2. For submission for registration of GM food, an applicant is required to complete an application form and provide the following information:
   (1) Background information about the applicant.
   (2) Background information about the GM food.
   (3) Synopsis of the safety assessment on the GM food.
   (4) Safety assessment on the GM food.
   (5) A list of references and relevant research papers on the GM food.
   (6) A reference sample.
   (7) A registration fee.
3. The "Guidance for Safety Assessment of Genetically Modified Food" and the application form for GM food are attached as Annex I and Annex II, respectively.
4. Effective dates: Beginning on 1 January 2003, any GM soybean or corn shall not be manufactured, processed, prepared, packed, imported or exported for food use, unless registered with and approved by the DOH. All GM varieties of soybean and corn currently on the market in Taiwan must register with the DOH before 30 April 2002.

Annex I. The Guidance for Safety Assessment of Genetically Modified Food is available from the DOH website at: http://food.doh.gov.tw
Annex II. The application form is available from DOH website at: http://food.doh.gov.tw

2. INDIA (1)

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INTRODUCTION

In recent years there have been spectacular discoveries in the field of plant tissue culture and recombinant DNA technology. The application of these techniques has given birth to a branch of science which is known as "Plant Biotechnology". The ability of scientists to tailor make genes has provided unlimited opportunities especially for crop and livestock improvement and have given hope for meeting the challenge of combating protein and energy malnutrition. The vast opportunities thrown open as a result of this new technology are immense. In India we are faced with the twin problem of increasing population and decreasing available land for agriculture. India's long-term economic prospects depend heavily on the agriculture sector which contributes a quarter of the GDP and provides livelihoods to two-thirds of the population. If the targeted rate of GDP growth of 8 percent envisaged under the 10th Five-Year Plan is to be achieved the agriculture sector must grow at a rate of 4 percent per annum. To achieve this growth rate it may not wise to depend entirely on conventional technologies. It calls for the use of new cutting edge technologies for increasing crop production substantially, while maintaining the sustainability of the natural ecosystem. We are endowed with rich biodiversity in India. This provides a resource to harness useful genes for developing plant types with built-in resistance to insect pests and diseases, resistance to abiotic stress and improved nutritional quality.

Realizing the importance of biotechnology for bringing economic benefits to farming community and for improved human health, the Government of India gave rightful importance to the development of not only skilled human resources in this area but also the establishment of strong centers of plant molecular biology in the country. In recognition of the potential benefits, the Government of India established a separate Department of Biotechnology (DBT), which promoted many of the developments with respect to infrastructure as well as the capabilities to harness this new cutting edge technology for better human health. The strength of human resources in Indian Council of Agricultural Research (ICAR), Council of Scientific Industrial Research (CSIR) and also in the State agricultural and general universities helped in the rapid growth of molecular biology and biotechnology in the country. In just about two decades, the country has developed strong centers of plant molecular biology and biotechnology with modern infrastructure facilities and human resource competence at several places in the country.

A large number of scientists from several organizations were trained taking advantage of the experts under the TOKEN program of CSIR, liberal grants from the DBT, Government of India and the Agricultural Human Resource Development (AHRD) program under ICAR to develop much needed skilled human resources. For the present strength that India enjoys, we need to compliment DBT for their vision and determination. ICAR also equally helped in strengthening biotechnology research in the country. The synergy between ICAR and DBT helped in the rapid growth of plant molecular biology and biotechnology in the country and the fruits of this are quite visible in the form of research achievements. Indian research groups started to work in late 1980s in the area of plant biotechnology and visible progress has been made in the last 10 years, several scientific groups have utilized transgenic technology to answer basic questions in plant molecular biology. We have also demonstrated our ability to use model systems like tobacco and developed transgenics carrying important agronomic traits like tolerance to biotic and abiotic stresses.

CURRENT SCENARIO

Plant biotechnology research in India has progressed well with an initial lag period during early 1990s. Now, capabilities and expertise have been built up in many institutions to reap the benefits of biotechnology. Transgenic rice cultivars are being developed in a number of ICAR laboratories and other labs in the country. The main focus on rice transgenics is resistance against yellow stem borer using the *Bacillus thuringiensis (Bt)* genes. At National Research Center (NRC) on Plant Biotechnology (NRCPB) (ICAR), *Bt* rice transgenics in agronomically superior cultivars such as IR 64,. Karnal Local and Pusa Basmati 1 have been developed and are being tested in limited field field trials for resistance against yellow stem borer. At the Directorate of Rice Research (DRR) (ICAR), Hyderabad, rice transgenics resistant via a *Bt* toxin gene against yeliow stem borer and transgenics with chitinase gene for resistance to sheath blight disease are in advanced stages of testing. Bose Institute, Calcutta is also testing *Bt* transgenics for resistance to yellow stem borer.

Work on the development of insect-resistant transgenic crop plants deploying *Bt* technology and protease inhibitors or lectin genes is in progress in a number of laboratories (mostly ICAR) in the country. At NRCPB (ICAR), some of the vegetable crops like brinjal, tomato, cabbage and cauliflower have been developed. Brinjal and tomato have been field tested at Indian Agricultural Research Institute (IARI) and multi-location field trials are likely to follow soon. In addition to vegetables, the focus has now shifted to pigeon pea, chickpea and mustard. Work is in progress at NRCPB (ICAR) on these crops using *Bt* genes as well as plant genes such as protease inhibitor or lectin genes. At Central Institute of Cotton Research (CICR) (ICAR), Nagpur, development of *Bt* cotton is in progress in collaboration with NRCPB (ICAR) under mission mode National Agricultural Technology Project (NATP). Work is also in progress at Central Potato Research Institute (CPRI) (ICAR) on isolating a novel osmotin gene and development of transgenic potatoes with resistance to late blight caused by *Phytophthora infestans*. One season's field trial has already been completed and further evaluation is in progress at Central Tobacco Research Institute, Rajamundry with the *Bt* tobacco for resistance against *Spodoptera !itura*. Similar work is in progress at the University of Agricultural Sciences (UAS), Bangalore.

Transgenic mustard tolerant to salinity is underdevelopment using genes isolated from salt-tolerant mangroves at the M. S. Swaminathan Research Foundation (MSSRF), Chennki. Extensive efforts are in progress in other important crops as well, such as rice, wheat, maize, pigeon pea and some vegetable crops for introducing abiotic stress tolerance at NRCPB (ICAR), International Centre for Genetic Engineering and Biotechnology (ICGEB) and Jamia Milia Islamia, New Delhi. The transgenics have been developed for drought and salinity and are at the greenhouse stage of testing.

Improvement of nutritional quality in terms of over-expression of an Amaranthus protein *Ama* 1 with balanced composition of essential amino acids has been achieved in transgenic potato and is being tested in the field in collaboration with CPRI, Shimla. Similarly two storage protein genes of chickpea and seed-specific promoters for chickpea have been isolated and characterized at NRCPB (ICAR). They are further being manipulated for improvement of protein quality of seed storage protein. Work is also in progress on the development of transgenic rice enriched in beta-carotene at South Campus, University of Delhi and transgenic tomatoes and mustard rich in beta-carotene at the NRCPB and the Energy and Resources Institute (TERI), New Delhi, respectively.

Another important trait being introduced into crop transgenics in India is resistance to diseases caused by viruses, fungi and bacteria. Work is in progress in different laboratories on rice, mustard, cotton and tomato. Transgenics of cotton and mustard with male sterility are being generated at South Campus, University of Delhi, New Delhi. Transgenics in these crops have been developed and are at various stages of testing. plant-based edible vaccines are being developed at UAS, Bangalore and at the Plant Molecular Biology (PMB) Department, South Campus, University of Delhi, New Delhi. Transgenic muskmelon has been developed with rabies glycoprotein gene at UAS, Bangalore and is being tested for immunogenic response in mice. Edible vaccine for cholera is being developed in transgenic tomato at the PMB Department, University of Delhi.

As regards the private sector, the Maharashtra Hybrid Seed Company (Mahyco)-Monsanto joint venture has conducted field trials at different locations in the country with *Bt* cotton to protect the cotton plants from lepidopteran insect pests. Repeated field trials have been conducted with this transgenic *Bt* cotton to verify the agronomic aspects and monitor gene flow. The Mahyco-Monsanto *Bt* cotton has been approved by the

Genetic Engineering Approval Committee (GEAC) for commercial cultivation at eight places in the country. Another private venture in progress in the country is the development of transgenic variety of male sterile mustard for hybrid seed production by ProAgro-PGS and ready for commercial release. The ProAgro-PGS is also likely to commercialize in next few years transgenic cultivars of tomato, cabbage and brinjal with *Bt* genes for insect protection.

MAJOR ISSUES IN USE OF GM FOOD AND GM CROPS

Except *Bt* cotton, no other transgenic or genetically modified (GM) food crop has yet been commercialized in India, though as discussed above, extensive efforts are in progress at different laboratories across the country to develop the GM food crops. Before we reach the commercialization stage, it is imperative to build public confidence through a proper communication system so that the public at large is well informed about the benefits (and risks, if any) of the GM foods. With regard to the use of GM foods, the following issues assume importance.

Uptake of Genes Via the Food Chain

One fear is that the genes from the GM foods could be easily taken up by consumers when eaten, and thus become part of their own genetic makeup. However, experiments have failed to show survival of intact DNA in either stool or blood of animals fed with large quantities of DNA. Moreoever, DNA after digestion gets fragmented into small pieces which are insufficient to be complete genes and thus fail to express. There is, however, a need to identify institutions for carrying out toxicological evaluation of GM foods.

Antibiotic Resistance Genes in GM Food

Another fear concerns the transfer of antibiotic resistance from the GM food consumed by people into the bacteria inhabiting the human gut, which might result in a disease causing bacterial population to become resistant to antibiotics. However, experiments have shown that this does not happen. Nevertheless, research is necessary to determine whether such gene transfer could occur, and to what extent. The transgenic developers should continue to more rapidly remove all such markers from GM plants and utilize alternative markers for the selection of new varieties.

Biosafety

There are several related areas of concern regulating the use of GM crops food. These include toxicity, allergenicity, carcinogenicity, food intolerance and nutritional value. While supporters of the technology argue that the foods produced through biotechnology are just as safe if not safer than conventionally produced foods because they are subjected to highly rigorous testing, critics of GM food have even coined a new term *Frankenstein foods* for GM foods. In our opinion, science-based risk assessment of GM crop plants is the only way to address these public concerns.

Labeling GM and Non-GM Food

With the kind of concerns witnessed among the public, keeping GM and non-GM products separately with appropriate labeling, perhaps also through color codes for illiterate people, may be absolutely necessary. The related issue is the need for a certification agency specializing in certifying the GM nature of a product. This is not necessary because these food products are going to pose risks to human and animal health but this will essentially allow consumers to have a choice either to use or not to use GM foods for consumption.

Environmental Concerns

Most of the environmental concerns about GM technology in plants have derived from the possibilities of gene flow to close relatives of transgenic plants creating super weeds or causing gene pollution in other crops. That genes may ‘escape’ through pollen into the nearby farms and fields, to another non-GM cultivar or to wild weedy relative is not just a possibility but a reality. However, that these ‘escaped’ genes may lead to weeds becoming ‘super weeds’ seems very unlikely. Chances are that such genes will become diluted in succeeding generations. On the other hand, we may have a possibility in which a weed comes up with multiple resistance and better competitive ability. Whether this really happens or not can be known only after a long period of cultivation of several GM plants.

Effect on Biodiversity

A major concern, voiced by several researchers and environmentalists, is that the commercialization of transgenic crops in general and particularly those with technologies such as 'terminator' could lead to erosion of biodiversity and 'pollute' gene pools of endangered plant species. While many endangered plant species are indeed threatened by habitat loss and/or hybridization with cultivated plants in conventional agriculture as well, the threat level is perceived to be of higher magnitude when large-scale commercialization of transgenic crop occurs. The potential impact of transgenics on biological diversity may vary according to the specific application and will also depend on the crop type, the type of agricultural ecosystem, as well as the geographic region in which the technology might be applied. The potential transfer of a transgene to local flora and its any possible subsequent impact on specific plant species is thus an issue that needs to be kept in view before commercial release of specific transgenes.

Public Awareness

Consumer response is based on perceptions about risks and benefits of GM foods. In order to maximize consumer trust, it is essential that relevant and reliable information about GM food is communicated to the consumers and stakeholders. It is possible that food safety evaluation of GM plant may reveal some unavoidable effects. The media, individuals or groups have the right to educate the public about such possibilities. A participatory approach is required if the biotechnological products are to be accepted by the farmers and consumers.

REGULATION OF GMOs IN INDIA

The Indian Government created the rules and procedures for dealing with genetically modified organisms (GMOs) in 1989 under the Indian Environment Protection Act. India is one amongst very few countries in the developing world to have laid out detailed biosafety guidelines for genetically engineered organisms. The guidelines were prepared by the Recombinant DNA Advisory Committee constituted by DBT, Government of India, which is responsible for the development of biotechnology in the country. The recombinant DNA safety guidelines are based on a three-tier system involving:

i) Institutional Bio Safety Committees (IBSCs)
ii) the Review Committee on Genetic Manipulation (RCGM)
iii) the Genetic Engineering Approval Committee (GEAC).

The IBSC is established at every institution engaged in research on genetically engineered organisms. The RCGM and GEAC closely monitor the field experiments involving transgenics before their commercialization is contemplated. The RCGM is the national committee functioning under the DBT and has the function of reviewing the approval of ongoing research and development (R&D) projects on GMOs, undertaking field visits of the sites of experimental facilities and issuing clearances for import/export of vectors, germ plasm, etc. needed for experimental purposes, training and research. Based on the recommendations of the RCGM, trials permits are issued by the DBT. Environmental safety, including human health, gene flow, etc. are required to be investigated before commercialization.

GEAC functions under the Department of Environment as the statutory body for review and approval of GMOs and their products in R&D or environmental release and field applications. Following the GEAC clearance, the applicants are to seek the clearance of the Ministry of Agriculture (MOA) that in turn follows procedures of the All India Coordinated Trial (AICT) through the ICAR. The final clearance of the transgenic crop varieties/microorganisms for agricultural use shall be accorded by the MOA, through its well established wing of assessment. The GEAC, based on the information generated elsewhere by the applicant or through the RCGM mechanism in India, may accord approval to the applicant to proceed further for AICT. Exclusive and rigorous testing of each transgenic on a case-by-case basis by the guidelines laid down by the regulatory agencies in India would essentially ensure that the GM crops are not released unless they are proven unsafe.

The regulatory agencies in India, have so far done an excellent job of formulating detailed guidelines for GMO field experiments. It is important to provide a balanced view of relevant and reliable information to the farmers and public in general regarding the potential benefits and the possible constraints of GM crops and foods. Therefore, there is need to ensure that the guidelines on GMO are well advertised to increase public awareness on the subject and to ensure that technology is well received.

3. INDIA (2)

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INTRODUCTION

About 42 percent of the crop productivity in India is lost every year due to pests, diseases and weeds and an additional 10-30 percent due to postharvest losses. The use of pesticides to tackle these problems has led to widespread resistance of pests as well as soil and water pollution. This has also affected soil fertility and resulted in higher pesticide residue levels in foods. Although Integrated Pest Management, Integrated Nutrient Management, etc., should have helped to alleviate these problems, the adoption of these practices among farmers is not fast due to a high level of illiteracy among the farming population. However, biotechnology seems to offer solutions to these problems. Biotechnology has the potential to move farming closer to ecologically sustainable practices and thus could make a considerable impact on agricultural systems in the future for producing high quality crops, development of new germ plasm with high-yielding varieties tolerant to various types of stresses, etc. It serves an important tool in today's agriculture to feed the growing populations.

Introduction of genetically modified organisms (GMOs) has drawn the tallest claims and the wildest accusations from the scientists and opponents. Nevertheless, GMO technology is here to stay and the scope of GMO in agriculture is manifold. DNA technology greatly helps to develop transgenic plants with genes of value.

A transgenic plant is simply a normal plant with one or more additional genes from diverse sources. Transgenic plants are produced through regeneration of whole plants from transformed protoplasts/cells. Now there are more than 50 plant species where transgenic plants have been successfully produced. Transgenic plants are produced for many purposes like resistance to herbicides, insects, viruses, etc., which mainly increase the efficiency of crop production systems.

Transgenic Plants in Global Market

The People's Republic of China was the first country to commercialize transgenic crops in the early 1990s with the introduction of virus-resistant tobacco. In 1994, U.S.A. commercialized a genetically modified (GM) "Flavr Savr", delayed ripening tomato. Monsanto launched its first genetically engineered seed 'Roundup Ready (RR) Soy' in 1996. Four major transgenic crops currently dominate world markets: RR soy accounts 58 percent or 25.8 million ha of total area under GM crops; transgenic corn for 10.3 million ha; transgenic cotton for 5.3 million ha.; and GM canola for 2.8 million ha. Argentina and the U.S.A. lead in GM crops. In Argentina 95 percent of all soybean is transgenic and in the U.S.A., 54 percent. The world area under commercially grown GM crops has been rapidly increasing since they were first introduced in 1996. The estimated global area of biotech crops for 2001 is 130 million acres. Around 5.5 million farmers have adopted biotech crops.

Bacillus thuringiensis (Bt) Transgenic Crop

Plant Genetic Systems, a Belgian Biotechnology Co., in July 1987 was the first to report development of transgenic plants of tobacco containing delta-endotoxins against *Manduca sexta* and *Helicoverpa virescens*. Subsequently transgenic plants were developed in tomato, cotton, potato, corn, rice, etc. The delta-endotoxins have two important properties, namely; high toxicity towards the target insects and safety for human consumption. This is due to the fact that the toxins remain intact and effective in the gut of the insect larva while the toxins are rapidly destroyed in mammalian digestive systems.

STATUS OF GENETIC ENGINEERING IN INDIA

India spends US$25 million per year in the area of plant biotechnology. Indian scientists have been working on *Bt* cotton for a decade and yet we are not close to field trials. But, despite minimal investments, there are very promising leads, such as potato with balanced proteins, mustard with low erucic acid and glucosinilate, *Bt* cotton, rice and vegetables, virus-resistant tomato, chili, etc. The Department of Biotechnology (DBT) is behind all these successes and is pushing hard not only for research in the laboratory, but also for demonstration trials. As a result, successful research on transgenic plants is going on in many places in India.

* Some meaningful work has been initiated at Indian Agricultural Research Institute (IARI), New Delhi to incorporate *Bt* gene in the brinjal cv. 'Pusa Purple', in rice varieties 'Pusa Basmati', IR 64 and Karnal Local and the chitinase gene in the mustard cultivar 'RLM198'.
* Tamil Nadu Agricultural University (TNAU), Coimbatore is attempting to incorporate chitinase gene and *Bt* gene into rice to provide resistance to *Rhizoctonia solani* and stem borer, respectively.
* Central Tobacco Research Institute (CTRI), Rajamundry is working on '*Bt* tobacco'.
* The Maharashtra Hybrid Seed Company, Ltd. (Mahyco) is engaged in developing *Bt* cotton in transferring the *Bt* trait into 40 Indian cotton lines.
* The National Botanical Research Institute (NBRI), Lucknow is working in developing *Bt* cotton.
* Transgenic cabbage cultivar 'Golden Acre' with *Bt* gene has been developed by Indian Institute of Biotechnology, New Delhi against diamondback moth.

Views of Proponents on GMOs

The ecological implications of GMOs are often perceived in negative terms. Even though there are attempts in other areas to alleviate human suffering due to hunger, disease and poverty, these problems have not been totally eliminated. The use of GMOs is another potential tool to address such problems but is facing endless debate between proponents and opponents. One issue in the debate is the possibility that resistance to, for example, the *Bt* toxin, will develop in the target insect species. After all we are living with drug-resistant malaria, and tuberculosis. Alternate strategies are always worked upon and this is true with the *Bt* gene as well. The resistance to *Bt* gene will develop in insects in the field, but it will take a long time. In the meantime we should utilize *Bt* cotton and derive maximum benefit during its useful period, while developing strategies to face insect resistance. We can afford to use the benefits of biotechnology if the plus points outweigh the negative points. Human safety to exposure to new genes is also an important consideration. There is ample literature that *Bt* gene is safe to humans.

Views of Opponents on GMOs

Unfortunately, conservative scientists in agricultural research and some NGOs are not yet convinced about the potential of GM technology. The objections leveled by them are:

* development of resistance to insect populations
* creation of super pests or super weeds
* *Bt* toxins pose threat to beneficial species
* risk of genetic pollution and the destruction of biodiversity
* risk of harmful effects of the transgenic food on the human health.

These are only assumptions and not based on any scientific studies. To all the doubts, Asian Intelligence Wire, 29 July 2002 answered that:

* genetically improved foods available in the market are as nutritious as their traditional counterparts.
* the US Food and Drug Administration confirms the safety of antibiotic-resistant marker genes. The concern that genes could be transferred to microorganisms within human beings has been discounted.

* biotechnology doesn't use genetic material from plant foods commonly associated with allergies. In addition, modern biotechnology makes it possible to identify and remove known allergenic agents from foods.
* in real life conditions, no proteins expressed by novel genes currently on the market survive the passage through the entire human digestive tract.
* biotech crops can be more beneficial to the environment than their conventionally developed counterparts. Though these crops may repel invasive species now, over time the species will become immune.

REGULATIONS OF GMOs IN INDIA

In India, laws to regulate genetically engineered organisms were included under the "Environmental (Protection) Act, 1956" in 1989. The biosafety laws were entitled as "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells". DBT in January 1990 issued a compendium of guidelines under the title "Recombinant DNA Safety Guidelines". A revision was made in 1994 under the title "Revised Guidelines for Safety in Biotechnology".

Revised guidelines have been issued again under the title "Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity, Evaluation of Transgenic Seeds, Plants and Plant Parts" in 1998 in light of the enormous progress that has been made in recombinant DNA research, its widespread use in developing improved microbial strains, cell lines and transgenic plants for commercial exploitation. The guidelines also deal with import and shipment of GM plants for research use only.

Statutory Bodies Dealing with r-DNA Works

1. ***GEAC (Genetic Engineering Approval Committee)***

This committee gives permission/approval for any import, large-scale field trials, large-scale use or deliberate release of organisms into the open environment. Field trials in which a GM crop interacts with soils, other plants, insects and animals need GEAC approval.

2. ***IBSC (Institutional Biosafety Committee)***

The IBSC is the nodal point for interaction within an institute/university/commercial organization involved in r-DNA research for the implementation of the r-DNA guidelines. The organizations intending to carry out research activities should constitute their IBSC in accordance with the Review Committee on Genetic Manipulation (RCGM) notification. The IBSC is the mediating body between the Project Investigator (PI) and the RCGM. The PI of a particular project should apprise the IBSC about the nature of the experiments being carried out. The IBSC will give permission to carry out routine r-DNA experiments. In case risks involved, the PI should seek permission of the RCGM through its IBSC.

3. ***Review Committee on Genetic Manipulation***

The Ministry of Environment and Forests empowers RCGM to lay down procedures restricting or prohibiting production, sale, importation and use of genetically engineered organisms or cells. RCGM shall include representatives of a) DBT; b) Indian Council of Medical Research; c) Indian Council of Agricultural Research (ICAR); d) Council of Scientific and Industrial Research; and e) other experts in their individual capacity. RCGM shall meet at least twice in a year.

The functions of RCGM are:

* monitoring all projects of genetic engineering;
* reviewing the reports of all approved projects involving high risk category and controlled field experiments;
* issuing of clearances for import or export of transgenic materials for research use;
* giving permission to PIs for conducting research involving risks;
* approving the protocols for conducting limited field trials in multiple locations in the country. The protocols will be designed to seek answers on environmental hazards including risks related to animals and human health, economic advantages of the trangenics over the existing varieties;
* prescribing specifications for lab and greenhouse; and
* inspecting the experimental site for safety, etc.

The RCGM also asks for long-term environmental safety data from the applicants seeking release of transgenic plants into the open environment and who have complied with initial safety evaluation.

Categories of Genetic Engineering Experiments on Plants and Their Notifications (cloning and transfer of donor genes)

Category I

Routine recombinant DNA experiments in contained environment using microorganisms, which are "GENERALLY RECOGNIZED AS SAFE" (GRAS) to human, animals and plants. Category I experiments need only be notified to the IBSC in the prescribed format available with the RCGM.

Category II

This category includes lab and greenhouse experiments in contained environment where defined DNA fragments non-pathogenic to human and animals are used for genetic transformation of plants. Information on molecular experiments will be provided to IBSC which will notify RCGM before the execution of the experiments. The RCGM would put this information on record.

Category III and Above

This category involves high risk experiments (not belonging to I and II) where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, the plants and animals by dispersing new genetic traits. Such experiments should be conducted only after clearance from RCGM and after notification by the DBT.

In all the above experiments, RCGM prescribes specifications for lab and greenhouse. RCGM also provides for and approves the design of the experimental field plots.

Monitoring and Evaluation Mechanisms for Greenhouse Experiments and Limited Field Trials

A special monitoring cum evaluation committee of the following constitution will be set up by RCGM to monitor the activities of projects involving transgenic plants.

a.	Chairman of the committee:	Secretary, DBT and Secretary, Department of Agricultural Research and Education (DARE) shall jointly discuss and elect a leader of the committee
b.	Eminent plant biotechnologists:	3-4 (numbers) nominated by RCGM
c.	Seed technologists:	2-3 (numbers) nominated by ICAR
d.	Plant breeders:	2 (numbers) nominated by ICAR
e.	Plant ecologist/environmentalist:	2 (numbers) nominated by RCGM
f.	Nominee of National Bureau of Plant Genetic Resources (NBPGR):	1 (number) nominated by ICAR
g.	Nominee of Ministry of Environment and Forests:	1 (number) nominated by Chairman, GEAC
h.	Member-Secretary:	Member-Secretary, RCGM.

This committee will undertake field visits at the experimental sites and assist RCGM in collecting, consolidating and analyzing the field data for evaluating the environmental risks emanating from the transgenic plants. This committee shall also advise the RCGM on the risks and benefits from the use of the transgenic plants under evaluation. It recommends through the RCGM those transgenics which would be found to be environmentally safe and economically viable for consideration by the GEAC for release into the environment.

BIOSAFETY ASPECTS OF THE TRANSGENIC PLANTS

The following data are required to be generated from the experiments designed to identify the hazards and risks.

1. ***Characteristics of the Donor Organisms Providing the Target Nucleic Acid***

This includes the name and identification characteristics of the donor organisms, pathogenicity, toxicity and allergenicity characteristics, geographical distribution and method of transfer of its genetic materials to other organisms.

2. ***Characteristics of the Vectors Used***

This includes origin, identity, habitat, sequence and frequency of mobilization, specificity, abilities of the vectors to get established in other hosts, name of the host, marker gene, etc.

3. ***Characteristics of the Transgenic Inserts***

This includes specific functions coded by the inserted nucleic acid sequences, expression of the nucleic acid products and their properties and toxicity of the expression products on the host plant, human and animals.

4. ***Characteristics of the Transgenic Plant***

This includes methods of detection of the transgenic plant and escaped transgenic traits in the environment, methods of detection and characterization of the toxicity and pathogenicity of the transgenic plants to other plants in the ecosystem and the environment, possibility and the extent of transgenic pollen escape and pollen transfer to wild near relatives and the consequences to the environment and pathogenicity, toxicity and allergenicity of the transgenic plants and their fruits to human and animals.

For generating toxicity and allergenicity data, standard protocols developed by international agencies could be used. The national toxicological laboratories like Industrial Toxicological Research Centre, Lucknow or Central Food Technology Research Institute, Mysore could also be consulted to generate appropriate protocols. All the above information are to be compiled in the form of a document which would be called the 'registration document'.

Import and Shipment of Transgenic Germ Plasm for Research Purposes

* The RCGM will issue an import certificate after looking into the documents related to the safety and the national need.
* The importer of a transgenic material may import the material accompanied by an appropriate phytosanitary certificate issued by the country of export and such import should be routed through the Director, NBPGR on the basis of the import permit issued by the DBT based on the recommendation of the RCGM.
* The import certificate would be cancelled if NBPGR would not provide the phytosanitary certificate.
* Parts of the seed material will be kept at NBPGR in a double lock system to be used as a source material in case of any local dispute.

CURRENT USAGE OF GMOs IN INDIA

Though initial protests erupted against the field testing of GM *Bt* cotton in India, the country is now mentally preparing itself for developing and releasing transgenic plants for their commercial cultivation.

Although few companies carried out large-scale commercial field trials between 1995 and 2000, large-scale *Bt* cotton trials in the private sector are approved today in India. Based on the results of the *Bt* cotton field trials, approval has been given to Mahyco to commercialize its *Bt* cotton (Bollgard ™) in India. The field studies conducted indicated that *Bt* cotton is not an aggressor on natural flora or the habitat and it is non-toxic and non-allergenic to mammals.

In 2002, *Kharif* season, Mahyco-Monsanto Biotech India Ltd. (MMB), the 50:50 marketing joint venture has sold 105,000 packets of genetically improved *Bt* cotton hybrid seeds, conferred with resistance to the dreaded American boll worm to six States.

Maharashtra:	39,200 packets
Karnataka:	21,000 packets
Gujarat:	15,000 packets
Tamil Nadu:	14,000 packets
Andhra Pradesh:	11,000 packets
Madhya Pradesh:	4,500 packets
Total:	104,700 packets

Bt hybrids were sold to farmers at Rs.1,600 (US$33) per packet each containing 450 gm of seeds to cover 1 acre. This is against a maximum retail price of Rs.380 (US$8) for a similar packet of Mahyco's non-*Bt* cotton hybrids. Farmers have been advised to grow five surrounding rows of non-*Bt* cotton as refuge for every acre of *Bt* crop.

The 'golden rice' with enriched pro-vitamin A is expected to arrive in India from the International Rice Research Institute (IRRI) for laboratory trials by January 2003. Golden rice is developed without the use of antibiotic-resistance markers. This is the first public sector (non-corporate) GMO products.

Recently GEAC has rejected the commercial cultivation of GM mustard in India on the ground that the data provided by the ProAgro is inadequate to assess the safety on human health aspects.

CONCLUSION

It is now being viewed that GM crops could significantly and substantially enhance and stabilize the production of our major food and fiber crops in India. The use of GMOs may provide an answer to the problem of food security to be faced by the ever-growing population of India which is likely to touch 1.5 billion mark by 2020. India is rich in biodiversity and our soil and climatic conditions are congenial for producing a number of crops, vegetables and fruits, etc. We can afford to use the benefits of biotechnology either in enhancing or to stabilize our present food grain production level if the plus points outweigh the negative points.

There is a large potential for transgenic plants in India to meet the growing demand for food and fiber. India is importing 30 percent of its requirements for cotton to meet the growing demand of Indian textile and clothing industry. Already *Bt* cotton has been introduced for commercial cultivation in India. This will help make India self-sufficient in cotton production by protecting from the loss due to boll worms. Also *Bt* rice is under field testing and the development and use of such varieties might boost the rice production in India. For example, the leaf folder alone causes 20 percent yield loss in the State of Tamil Nadu. If a transgenic rice with resistance to leaf folder is released, the yield loss of 20 percent would be minimized, which in turn would increase rice production by 20 percent in Tamil Nadu. These additional benefits accrued through adoption of GM crops will go a long way to bring down the menace of hunger and poverty. However, we should neither overestimate nor underestimate the role of biotechnology to our agriculture. The people of India should be allowed to use these GMOs wherever it is appropriate, economic, usable and, safe to the chain of ecology and sustainable agriculture.

4. INDONESIA

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INTRODUCTION

Modern biotechnology has tremendous potential and offers remarkable innovations to support our country's effort to attain food security and global competitiveness. Its benefits to developing countries in the areas of food and agriculture, health and medicine, environmental protection, trade and industry are expected to be more than those benefits gained by developed countries where food and feed overproduction exists.

Products of modern biotechnology promise to reduce farmers' high input cost by reducing the use of pesticides and herbicides, increasing their yields while keeping the ecosystem intact, and enabling crops to grow under normally unfavorable conditions. Biotechnology products can even provide greater benefits to consumers, who have always been the ultimate beneficiaries of technological innovations. For instance, modern biotechnology can be a useful tool to attain greater nutritional security, through enhanced vitamin content and prolonged shelf life. Modern biotechnology can also produce healthier oils and produce vaccines to fight dreadful diseases like cholera and malaria.

Nowadays, food products produced through modern methods of biotechnology are emerging from research and development into the marketplace. It is these products that many people refer to as "genetically engineered foods". The European Commission refers to these foods as "Genetically Modified Organisms" (GMOs). The United States uses the term genetic modification to refer to all forms of breeding, both modern, i.e., genetic engineering, and conventional (Maryanski, 1999).

The new gene splicing techniques are being used to achieve many of the same goals and improvements that plant breeders have sought through conventional methods. These modern techniques are different from their predecessors in two significant ways. First, they can be used with greater precision and allow for more complete characterization and, therefore, greater predictability about the qualities of the new variety. These techniques give scientists the ability to isolate genes and to introduce new traits into foods without simultaneously introducing many other undesirable traits, as may occur with traditional breeding. This is an important improvement over traditional breeding. Second, these modern techniques give breeders the power to cross biological boundaries that could not be crossed by traditional breeding. For example, they enable the transfer of traits from bacteria or animals into plants.

The term "genetically modified" (GM) is commonly used to describe the application of recombinant deoxyribonucleic acid (rDNA) technology to the genetic alteration of microorganisms, plants and animals. This advanced molecular technology, first developed in 1973, allows for effective and efficient transfer of genetic material from one organism to another. In plant breeding, instead of crossbreeding plants for several years to acquire a desired trait, scientists can identify and insert a single gene responsible for a particular trait into a plant with relative speed. Genes do not have to come from a related species in order to be functional, hence, genes can potentially be transferred among all living organisms (Institute of Food Technologists [IFT], 1999). A GMO produced by mean of transferring gene(s) from one organism to another is referred to as a transgenic organism. In the field of agriculture, transgenic crops have been produced from modern biotechnology research through various methods of transferring genes (Herman, 1999; Mulyoprawiro, 2000; and Loedin, 2000).

ISSUES ABOUT GMO

Transgenic products are now used and commercialized in global markets. However, transgenic products still face pro and contra arguments in the international community including in Indonesia. Despite the benefit from production of GM crops, there are concerns on their impacts on the environment, biodiversity, non-target organisms, and human health.

The pro issues are mainly judged from the economic value of biotechnology crops to increase crop production and crop quality and reduce the utilization of agricultural inputs such as pesticides, herbicides, fertilizers, etc. in the agriculture business. The production of GM crops, therefore, will be more effective, efficient, and profitable. It is hoped that through the use of GM crops, agricultural production will significantly increase so that it can help our efforts to overcome food crisis in some parts of Indonesia.

Meanwhile, the contra issues are mainly concerned with the impacts of the GMO to biodiversity, biosafety, environmental safety, food safety and human health. Most Indonesian people still do not understand anything about GMOs or their products, but educated people may agree or disagree with the utilization of GMO products in Indonesia. Those who disagree have concerns about the impacts of GMOs especially to biosafety and food safety. Some people believe that consuming the GMO products may cause a disease to human such as that of allergy, cancer, and eosinophilia-myalgia syndrome (EMS). Some also believe that GMOs may have negative impacts on the environment as they may transform the transgenic products to become a super weed, to be harmful for non-target insects, or to cause insect-resistance for cultivated crops. All these issues have, however, been clarified by the Indonesian scientists through seminars and publications (Adiwilaga, 2000; and Jhamtani, 2000).

DEVELOPMENT OF TRANSGENIC CROPS

According to the International Service for Acquisition of Agri-biotechnology Applications (ISAAA), commercialization of transgenic technology in the agriculture has been initiated since 1995 and it has achieved significant progress to date. The development of transgenic crop plantings during 1998-2000 shows a rapid increase from year to year as it can be seen in Table 1. Judging from its planting areas, transgenic cotton shows the most rapid growth rate (45.6 percent), followed by soybean (34.2 percent), corn (13.2 percent) and rapeseed (10.4 percent). Distribution of the planting areas for these transgenic crops is mainly dominated in the world producing and exporting countries (Table 2), namely; the U.S.A., Argentina, Canada, China, and Australia.

Table 1. Global Development of Transgenic Crop Plantation

Crop Species	Planted Areas (million ha)			Growth Rate (percent)
	1998	1999	2000	
Soybean	14.5	21.6	25.8	34.2
Corn	8.3	11.1	10.3	13.2
Cotton	2.5	3.7	5.3	45.6
Rapeseed	2.4	3.4	2.7	10.5
Other	0.1	0.1	0.1	0.0
Total	27.8	39.9	44.2	27.2

Source: C. James, 2000.

Table 2. Distribution of Transgenic Crop Plantation among Countries
(Unit: Million ha)

Country	1998	1999	2000
U.S.A.	20.5	28.7	30.3
Argentina	4.3	6.7	10.0
Canada	2.8	4.0	3.0
China	<0.1	0.3	0.5
Australia	0.1	0.1	0.2
South Africa	<0.1	<0.1	0.2
Other	<0.1	<0.1	<0.1
Total	27.8	39.9	44.2

Source: C. James, 2000.

The rapid development of global transgenic crops either in the research, field trials and commercialization will have important implications for Indonesian agriculture. Indonesia has so far imported large amounts of basic crop commodities including rice, wheat, corn, soybean and cotton (Table 3). These crop commodities are mainly imported from countries as listed in Table 2, i.e., the countries where transgenic crops are intensively investigated and widely grown. It can be assumed that during the last three years Indonesia has imported transgenic crop products from those countries, especially for corn, soybean and cotton. Looking at the intensive research on modern biotechnology for rice and wheat in the exporting countries such as in the U.S.A., Canada, Australia and China, it is not impossible that transgenic rice and wheat will soon be available in the global market and be exported to Indonesia as well.

Table 3. Indonesian Import Volume for Corn, Soybean, Rice, and Wheat

(Unit: 000 mt)

Commodity	Imported from	1996	1997	1998	1999
Corn	U.S.A.	151.5	171.7	180.4	190.5
	Argentina	287.6	429	28.5	35.8
	China	-	297.5	250.8	363.7
Soybean	U.S.A.	732.9	610.8	818.8	1,148.4
	Canada	2.4	2.5	2.6	33.6
	China	1.8	2.5	3.1	40.5
Rice	Thailand	793.0	775.7	995.3	1,373.5
	Vietnam	272.1	132.9	1,136.6	1,803.8
Wheat	Canada	1,154.4	1,163.9	1,012.5	582.6
	Australia	2,301.4	2,019.6	2,060.3	1,457.8
	U.S.A.	541	66.4	163.7	601.2

As a producer of the agricultural products, on the other hand, Indonesia should also be aware of productivity competitiveness in the open market. Transgenic technology has been reported to have significantly increased crop quality while reducing production costs. This means that conventional agricultural production will not be able to compete with the transgenic products imported from other countries.

RESEARCH ON TRANSGENIC CROPS

Indonesia has been accommodating for modern biotechnology research and utilization of its products including transgenic crops. This point is reflected in the willingness to approve the commercialization of transgenic crops by some private companies and in the enhancing of modern biotechnology research activities in some research institutes and universities. This effort is of importance for agricultural development in the future in view of Indonesia's current reliance on food imports.

Imported crop commodities such as soybean, corn, wheat, rice, and cotton are the most common crops produced using transgenic technology. The chance that these imported commodities contain transgenic products will be higher than before due to the rapid increase in research findings and commercialization of the transgenic crops in the producing and exporting countries. To some extent, Indonesia has also been doing intensive research on transgenic technology to produce some transgenic crops (Herman,1999; Mulyoprawiro, 2000; and Loedin, 2000). Various biotechnology researches are conducted by the official research institutes and universities, and also in collaboration with foreign counterparts.

Most biotechnology research in Indonesia has been dealing with GM crops for improved resistance to biotic and abiotic stress by transferring resistance genes from another organism into a cultivated crop. Several methods used in transferring genes have been reported and described (Herman,1999; Mulyoprawiro, 2000; and Loedin, 2000). Through this research, some transgenic crop species including corn, peanut, cacao, soybean, rice, papaya, sugar cane, tobacco, sweet potato, and potato are now available in Indonesia. Some of these transgenic crops have been developed from the research efforts of several research institutes and universities in Indonesia (Table 4). Others have resulted from joint biotechnology research between local research institutes and foreign research counterparts (Table 5). Recently, some transgenic crops, i.e., cotton, corn, and soybean have been imported to Indonesia by private companies. The status of all available transgenic crops is still under intensive investigation in limited field trials (Table 6).

Table 4. Research on Transgenic Crops in Indonesia

Crops	Traits	Genes	Institutes
Corn	Resistance to stem borer	Pin II[a]	Balitbio[b]
Peanut	Resistance to PSTV[c]	CP[d]	Balitbio and IPB[e]
Cacao	Resistant to fruit borer	*Bacillus thuringiensis (Bt)*	UPBP[f]
Soybean	Resistance to pod borer	Pin II	Balitbio
Rice	Resistance to stem borer and brown planthopper	*Bt* and GNA[g]	Balitbio and P3B LIPI[h]
Papaya	Resistance to PRSV[i]	CP	Balitbio, Balitsa[j] and Balitbuk[k]
Sugarcane	Resistance to stem borer	*Bt*	P3GI[l]
Tobacco	Resistance to TMV[m]	CP	Balitas[n]
Sweet potato	Resistance to *boleng*	Pin II	Balitbio

Source: Mulyoprawiro, 2000.

Notes: [a] Proteinase inhibitor II; [b] Research Institute for Food Crop Biotechnology; [c] peanut stripe virus; [d] coat protein; [e] Bogor Agricultural University (*Institut Pertanian Bogor*); [f] Research Institute for Estate Crops; [g] *Galanthus nivalis* agglutinin (snowdrop lectin); [h] Research and Development Center for Biotechnology, Indonesian Institute of Sciences; [i] papaya ring spot virus; [j] Research Institute for Vegetable Crops; [k] Research Institute for Fruit Crops; [l] Sugarcane Research Institute; [m] tobacco mosaic virus; and [n] Research Institute for Tobacco and Fiber Crops.

Table 5. Transgenic Crops Resulted from Collaboration Research with the International Institutes

Crops	Traits	Genes	Institutes
Corn	Resistance to stem borer	*Bt*	Balitbio/ICI Seed Co.
Peanut	Resistance to PSTV	CP	Balitbio/ACIAR[a]
Potato	Resistant to PTM[b]	*Bt*	Balitbio/MSU[c]
Sweet potato	Resistance to SPFMV[d]	CP	Balitbio/Monsanto

Source: Mulyoprawiro, 2000.

Notes: [a] Australian Center for International Agricultural Research; [b] potato tuber moth; [c] Michigan State University; and [d] sweet potato feathery mottle virus.

Table 6. Status of Limited Field Trials for Biosafety of Various Transgenic Crops in Indonesia

Crops	Characteristics	Institute/Company	Trial Status
Bt corn	Resistant to ACB[a]	Pioneer	-
Bt corn	Resistant to ACB	Monsanto	Done
Pin II corn	Resistant to ACB	Balitbio/ABSP[b]	-
RR[c] corn	Resistance to glyphosate herbicide	Monsanto	Done
Bt cotton	Resistant to CBW[d]	Monsanto	Done
RR cotton	Resistant to glyphosate herbicide	Monsanto	Done
Peanut	Resistance to PSTV	Balitbio/ACIAR	-
RR soybean	Resistant to glyphosate herbicide	Monsanto	Done
Bt potato	Resistant to PTM[e]	Balitsa/MSU	Soon
Bt rice	Resistant to stem borer	P3B-LIPI	-
GNA rice	Resistant to planthopper	P3B-LIPI	-

Source" Herman, 1999.

Notes: [a] Asian corn borer; [b] Agricultural Biotechnology for Sustainable Productivity; [c] Roundup Ready; [d] cotton bollworm; and [e] potato tuber moth.

Available transgenic crops in Indonesia are categorized into three groups. Group I consists of those crops which have resulted from biotechnological research conducted by local research institutes and universities. It includes corn, peanut, cacao, soybean, rice, papaya, sugarcane, tobacco, and sweet potato (Table 4). Group II consists of those crops which have resulted from joint research between Indonesian and foreign research counterparts. It includes corn, peanut, potato, and sweet potato (Table 5). Group III consists of those crops which have been imported by the private companies. It includes corn, cotton, and soybean (Table 6).

Most available transgenic crops have agronomic characters of resistance to insects and diseases, and also to glyphosate herbicide. Through intensive biotechnology research, responsible gene(s) for resistance have successfully been inserted to the crops. These resistance genes include Pin II, CP, *Bt*, and GNA. These resistance genes have been proven to be effective to control crop insect and diseases such as ACB, CBW, PSTV, PTM, PRSV, and TMV.

Several research institutes and universities have been involved in biotechnological research to study and produce GM crops. These research institutes and universities include:

1. Research Institute for Food Crop Biotechnology (Balitbio)
2. Bogor Agricultural University (IPB)
3. Research Institute for Estate Crops (UPBP)
4. Research and Development Center for Biotechnology, Indonesian Institute of Sciences (P3B-LIPI)
5. Research Institute for Vegetable Crops (Balitsa)
6. Research Institute for Fruit Crops (Balitbu)
7. Sugarcane Research Institute (P3GI)
8. Research Institute for Tobacco and Fiber Crops (Balitas).

Research on modern biotechnology is also conducted through collaboration between the local research institutes and universities with foreign research counterparts including ACIAR, MSU, and ABSP. Collaborative research with the international private companies involves that with Pioneer, ICI Seed Company, and Monsanto.

REGULATION IN INDONESIA

The Government of Indonesia has made strict regulations in order to anticipate the negative impacts of the transgenic products. Before being used in commercial scale, all transgenic products must pass through certain testing and assessment procedures of application for their utilization in Indonesia. It is believed that transgenic crops can contribute significant benefit to the agricultural development, but it requires very careful evaluation and assessment so that they will not have a negative impact on humans. Therefore, biosafety and food safety regulations are needed.

In relation of biosafety aspects of GMO, the Minister of Agriculture has signed a decree No. 856/Kpts/HK.330/9/1997 on the provisions of biosafety of genetically engineered agricultural biotechnology products in September 1997. Because this decree did not yet accommodate the food safety aspects of GMO, it was then amended in 1999 to cover both biosafety and food safety aspects through the decree No. 998.1/Kpts/OT.210/9/99, 790a./Kpts-IX/1999, 1145A/MENKES/SKB/IX/1999, and 015A/Nmeneg PHOR/09/1999 which was signed jointly by the Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister of Food and Horticulture as biosafety and food safety for genetically engineered agricultural products. This regulation is valid for all GMO and its products used in Indonesia including microorganisms, animal, fish, and plants.

In the implementation of the decree, the Indonesian Government has formed a National Biosafety and Food Safety Commission. The tasks of this Commission are to help the Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health and State Minister of Food and Horticulture provide suggestions, considerations and recommendations about the utilization of GMO in Indonesia. In carrying out their tasks, this Commission is assisted by a Technical Team for Biosafety and Food Safety which has been formed based on the decree No. HK.330.102.1997. The tasks of this Technical Team are to help the Biosafety and Food Safety Commission evaluate applications for carrying out further technical studies or testing the applied GMO in a biosafety containment or in a confined field.

In carrying out its duty, the Technical Team for Biosafety and Food Safety follows guidelines, procedures and standard protocol for testing, evaluation, and assessment of GMOs. The Guidelines for Testing of Biosafety of GMOs, consisting of five series, i.e., General, Plant, Fish, Animal, and Microorganisms, have been documented and published by the TTB (Herman, 1999). Procedures for Laboratory studies with biosafety containment and confined field testing for evaluating and assessing the applied GMO are available at Balitbio in Bogor.

All transgenic crops must pass through an assessment and evaluation in the laboratory with biosafety containment and must also undergo confined field testing. The Technical Team in that laboratory has completely evaluated some transgenic crops including *Bt* corn resistant to stem borer, *Bt* cotton resistant to boll worm, Roundup Ready corn, cotton, and soybean resistant to glyphosate herbicide (Herman, 1999).

CONCLUSION

Indonesia has been accommodating and supportive in regard to the development and utilization of GMOs. This stance is important from the viewpoint of the future agricultural development of the country since Indonesia is now one of the biggest food-importing countries in the world. Some transgenic crops have already been available from limited field trials in Indonesia. These transgenic crops come as results of biotechnology research conducted by Indonesian research institutes and universities, and also in collaboration with foreign research counterparts. Most of these transgenic crops have agronomic traits of resistance to insects and diseases, and also to glyphosate herbicide.

The Government of Indonesia has established strict regulations in order to anticipate the negative impacts of these transgenic products. To cover both biosafety and food safety aspects of GMOs, a decree was signed jointly by the Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister of Food and Horticulture in 1999. This regulation is valid for all GMOs and its products used in Indonesia including animal, fish, microorganisms, and plants. For its implementation, a National Biosafety and Food Safety Commission has been formed. This Commission is assisted by a Technical Team for Biosafety and Food Safety. All transgenic crops must pass through the assessment and evaluation in the laboratory of biosafety containment and confined field testing.

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5. REPUBLIC OF KOREA

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DEVELOPMENT OF GENETICALLY MODIFIED (GM) AGRICULTURAL PRODUCTS

Since the early 1980s, Korea has made efforts to promote biotechnology with research and development (R&D) investment. Despite a relatively short history in the development of biotechnology, it is known that some of the country's technological achievements are at the cutting edge of biotechnology. For example, the recent development of somatic cell reproduction and AIDS DNA vaccines in Korea is comparable with that of advanced countries. But overall, Korea is far behind the United States and Japan in the areas of patents and the level of investment in research. Given rapid changes in its international surroundings, the government has committed itself to foster biotechnology as a strategic industry in the 21st century and then proclaimed 2001 as "the year of biotechnology".

As for agricultural biotechnology, the Rural Development Administration (RDA), a government agency, established the Department of Agricultural Genetic Engineering in 1986 and then founded the Agricultural Genetic Engineering Institute in 1991. The Institute was consolidated into the National Institute for Agricultural Science and Technology (NIAST) in 1994 as a consequence of government reforms in the country. Continued efforts to secure genetic resources and microorganism resources have caused NIAST to maintain a basic infrastructure for biotechnology, building on the highest level of its traditional breeding base.

Given the basic infrastructure, it is deemed that extensive investment in selected areas would bring about significant economic benefits to the country. The Ministry of Agriculture and Forestry (MAF) initiated the "Plan for Promoting Agricultural Biotechnology" in early 2001 and set out 20 strategic projects in five core areas (MAF, 2001) with which Korea could account for 5 percent of the world market in crops and livestock. This Plan will be accommodated by ₩700 billion (about US$600 million) over the 10-year period. With a view to implementing this Plan, the government established the National Institute of Agricultural Biotechnology within the RDA in 2002 and has strengthened research capacity and resources. A biotechnology research consortium that is primarily comprised of universities, private institutes and industries represents a collaborative R&D effort toward this goal. In 2001, the government invested about ₩28 billion (about US$23 million) through MAF, RDA, Korea Forest Service, and Korea Food Research Institute and plans to extend its expenditure to ₩45 billion (about US$37 million) in 2002.

As Table 1 shows, Korea is currently developing 16 transgenic crops and animals with 40 traits.

The transgenic crops account for 14 products with 35 traits, including cereal grains, fruits and vegetables, and tubers and roots. Most transgenic crops are at an experimental stage in laboratories but rice and potatoes have proceeded to the level of open-field tests. There are on the other hand two transgenic animals with five species. Transgenic pigs are basically under a development stage of verification and examination and transgenic chickens are explored in laboratories.

The fact that neither transgenic crops nor animals developed in the country are submitted to risk assessment and evaluation means that there are no commercially growing GM crops and animals in the country. In the future, it is likely that the transgenic crops and animals under greenhouse and field-level experiments such as rice, wheat, cabbage, potatoes and pig could be diffused and marketed in five years. At present, then, all the GM crops that are currently marketed in Korea are imported from foreign countries.

Table 1. Transgenic Crops and Animals under Development

Crop and Livestock		Characteristics	Experimental Stage
Crops:	Rice	Herbicide-resistant	Field
		Photosynthesis improvement	Greenhouse
		High amino acids content	Greenhouse
		Green leafhopper-resistant	Greenhouse
		Leaf blight-resistant	Laboratory
		Bacterial soft rot-resistant	Laboratory
		Drought tolerant	Laboratory
	Wheat	Rust-resistant	Greenhouse
	Cabbage	Herbicide-resistant	Laboratory
		Genic male-sterility	Laboratory
	Chinese cabbage	*Plutella xylostella*-resistant	Greenhouse
		Herbicide-resistant	Laboratory
		Disease-resistant	Laboratory
	Tomato	Expression control	Laboratory
	Lettuce	Vitamin E fortified	Laboratory
	Red pepper	Spicy taste control	Laboratory
		Flowering control	Laboratory
		Herbicide-resistant	Laboratory
	Potato	Virus-resistant	Field
		Bacterial disease-resistant	Greenhouse
		Salinity-tolerant	Greenhouse
		Disaster-resistant	Greenhouse
		Herbicide-resistant	Greenhouse
	Perilla	Herbicide-resistant	Laboratory
		Vitamin E fortified	Laboratory
	Chrysanthemum	Early flowering	Laboratory
		Herbicide-resistant	Laboratory
		Cytokinin synthesis	Laboratory
	Garlic	Heat-tolerant	Laboratory
		Herbicide-resistant	Laboratory
	Lily	Flower color altered	Laboratory
	Watermelon	Herbicide-resistant	Laboratory
	Apple	Starch synthesis	Laboratory
		Flowering control	Laboratory
		Coloring enhanced	Laboratory
Animals:	Pig	Hematopoiesis promoted	Production verification
		Thrombosis remedy	Laboratory
		Cellulose decomposition	Bioassay
	Chicken	Albumin production	Laboratory
		Obesity control	Laboratory

Source: MAF internal document.

MARKETED GM CROPS

Taking into account international development of genetically modified organisms (GMOs), one may not be mistaken to state that GM soybeans, corn, cotton and rapeseed are the leading farm products that are traded in the world market today. It has, however, been impossible for an importing country to estimate what portion of its total imports was comprised of GMOs. Even for the exporters, the lack of systematic market segments or identity preservation in the supply chain prevented them from segregating between GMOs and non-GMOs.

According to Lim and Park (2001), the estimated importation of GM soybeans increased from 20,900 mt (or 0.9 percent of total soybean imports) to 888,600 mt (or 32 percent) over the 1997-2000 periods. Importation of GM corn also rose from 39,400 mt (or 0.5 percent) to 773,500 mt (or 9 percent) in the same period. But, the share of total imports peaked in 1999 as over 20 percent. While the share of GM cotton remained lower than 1 percent, the share of GM rapeseed imports jumped to almost 60 percent in the period.

Since the introduction of a mandatory labeling scheme requires identifying whether imported items are GMOs or not in accompanying documents, it has become technically possible to determine the volume of GMO imports. Table 2 summarizes actual volumes of GMO-labeled and unlabeled imports of soybeans and corn, and processed food over the period of July 2001 and May 2002.

Table 2. GMO and non-GMO Imports

		Number of Import	Imported Volume (000 mt)	Volume Share (percent)
GMO-labeled	Soybean	71	858	-
	Corn	154	551	-
	Process food	896	4	-
	Sub-total	1,121	1,413	44.9
Unlabelled		4,638	1,733	55.1
Total		5,759	3,146	100.0

Source: Korea Food and Drug Administration (KFDA), 2002.

According to the KFDA, GMO-labeled soybeans and corn imports recorded 858,000 mt and 551,000 mt, respectively in the period. Compared with the total annual imports in 2001, they account for about 63 percent and 6 percent, respectively.

In soybean imports for food use, the Agricultural and Fishery Marketing Corporation (AFMC) is a dominant player, accounting for about 68 percent of the total imports in 2001. Reflecting domestic market development, the AFMC has imported only non-GM soybeans since 2001 (Lim, 2002). At the same time, because other industries and private companies also tend to import mostly non-GM soybeans for food use, there are few GMO-labeled products in the market.

The imported GM soybeans are mainly used for making edible oil and the leftover soybean meals are used as feed. GM corn products are used as ingredients for cornstarch and sugars so that their GM contents no longer remain in the final products. Exclusion of feed from labeling requirements as well as food that may be derived from GMOs but no longer has GMO contents in it means that very few consumer products in the markets have GMO labeling.

REGULATORY DEVELOPMENT FOR GMOs

The regulatory framework for GMOs can be divided into two areas. One refers to health and environmental safety and the other addresses consumer information. As Table 3 shows, various laws and regulations have been established to deal with safety issues associated with GMOs.

Despite the development of a regulatory framework in recent years, Korea is still far behind developed countries. As a late starter toward biotechnology Korea has experienced difficulties in catching up with early adopters. Especially, a limited knowledge of the technology along with insufficient capital resources has become a stumbling block to the establishment of concrete systems for health and environmental risk assessment. It is therefore vital to develop risk assessment technology and reinforce data production and information dissemination.

The GMO labeling scheme was introduced for food crops (soybeans, corn and soy-sprouts) in March 2001 and then potatoes were added later in 2002. Note here that feed grains are not subject to the labeling scheme. A threshold level of unintended mingling of GMOs into non-GM crops was set at 3 percent and thus any crop beyond the threshold level of GMO contents must be labeled so. Depending on specific requirements, there are three different ways to label GMO crops: 'GMO crop', 'GMO crop included' and 'may contain GMO crop'.

Table 3. Regulatory Development for GMO Safety

Regulation	Competent Ministry	Date	Main Content
Biotechnology Promotion Law	Ministry of Science and Technology	December 1983	Action plans for biotech promotion
Guideline of Genetically Recombinant Organisms Experiment	Ministry of Health and Welfare	April 1997	Procedures to secure experimental safety and prevent from unintended spread of GMOs
Guideline of Safety Assessment for GM Foods and GM Food Additives	KFDA	August 1999	Approval requirements for manufacturers or importers to sell GM foods in the market
Regulation for Agricultural Research-related Genetically Recombinant Organisms Experiment and Handling	RDA	December 1999	GMO safety assessment methods and GMO handling methods
Law on Transnational Movement of GMOs	Ministry of Commerce, Industry and Energy (MOCIE)	March 2001	Approval requirements for GMO import production research laboratory management
Guideline of Environmental Risk Assessment for Agricultural GMOs	MAF	January 2002	Procedures for environmental risk assessment committee and fields tests

Source: Kim, 2002; and authors' addition.

As for processed GM food, the KFDA established a labeling scheme in July 2001, similar to the case of GM crops. The scheme encompasses 27 processed foods based upon soybeans, corn and soy-sprouts. It is also applicable only if genetically recombinant DNA or foreign proteins remain in the final food. Put differently, bean oil or corn oil are not subject to the labeling scheme.

Having nothing to do with health or environmental safety concern, the labeling system aims at ensuring consumers to exercise their 'right-to-know' and 'right-to-choose' in the market. Economic theories say that an introduction of a labeling scheme may generate beneficial outcomes by narrowing information asymmetry between producers and consumers. Nevertheless, there is a counter-argument against the labeling policy. It states that mandatory labeling systems would deliver biased information to consumers and thus generate negative public perception of GMOs. It is further argued that GMO labeling would be *de facto* a trade barrier precluding the entry of foreign farm products into the domestic market.

As countries are increasingly adopting labeling polices in tandem with the expansion of GMO production in major exporting countries, potential conflicts on domestic labeling schemes are mounting and are likely to result in challenges being brought to international organizations. Especially, as seen from the discussions in the Codex, the Cartegena Protocol on Biosafety and the WTO, trade implications related to GMOs and GMO labeling schemes would be of immense concern and have to go through rule-based tests for their legitimacy and compliance.

Various surveys indicate that a majority of consumers in Korea strongly support the adoption of a mandatory labeling system for GMOs (Lim and Park 2001). It is also shown that public sentiment against GMOs is largely due to underlying uncertainty on potential risks to health and the environment. Interestingly enough, the survey results do not appear to support a premise that information provision would contribute to public acceptance of GMOs. No statistically significant relationship has been found between educational levels or understanding about GMOs and public acceptance.

ENVIRONMENTAL RISK ASSESSMENT FOR AGRICULTURAL GMOs

As for "Guideline of Environmental Risk Assessment for Agricultural GMOs" (Table 4) the risk assessments of GMOs are independently managed by the Ministry of Science and Technology (management of GMOs for the research purpose), the MAF (management of GMOs as raw materials), the MOCIE (management of GMOs for industrial use), the Ministry of Health and Welfare (management of GM food), Ministry of Environment (biohazard management of GMOs in the ecosystem), Ministry of Maritime and Affairs and Fisheries(management of GMOs in the marine environment).

Table 4. Work Assignment for GMO Safety

Competent Ministry	Main Content	Transgenic Crops and Animals
Ministry of Health and Welfare	Safety assessment of GM food for human health impact	GM crops (soybean and maize)
MAF	Biosafety assessment of agricultural products	GM crops and livestock
Ministry of Maritime Affairs and Fisheries	Safety assessment of environmental impact for marine products	GM super-roach and rainbow trout
MOCIE	Safety evaluation of GMO for industrial use	GM microorganism for industrial process
Ministry of Environment	Biohazard evaluation of the release of GMOs into the environment	Seeds, microbial pesticide
Ministry of Science and Technology	Risk assessment of GMOs for research purpose in the laboratory (exceptionally pathogens belong to Ministry of Health and Welfare)	GMOs for research purpose in the laboratory

Source: MOCIE, 2002.

The Korean Agency for Technology and Standards (KATS) under the MOCIE has established seven Korean standards (KS) related to the safe management of GMOs such as guidelines on monitoring strategies for unintentional release into the environment during produce, transport and sale (October 2002).

REFERENCE

Kim, Tae-San, 2002. "Regulatory Framework for GM Crops in Korea", paper presented in the 3rd International Seminar on Biosafety of Living Modified Organisms, June 2002, Seoul.

Korea Food and Drug Administration, 2002. Labeling Management for Genetically Recombinant Food (in Korean) (http://www.kfda.go.kr/korea/food/pdf/you20020723.pdf).

Korean Agency for Technology and Standards, 2002. *Korea Standard of Safety Assessment and Management for GMOs*.

Table 5. Korea Standard of Safety Assessment and Management for GMOs

KS No.	Title	Contents
12305	Guidance for the sampling strategies for deliberate release of GM plant	To decide the statistically effective sampling strategy including design, performance and document preparation
12468	Guidance for the monitoring strategies for deliberate release of GM plant	To decide the surveillance of emerging frequency, sustainability, and distribution of GMOs in the environment
12683	Guidance for the characterization of GMO by analysis of the functional expression of the genomic modification	To decide the experimental design and performance for genetic expression: characterization of intrinsic/extrinsic factors and identification of expressed products, etc.
12683	Guidance for the characterization of GMO by analysis of the molecular stability of the genomic modification	To decide the evaluation of molecular stability for GMOs influenced by genetic homeostasis and external factors
12685	Guidance for the monitoring strategies for deliberate release of GM microorganisms, including viruses	To decide the environmental impacts, emerging frequency, sustainability, and distribution of GM microorganisms including viruses
12686	Guidance for the sampling strategies for deliberate release of GM microorganisms, including viruses	To decide the sampling strategy for genotype-dependent microorganisms modified by genetic manipulation
12687	Guidance for the characterization of the GMO by analysis of the genomic modification	To decide the valid methods of detection and identification of GMOs by biochemical, immunological, and molecular biological approach

Source: KATS.

Lim, S. S. and Y. H. Park, 2001. "Management and Labeling Schemes for Genetically Modified Agricultural Products", *Korea Rural Economic Institute Research Report* R433 (in Korean).

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Ministry of Agriculture and Forestry, 2001. *Plan for Promoting Agricultural Biotechnology* (in Korean).

6. MALAYSIA

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INTRODUCTION

In Malaysia, the focus of biotechnology work centers on the needs of the nation. Improving food production has been and will continue to be one of the top priorities and commitments of government agencies involved in biotechnology. As far as agriculture is concerned, Malaysia is blessed with a lot of assets and features. The nation is rich in natural resources and blessed with favorable climate all year around suitable for tropical agriculture. Malaysia has been a world leader in a number of plantation crops, such as oil palm, rubber and cocoa.

The economic crisis of the late 1990s prompted the government to have a second look at the importance of agriculture, especially in food production to the national economy. The government has stressed the need for producing sufficient amounts of food for national security and stability. The huge and growing costs of food and feed imports clearly indicate the need to transform our agriculture sector in order to produce enough food for the people. Research and development in biotechnology is geared to meet this challenge.

BIOTECHNOLOGY IN MALAYSIA

Biotechnology receives large-scale support from the Malaysian Government. Biotechnology has been earmarked as one of the areas of advancement under the 8th Malaysia Plan (2001-05). To accelerate biotechnology development in Malaysia, the Ministry of Science, Technology and the Environment (MOSTE) set up the National Biotechnology Directorate (BIOTEK) in May 1995. BIOTEK is entrusted with the task of spearheading and coordinating biotechnology research in Malaysia.

To streamline biotechnology research, BIOTEK had established seven Biotechnology Cooperative Centers (BCC) in the areas of plant, food, animal, molecular biology, medical, environment/industry and biopharmacy. The BCCs help to coordinate biotech research in the various research organizations to improve cooperation and reduce duplication.

The following is the list of research organizations and their research emphasis:

Organization	Research
Malaysian agricultural Research and Development Institute (MARDI)	* Disease resistance in rice, chili and papaya * Delayed ripening in papaya * Floral color and senescence in orchids
Malaysian Palm Oil Board (MPOB)	* Yield improvement * Improved oil quality * Production of bio-plastics
Rubber Research Institute, Malaysia (RRIM)	* Yield improvement * Disease resistance * Production of high-value proteins
Institute of Medical Research	* Medical diagnostic kits * Screening of local herbs for pharmaceutical properties

University Kebangsaan Malaysia (UKM)	* Molecular biology of *Burkholderia pseudomallei* * Antibody engineering * Gene and genome analysis of *Anopheles maculates* * Molecular biology of protozoan parasites * Molecular studies of *Glomerella cingulata* and its pathogenesis of Cry proteins * Molecular systematic studies of wildlife and domestic animals
University Malaysia Sarawak	* Screening of local plants for anti-malarial drug * Genetic studies of high-risk populations on nasopharyngeal carcinoma (nasal cancer) * Transgenic sweet potato with Japanese encephalitis vaccine for pigs
University Putra Malaysia	* Oil palm expressed sequenced tags (ESTs) * Plant transformation * Gene expression * Floral/meristem/embryo development * Plant defense stress response

Biotechnology in Malaysia recently received a further boost with the announcement of the BioValley initiative. The BioValley will consist of a concentration of biotechnology research institutions, universities and companies within the Multimedia Super Corridor (MSC). BioValley will include three new research institutions conducting research in genomics and molecular biology, nutraceuticals and pharmaceuticals, and agricultural biotechnology.

Another initiative to boost biotechnology in Malaysia is the Malaysia-MIT (Massachusetts Institute of Technology) Biotechnology Partnership Programme (MMBPP). It is a collaborative effort between Malaysian academic, industrial and government research organizations, including six BCCs, through Malaysia's National Biotechnology Directorate and the MIT. The Programme is supported by the MOSTE. The primary goal of this partnership is to build a foundation for a sustainable biotechnology industry in Malaysia through research development, as well as human resource training.

This Programme hopes to facilitate the interaction, development and training of scientists in critical areas like genomics, bioinformatics and bioprocessing through the exchange of Malaysia and MIT research personnel. The aim of the training is to develop a group of professionals who will be able to spearhead the development of biotechnology industry in Malaysia.

REGULATIONS GOVERNING THE APPLICATION OF GM TECHNOLOGIES AND USE IN MALAYSIA

In Malaysia, MOSTE is the focal point and is responsible for coordinating all matters pertaining to biological diversity including biosafety under the Convention on Biodiversity (CBD). A Genetic Modification Advisory Committee (GMAC) was established in March 1996 under the ambit of the National Committee on Biodiversity (NCB), MOSTE. Its objective is to ensure that any risks associated with the use, handling and transfer of genetically modified organisms (GMOs) be identified and safely managed; and to advise the government about matters pertaining to genetic modification technology and its application.

Following its establishment, GMAC, has formulated the National Guidelines on the Release of GMOs into the Environment. It is part of the overall effort to provide a national framework for addressing biosafety issues with regards to regulation, assessment and management of risks associated with the use and release of GMOs into the environment. The Guidelines require the establishment of an Institutional Biosafety Committee (IBC) in all related research government institutions. The IBCs will ensure that experiments relating to genetic modification and release undertaken by the institution conform to the provisions of the Guidelines. As a result, many universities and government research institutions have already established their own IBCs.

Implementing the Guidelines

Currently, the importation of GMOs is regulated by sectoral legislation; meaning the existing law enforced by respective agencies or government departments. These government departments or agencies are recognized as competent authorities. In Malaysia the competent authorities consist of the Department of Agriculture for plants, the Department of Fisheries for fish, the Department of Veterinary Services for animals and the Ministry of Health for food.

Applications to import GMOs are sent to the respective competent authorities for approval. The competent authorities shall seek the advice of GMAC by providing a copy of the relevant documents and information on the GMOs proposed to be imported. Approval to import is issued by the competent authority based on the recommendations of the GMAC.

The guidelines further require the proponents to submit applications to the NCB Secretariat for consideration by GMAC on every aspect of trials until the GMOs is placed in the market.

Biosafety Law

Genetic engineering is to be promoted with the necessary safeguards so that biotechnological processes are properly regulated along socially and ethically desirable channels. Being a country naturally endowed and recognized as one of the 12 megadiversity countries of the world, Malaysia is purported to harbor more than 150,000 species of invertebrates, 286 mammal species, 736 bird species and 15,000 flowering plant species. As such, it is very necessary for this country to carefully regulate the gene technology so that this vast natural treasure of biodiversity is not adversely affected. Currently, GMOs are regulated using the guidelines formulated by GMAC. However, these guidelines are not law, meaning that there are no provisions to impose penalties on any party not following these guidelines. Thus the current means of regulating GMOs is ineffective due to its inherent enforcement limitations. Realizing this fact, the government in June 1997 has directed GMAC to draft a Biosafety Bill with the specific objective of regulating GMOs.

The Malaysian Biosafety Bill has already been tabled at the National Consultation Forum in September 2001. Based on the feedback received from the stakeholders during the consultation, some fine tuning has been undertaken especially with regard to its scope, and its provisions on labeling, export and contained use. In general a Biosafety Council will be established to approve application for importation of GMOs, deliberate release and use and placing on the market. In this regard, GMAC will carry out technical risk assessments and make recommendations to the Council for consideration. Enforcement activity will be implemented by existing agencies responsible for regulating and protecting human, plant and animal life and health. As an example, Department of Agriculture is responsible for regulating plant health, Ministry of Health is responsible for in regulating food safety. The Bill is expected to tabled to the Parliament in 2003 for high-level policy decision.

Similarly, a Bill on the regulation of GM food has been drafted and is expected to be tabled in the Parliament in 2003. This Bill is complementary to the Biosafety Law. This regulation will cover general provisions on import, preparation, advertisement for sale, or sale of food ingredients obtained through genetic modification. It will also cover labeling of GM food.

APPROVED USE OF GMOs FOR CONFINE FIELD RELEASE

In Malaysia, all research on GMOs irrespective of their origins is still in the early phase under confined use. To date, the GMAC of Malaysia has undertaken three risk assessment exercises as follows:

Assessment for Confined Field Release of Transgenic Papaya Plants for Superior Postharvest Fruit Quality (Delayed Ripening)

The MARDI had submitted an application for a confined field release of transgenic papaya modified for delayed ripening to the GMAC in January 2002.

Risk assessment was carried out based primarily on the data provided by the proponent. Based on the available data, GMAC concluded that transformed papaya with antisense ACC (aminocyclopropane carboxyl) oxidase cDNA sequence is safe to eat and is not hazardous to agriculture and the environment. Therefore, GMAC approved the transgenic crop for confined field release to be performed in a netted house.

Assessment for Confined Field Release of Transgenic Oil Palm That is Tolerant to Herbicide Glufosinate Ammonium (Phosphinothricin, Basta 15)

The application for confined field release of transgenic oil palm was submitted by the MPOB (formerly known as PORIM – Palm Oil Research Institute of Malaysia) in March 2002.

Risk assessment was also carried out based on data provided by the proponent. However, the GMAC was not convinced on the proposed location of the field release and requested some additional information. The proponent was also requested to submit a new location for their confined field release. To date, this application is still pending.

Approval for Imported GM Soybean for Food and Feed

In October 1996, the Malaysian Government had received an application to import transgenic soybeans (*Glycine max*) for food and feed into the country. That application was the first assignment for GMAC of Malaysia to undertake a risk assessment for the release of a GMOs into the environment. The transgenic organisms was the glyphosate-tolerant "Roundup Ready Soybean", produced by Monsanto Co. (U.S.A.)

"Roundup Ready Soybean" was deregulated in the U.S.A. since May 1994. Thus the beans would not be differentiated from the conventional (non-transgenic) soybeans when they are imported into the country. The glyphosate-tolerant soybeans (GTS), line 40-3-2 contain two novel constituents, namely; the enolpyruvateshikimate-3-phosphate synthase (EPSPS) gene derived from *Agrobacterium sp*. strain CP4 and its gene product, the EPSPS enzyme. Risk assessment was based primarily on scientific data provided by the proponent, information derived from literature search and similar risk assessment of the same GMOs conducted in other countries.

Based on the available data, GMAC concluded that Roundup Ready Soybean line 40-3-2 was not different from conventional soybeans and hence safe for consumption either by human or animal. In addition, it was proven not to be hazardous to agriculture and the environment and unlikely to become a weed pest.

ISSUES ON REGULATION AND USED OF GMOs

Safety Aspect

Most of the GMO plants are being developed for pest resistance, herbicide resistance, viral disease resistance, stress tolerance, improving nutritional quality and, delayed ripening. However, the introduction of these superior genetic traits through genetic modification has been suppressed by overwhelming concern over their long-term effects especially on human health and environment.

Public Awareness on GMOs

There are significant gaps in knowledge and information on the interactions of GMOs and the environment among the public which lead to their unfounded fears and suspicions of the potential risks. It is therefore imperative for the producers of GMOs to disseminate accurate information on the GMO plants or foods produced to the general public as well as the regulators. There is also a need for collaborative efforts between producers and regulators to carry out awareness activities such as workshops, dialogues and public fora to different sectors of the public on the issues of GMOs. Opposition to biotechnology or GMOs is expected to subside when clarification and adequate information are made available.

Capacity Building

While the science of biotechnology has advanced in this region over the years, expertise in risk assessment and management of GMOs in the environment is generally lacking in Malaysia. Another problem encountered is the lack of expertise to carry out environmental risk assessment which includes the study of the extent of pollen flow, implications of out-crossing/cross-fertilization, susceptibility to diseases and pests, stability of the transgenic genome and resistance to abiotic stresses. Therefore, there is an urgent need to have adequate trained manpower in risk assessment and management of GMOs.

There is also the need to increase the infrastructure to handle GMOs such as by the establishment of up-to-date laboratories for monitoring and detecting GM plants or plant products or food at the point of import. At the same time we also need to train personnel to staff these laboratories.

Establishment of Recognized Detection Method for GMOs

The need to monitor and verify the presence of and the amount of GMOs in plants, plant products and foods has generated a demand for analytical methods capable of detecting, identifying and quantifying the DNA or protein(s) expressed in transgenic plants. Various methods of detecting GMOs have been developed, however, there is a need to establish the type of analytical techniques that will be acceptable by regulators.

Strengthening of Existing Sectoral Legislation and Drafting of New Legislation on GMOs

The potential risks associated with GM crops and foods may lead to the creation of an entirely new set of procedures, regulatory and legal issues in trade. Recognizing the global controversy over GMO crops and foods, Malaysia like most developing countries, is still skeptical of its effects on food and human health. Malaysia is in the process of reviewing and where appropriate, strengthening its existing sectoral legislation with a view to incorporate provisions for regulating and managing GMOs. In addition the new Biosafety Bill which is in process of being presented to the Parliament will further strengthen our control over GMOs.

CURRENT VIEWS ON THE FUTURE OF GMO PLANTS AND FOODS

Malaysia encourages the use of GMO plants, plant products and foods. However, research on the evidence for long- and short-term risk posed by GMOs needs to be generated as soon as possible to alleviate any fears and misconceptions about GMOs.

GM products or food in the market may require labeling to ensure transparency and allow for consumer choice.

GMO plants for which there is evidence to demonstrate there is no long- or short-term potential affects to human health and environment and which can benefit the country will be further encouraged for commercialization.

CONCLUSION

The Malaysian Government is well aware of the potential benefits of GM crops. However it has the responsibility to assure the public of the safety of the GM crops as well as to safeguards against their adverse effects (if any) on human health and the environment. Malaysia is supportive of activities that relate to biosafety capacity building such as practical training programs in risk assessment and management.

7. THAILAND (1)

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INTRODUCTION

Thailand is known as one of the world's largest net food exporters. The country remains a world leader in the production of several commodities such as rice, cassava, shrimp, canned tuna and canned pineapple. It is apparent that agriculture will continue to contribute a significant proportion of Thailand's GNP as the country move toward being 'the world's kitchen'.

The Thai Government is determined to maintain its position in world food production, and it also views that biotechnology will play an important role in increasing the competitive advantage of farmers and the country's agro-industry. Therefore, Thailand has been very active in research and development (R&D) seeking better varieties of plants using gene technology, among other forms of agricultural biotechnology. The setting up of Thailand's National Center for Genetic Engineering and Biotechnology (BIOTEC) in 1983 was naturally an important milestone that the government has laid down as the country's engine to promote R&D in this strategic technology.

Crops being developed in Thailand using transgenic technology include papaya, chili, rice and cotton. None of these has reached market-scale production. Apart from plant genetic engineering R&D performed on certain crops in local research laboratories, genetically modified (GM) crop seeds as the product of foreign multinationals were first introduced into Thailand in 1994. The first crop plant permitted, only for field trial, was Calgene Fresh Company's delayed ripening Flavr Savr tomato, earlier tested and permitted in the U.S.A. Later on, Monsanto's *Bacillus thuringiensis (Bt)* cotton and Novartis' *Bt* corn were permitted for field tests.

It was during mid-1990s, when many GM crops were commercialized in the U.S.A. that these biotechnology-derived food and feed commodities started to circulate in the global market, although with little distinction from conventional crops. However, toward the late 1990s the GM debate has sparked a fierce controversy across the Atlantic, mainly between U.S.A. and the EU. Growing public concern over the safety of genetically modified organisms (GMOs) to the environment and for consumption has spread from Europe to the rest of the world, including Thailand.

In the meantime, soybean and corn, commingled between GM and non-GM, has been imported into Thailand through routine trade practices since Thailand depends on imported grains from countries known to produce GM crops such as U.S.A., Argentina and Canada. Under this situation, the Thai Government has decided to take a realistic measure to allow these GM soybean and corn, approved overseas, into the country only for food, feed, and production.

Under these situations, issues concerning pros and cons over GMOs were presented and debated in newspapers and on television among members of civil society: mainly NGOs, journalists, government officers and scientists. Often, the debate focused around international trade conflicts, perceived health risks, regulatory issues and consumer's rights. The discussion on scientific facts looking at the current knowledge on real threats and benefits of GM crops went on but rather quietly, overshadowed by sensational news focusing on the negative side. This emotional debate has proceeded for several years without much progress in public policy formulation, resulting in lack of consensus in the public opinion. The uncertainty has evidently dissuaded policymakers from making appropriate and timely decisions, which in turn leaves the public confused and unsatisfied.

RESEARCH AND DEVELOPMENT

Efforts in plant biotechnology and genetic engineering have been aimed at the development of transgenic plants with superior properties to solve local problems of agricultural production, including the development of plants with resistance to diseases, insect pests and abiotic stress.

Research activities in this field were pioneered by the Plant Genetic Engineering Unit (PGEU), the satellite laboratory of the BIOTEC at Kasetsart University. Transgenic tomato plants carrying the coat protein gene of tomato yellow leaf curl virus (TYLCV) were developed to control the serious virus disease of tomato. The same approach was taken to develop transgenic papaya and chili for resistance to papaya ring-spot virus (PRSV) and chili vein-banding mottle virus (CVbMV), respectively. Another key biotic stress of crop production is the loss due to insect pests. Sri Somrong 60, a Thai cotton variety was successfully transformed with Cry1A(b) gene expressing a *Bt* toxin from *Bacillus thuringiensis*. Transgenic cotton plants will be used for controlling the cotton bollworm *Helicoverpa armigera*. For abiotic stress resistance, attempt has been made to transform Khaw Dawk Mali 105, an aromatic Thai rice with 1-pyrroline-5-carboxylate synthase for salt and drought tolerance by particle bombardment.

Although none of the crop plants under research in Thailand has reached market-scale production, transgenic papaya with resistance to PRSV is considered the most promising GM product and may be the first to be introduced to farmers in the country. Besides PGEU, two other research teams are working separately on the same product, one team at Mahidol University and the other at Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC), who went as far as undergoing large-scale field trial. Most of transgenic plants developed in Thailand, including all GM papayas, are now being tested under greenhouse conditions and field tests in accordance with the Biosafety Guidelines and are also undergoing food safety test following the GM Food Safety Guidelines.

In spite of the fact that the Thai Government has a liberal policy in biotechnology R&D in the country and fully supports development and strengthening of capacity in research involving GM food and agricultural products, funding available for research and training program is limited particularly after the economic crisis that swept the country in 1997. Most of the projects at governmental research institutes tend to focus on an immediate need or problem rather than aiming at long-term or strategic goals. Some private companies in Thailand are involved, though not intensively, in biotechnology R&D, such as seen with the CP Group's involvement in GM flowers. The wide gap between governmental R&D institutions and the industrial sector and also other end-users has lessened the benefit of biotechnology in Thailand.

Taking the current status into account, DOA is trying to put a greater amount of effort into restructuring R&D management regimes, promoting multidisciplinary research, developing infrastructure and manpower, strengthening and expanding research partnerships, as well as reaching out to farmers and the industry to achieve the greatest impact on Thailand's agriculture.

IMPORTATION FOR FIELD TESTS

GMOs from foreign origin were first introduced into Thailand in 1994. According to the Thai Plant Quarantine Act, promulgated in 1964 and amended in 1994, introduction of GM plants into the country can only be for research purposes and has to be permitted by the DOA, MOAC, after technical review and advice from the National Biosafety Committee (NBC), in accordance with Thailand's Biosafety Guidelines (see more details in '*Regulatory Issues*'). The first crop plant permitted under this regime, only for field trial, was Calgene Fresh Company's Flavr Savr tomato, a delayed ripening tomato earlier tested and permitted in the U.S.A. by USDA/APHIS (U.S. Department of Agriculture/Animal and Plant Health Inspection Service). The purpose of this field trial was to produce seeds destined for export only.

Since then, many other crops including Monsanto's *Bt* cotton and Novartis' *Bt* corn have been permitted for field tests. In order to have an effective system to monitor the field-testing, NBC and DOA have jointly established a monitoring workgroup. Experts from both institutions considered the design of experiments, made field visits, and recommended some postharvest practices. In the above case of Flavr Savr tomato experiment, four field visits were each made before and after the harvest.

To date, permission has been granted for the introduction of 16 GMOs into the country for research purposes including field trials. As the current import permits are strictly for research purpose, no GMOs have been permitted for commercial application. Among these, Monsanto's *Bt* cotton has undergone the most extensive field trials in the country, starting in March 1996. It was expected to be the first GM crop to be placed on the market for commercial planting. Amidst results showing its safety to the environment and applause by some groups of farmers who were involved in the trials, however, strong opposition by several NGOs took hold and the product has been suspended at the political level for several years now.

IMPORTATION FOR FOOD, FEED AND PRODUCTION

In the consumer's market – amidst the lack of a sufficient regulatory system, consumer's awareness and an overall policy framework – streams of GMOs started to flow into the country in the late 1990s as finished food products, feed ingredients, and raw material for production of food-related products such as vegetable oils. These GMOs were mainly from soybeans (Monsanto's Roundup-Ready) and corn (*Bt* corn and many others), commingled between GM and non-GM grains. The main source of these GM foods were exporting countries known to produce GM crops and exporting them to the world market and their own domestic market, e.g., U.S.A., Argentina and Canada.

In October 1999, as the controversy concerning the safety of GMOs was escalating around the globe particularly in the EU countries, Thailand's Committee on International Economic Policy issued a policy statement affecting the commercialization of GM plants. The statement prohibited any commercial import or release into the market of any GM crop plant, which was actually in accordance with the 1964 Plant Quarantine Act, amended in 1999. The Law, up to date, restricts importation of over 70 different varieties of transgenic plants unless is permitted on a case-by-case basis and only for research purpose. Therefore, field trials were still allowed under the jurisdiction of DOA. In addition, GMOs must be proven as safe before they can be permitted for use as food or food ingredients. Finished food products are not covered by the Plant Quarantine Act and the food safety issue is under the jurisdiction of Thailand's Food and Drug Administration (FDA).

One important aspect of the 1999 policy statement which has had profound effect on trade was that transgenic soybeans and maize grains (not seeds) receive exemption (from the Plant Quarantine Act) and are allowed into the country for use as human food, animal feed and for production. Since Thailand's major source of soybean and corn depends on imports, the decision was made, obviously, for the practical purpose not to disrupt industrial production. It was also based on two important facts that: food risk assessment has been performed on these commercial food crops; and they had been regularly traded in the world market for many years.

CAPACITY IN DETECTION AND TRACEABILITY: AN URGENT AND SHORT-TERM NEED

In Thailand, DNA typing or fingerprinting technology is also considered as a new agricultural biotechnology that has made great contribution to the raising of production efficiency and reduces costs. It also emphasizes bringing product quality and processing up to international requirements.

One such requirement has been the identity preservation of GMOs. The allowance of GM soybean and corn raw material into the country means that a variety of export products can possibly be GM positive. As the international market, especially EU and Japan, impose more restrictions on various GMOs, there is increasing interest among Thai producers to determine the presence of GMOs in their exported agricultural and food products. In many cases, firms producing products for specialty markets needed to verify that their products are free from GMOs, or to ensure that they meet tolerance levels established by end-users or partner country regulations.

Amidst increasing demand and rapid growth in the need for GMO testing facilities, the DNA Technology Laboratory (dnawww@dna.kps.ku.ac.th) was established by Thai Government in September 1999. The laboratory evolved from BIOTEC's DNA Fingerprinting Unit, which has performed R&D in DNA markers and crop plant breeding. BIOTEC has initiated a five-year program starting in 2000 to establish a specialized laboratory to provide reasonably priced DNA analysis service and GMO detection service to the public sector, the private sector and the general public. In the process, Kasetsart University has provided building accommodations at its Western Bangkok Campus and a number of supporting staff. The laboratory set out conducting the above program and has recently been certified ISO Guide 25 compliance.

The laboratory is now offering extensive services such as GMO testing, DNA fingerprinting, DNA sequencing, diagnostic kits and DNA marker development. The lab's GMO testing service uses real-time Polymerase Chain Reaction (PCR) capable of detecting quantitatively at the level of 0.1 percent GMO content. It tested 2,000-3,000 samples between October 2000 and June 2001, providing services to 197 organizations, including 177 private companies. Some orders came from overseas, although mainly customers are domestic. It also produces diagnostic kits and ready-to-use reagents and other tools for other laboratories.

At present there are at least four GMO-detection laboratories operating in the country:

1. DNA Technology Laboratory, BIOTEC
2. Laboratory at Office of Biotechnology Research and Development, DOA, MOAC
3. Department of Medical Science (DMSc), Ministry of Public Health
4. Detection Service Laboratory, National Food Institute (NFI).

These laboratories are all capable of providing service, mostly both qualitative and quantitative detection, to the private sector both to certify their export products and also to prepare for the implementation of the GM food labeling regulation due in 2003.

The private sector is also playing some role in sampling and detection of GMOs. Universal Systems Co., Ltd. (unisys@samart.co.th), a local company specialized in GMO detection, has recently marketed a variety of products, mainly test strips, that can rapidly detect proteins in GMO leaves and grains at low cost.

REGULATORY ISSUES AND RISK ANALYSIS: THE LONG-TERM CAPACITY BUILDING

Biosafety Guidelines for Research and Development

Thailand's current regulatory system does not specifically prohibit or control any research, development and production of GM crops developed domestically. The Biosafety Guidelines, a non-binding set of rules proposed and used by BIOTEC in 1992 was the first discipline in biosafety that researchers and developers (including plant breeders who involve in genetic engineering) in the country were encouraged to follow.

The Biosafety Guidelines made Thailand one of the first countries in the region to adopt its national guidelines on genetic engineering R&D both for laboratory work and for field testing and planned release. Although the guidelines were initiated by BIOTEC, their completion was largely the effort of individual scientists and officials of relevant governmental agencies.

Since 2001, the Biosafety Guidelines have undergone extensive review and update, with a new version expected to be published by BIOTEC by 2002.

The Role of National Biosafety Committee, Its Subcommittees and Institutional Biosafety Committee

In 1993 the NBC was established to encourage the dissemination and usage of the Biosafety Guidelines and also to advise and make recommendations to competent authorities on safety issues of genetic engineering and its products, with BIOTEC serving as the coordinating body and secretariat. Later on many Institutional Biosafety Committees (IBCs) were established at major research centers and academic institutes throughout the country to ensure that the guidelines are effectively implemented at the institutional level. Currently there are 16 IBCs, including one private enterprise laboratory, overseeing all the research activities that involve the use of GMOs.

DOA established its own IBC in December 1993 to inspect and monitor not only its own in-house research but also GMOs introduced from foreign origin for field tests. In addition, the IBC of DOA has set up six *ad hoc* working groups monitoring field tests of transgenic rice, cotton, maize, cucurbit, papaya and tomato.

In order to give sufficient technical support to various governmental competent authorities in their decision-making concerning the safety of GMOs, NBC has established four specialized biosafety sub-committees, each on plant, microorganisms, food and socioeconomic issues. These subcommittees are functioning as technical advisory groups and risk assessment bodies, working in close coordination with relevant government agencies in the approval process.

The Approval Process by the Thai Authorities

In accordance with the Plant Quarantine Act 1964 as amended in 1999, importation of GMOs into Thailand as ‘plants’ is prohibited. In 1994, the MOAC issued a notification identifying specific plants, plant pests, or carriers from certain sources as prohibited materials. More specifically, MOAC has listed 40 transgenic plant species from all sources as prohibited materials unless permitted by DOA for experiment and research purpose. The experiment must be handled in accordance with techniques deemed appropriate under the jurisdiction of DOA. Recently in 2002, DOA has recommended MOAC to list 37 additional transgenic plant species as prohibited.

As mentioned earlier in ‘*Importation for Field Tests*’, the first request for introduction and field testing of GMOs into Thailand under the above approval system was the Flavr Savr tomato. The DOA, acting with technical recommendations from the NBC, granted permission for the field trial of Flavr Savr tomato in 1994. The request for field trial of GM cotton with toxin gene from *Bt* was made in 1995. Field trial of this *Bt* cotton started in March 1996. But up to date, permission for the commercial release of *Bt* cotton is still pending. Moreover, in April 2001 the Cabinet announced a halting of all field trials by MOAC following a demand by a local pressure group. MOAC is requesting the Cabinet to review its decision in order not to let the strict regulation inhibit the scientific R&D progress in Thailand.

GM Food Risk Assessment: Guidelines, Implementation, and Labeling

The first transgenic food plant application for approval for use in food by industry was *Bt* cotton seed oil. The decision is still pending by the Thailand FDA. Recognizing the urgent need for building the country’s own risk assessment capability in GM food, the NBC’s Subcommittee on Food Safety drafted its own guideline for safety assessment of GM foods in 1999. The guideline is now undergoing an extensive review by the Subcommittee together with another similar guideline from DMSc, to be open for public comment and finally will soon be announced by FDA for official use as a national guideline on GM food risk assessment. Meanwhile the Subcommittee, using the 1999 guidelines, has performed risk assessments on Roundup Ready soybean and both *Bt* and Roundup Ready maize varieties from Monsanto. They have been evaluated as safe for human consumption.

Currently, the products being assessed by the Subcommittee include GM papaya for viral resistance developed domestically and separately by BIOTEC, DOA and Mahidol University.

One issue that was debated among pressure groups, consumer groups and the local officials is the labeling of GM foods in Thai consumer’s market. The FDA went through a year-long process considering this issue by committees, a workgroup and among the general public. Finally in mid-2002 the Ministry of Public Health announced a regulation on the labeling of GM food. According to the regulation, food with GM soybean or corn as one of its top three major ingredients and with more than 5 percent content will have to be labeled as GM. The regulation gives a one-year grace period and will be fully implemented by mid-2003.

Biosafety Guidelines for Industrial Scale Production

Since there have been some applications for the use of GM microorganisms in production plants to produce commercial products for the market, NBC was urged to consider formulation of another guideline: the guideline for industrial scale production using GMOs. The Subcommittee on Food Safety under NBC has undertaken this task since 2001 and has so far organized a study and two workshops among experts and competent authorities to raise awareness and discuss in detail the content of this guideline. It is expected to be finalized soon.

FORMULATING A LEGAL FRAMEWORK ON GMOs

Under the current situation, the DOA is the competent authority responsible for two relevant bills currently applied to the regulation of transgenic plants in Thailand. The Plant Quarantine Act 1964, amended in 1999, is applied to regulate the importation of GM plants into Thailand in order to prevent any harmful effects to the environment and agriculture. However, the Act has some serious limitations and a specific

‘Biosafety Law’ concept has been proposed to achieve more effective control of research and utilization of all GMOs in, into, and out of Thailand.

Another important law enforced by DOA is the Plant Variety Protection Act adopted in 1999. The purpose of this Law is to protect plant varieties by granting property rights to breeder and local communities, and to conserve and utilize general domestic, local domestic and wild plant varieties. Four different types of plants: (1) new plant variety; (2) local domestic plant variety; (3) wild plant variety; and (4) general domestic plant variety, may obtain plant variety protection. The owner of the protected new plant variety has an exclusive right to produce, sell, distribute, import, export and process of the propagating material of new plant variety. Validation of the certificate of registration of new annual plant species, perennial plant species and woody trees is 12, 17 and 27 years, respectively. Any new plant varieties derived from genetic modification procedure must pass biosafety test conducted by DOA or other agencies/institutions designated by Plant Variety Protection Commission.

Apart from labeling regulations which put their emphasis on giving information to consumers, consumer groups are demanding more comprehensive legal instruments that can protect and ensure consumers the safety of their food has been widely discussed. The issue of food safety together with biosafety has led to discussion on the formulation of a framework law to effectively regulate GMOs as an urgent agenda. Consensus, however, has not been achieved.

In light of these shortcomings, there has been much research conducted by scholars. For example, some studies on the regulation of GM plant, GM food, and liability issues of GM products were conducted by Ramkhamhaeng University. Some work even touched the socioeconomic implications, including research on human right issues as related to GMOs and agricultural biotechnology led by Dr. Jakkrit Kuanpoth – a renowned legal expert, research on the economic impact of labeling and other research on economic impact and policy options of adopting GM soybean were both conducted by Thammasat University.

There are two initiatives in formulating such a framework law: one under the MOAC and another under the Ministry of Science and Technology. Following a demand by Assembly of the Poor, a local pressure group which demanded a moratorium on all field trials until a biosafety law is in place, the government has set up a committee with one subcommittee to draft a biosafety law that focuses on agricultural biosafety. The other initiative is a work of the Subcommittee on National Biosafety Policy, under the Committee on Conservation and Utilization of Biodiversity. This latter initiative has clearer characteristics as a framework law since it places the whole biosafety issue under the framework law on biodiversity, thus following the structure of the Convention on Biological Diversity (CBD). The Biodiversity Framework Law, however, is still in early stage of drafting and may take a long time to accomplish.

PUBLIC AWARENESS/KEY STAKEHOLDERS’ INVOLVEMENT

In 1999 and 2000, BIOTEC has conducted a study on consumer perceptions toward GMOs in Thailand. The study showed for the first time consumer’s awareness of the GM debate, their preference toward food labeling, and their demand for more information from authorities.

In 2000, a public consultation meeting on *Bt* cotton and human rights organized by a research group took place at Sukhothai Thammathirat Open University (STOU). The meeting shed some light on the intellectual property rights (IPRs) issues and the acceptance of *Bt* cotton that was said to be illegally planted in the country and revealed different views among farmers, NGOs, and academics (while the NGOs believe that the *Bt* cotton was leaked or deliberately spread from experimental field, academics and farmers argue that because of delay over approval process and other factors, the farmers are now illegally using the GM cotton in a widespread manner).

At the beginning of the year 2001, three quasi-governmental organizations: BIOTEC, Thailand Biodiversity Center (TBC), and Natural Resources and Biodiversity Institute (NAREBI) jointly launched a program to start up a series of dialogues among different groups of Thai citizens involved in the GMO debate. First convened in March 2001, the series included four thematic stakeholder dialogue meetings each held separately: environmental impact, consumer’s health, trade conflict, human rights/legal issues, and finally concluded at a consensus conference. The whole process was carried out over a period of six months. The meetings were reported in many Thai local mass media, dubbed as ‘Four-step Ladder Project’ in the newspaper’s headline. The final consensus conference was attended by many participants from provincial region outside Bangkok. Members of the anti-GM NGO groups, BIOTHAI (Biodiversity and Community Rights Action, Thailand) and GREENPEACE were given equal opportunities to criticize the process and give further suggestions. A panel of members from many stakeholder groups discussed further cooperation among stakeholder groups and agreed to work together toward more disclosure and transparency of information and policy recommendation.

CURRENT GOVERNMENT POLICY/INSTITUTIONAL FRAMEWORK

There are currently four policy bodies related to decision-making in the GMOs issues:

1. Committee on International Economic Policy, chaired by a Deputy Prime Minister. The Committee specializes in international trade issues, with the Subcommittee on Biotechnology Product Policy, chaired by the Permanent Secretary of Agriculture.
2. Committee on Conservation and Utilization of Biodiversity, chaired by another Deputy Prime Minister. This Committee focuses on biodiversity issues, with the Subcommittee on National Biosafety Policy, chaired by Dr. Banpot Napompeth, who is also the Chairman of NBC.
3. Committee on Solving the Problems of Assembly of the Poor, chaired by yet another Deputy Prime Minister. It focuses on farmers' issues and has set up a Subcommittee on Biosafety Law, chaired by the Agricultural Minister.
4. National Food Committee, chaired by the Permanent Secretary of Public Health. This Committee supports and advice the Minister of Public Health on food safety and food standard issues. There is a Subcommittee on Safety Review of GM Food and a Workgroup on GM Food Labeling, both chaired by the FDA Secretary.

In principle, formal national policy is made and announced by the Prime Minister or Cabinet Ministers. Up to now, however, there were not many policy statements at that level: the Committee on International Economic Policy Statement in October 1999 confirming the prohibition of planting GMOs but allowing soybean and corn into the country for food and feed use, the Cabinet's acknowledgement in April 2001 of a request to place a moratorium on field tests, and the regulation on GM food labeling signed by Minister of Public Health in May 2002.

Prime Minister Thaksin Shinawatra, who assumed office nearly two years ago, has declared on many occasions the importance of science and technology in the development of the country. He became the first Thai Prime Minister to give emphasis on biotechnology as the country's strategic technology. Together with the utilization of the country's rich bioresources, they will become keys to strengthen its competitiveness in agricultural and medical industries, he said.

FUTURE CHALLENGES

Following Dr. Thaksin's vision, it is quite certain that Thailand will continue to invest and build capacity in biotechnology R&D, including genetic engineering. It is clear that not only the scientific community but also some policymakers including the Prime Minister realize that biotechnology is vital to the trade and competitiveness of Thai agro-industry. Capacity building in risk assessment and detection of GM food is considered an urgent area where the country still needs to extend its expertise and infrastructure, both to help protecting consumers and to assist export products.

Nevertheless, the dilemma lies in the public acceptance in GMOs at the global level, which readily and sensitively affects domestic perception and sentiment. At present all GM foods are of foreign origin and in most cases are products of foreign multinationals, adding subtlety to the issue.

Educational campaigns to provide scientific information on GMOs through government offices using mass media and publications have been undertaken by governmental institutes and some private partners. These campaigns are to promote understanding in not only the risk but also the benefit of the technology; they are targeted especially for young people who hope to become engaged in science and technology.

Finally, it is hoped that once the public realizes the positive benefits of biotechnology and tries to reap it, Thailand will have in place the proper management of the technology including the handling of its risks, and will not have already lost its preeminent position in the agricultural world.

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Annex 1.

Chronology of GMOs-related Events in Thailand

Date	Events
1983	Inauguration of Thailand's National Center for Genetic Engineering and Biotechnology (NCGEB, now BIOTEC)
1985	Establishment of BIOTEC's Plant Genetic Engineering Unit (PGEU) in Nakhorn Pathom, Thailand
1986	BIOTEC commissioned a status report on the prospects of biotechnology in agriculture stated the need for the country's biosafety regulatory system
1990	A feasibility study on biosafety by BIOTEC
1990	Biosafety Subcommittee was established under BIOTEC
April 1992	BIOTEC appointed an *ad hoc* subcommittee to draft Thailand's first biosafety guidelines
	Complete draft of biosafety guidelines (for laboratory and for field test)
June 1992	National Biosafety Committee (NBC) established with BIOTEC as secretariat, followed
January 1993	by establishment of Institutional Biosafety Committees (IBCs) at various research institutes.
	First application for importing transgenic plant for field test on seed production
1993	(Calgene's Flavr Savr tomato)
	A list of 40 prohibited transgenic plants added to the 1964 Plant Quarantine Act
1994	Flavr Savr tomato granted permission for field test
1994	Application of Monsanto's *Bt* cotton
1995	Establishment of DNA Fingerprinting Unit, BIOTEC in Nakhorn Pathom, Thailand
1995	*Bt* cotton field test experiment started in northeastern Thailand
March 1996	Establishment of Plant Biosafety Subcommittee under NBC
1997	Establishment of Food Biosafety Subcommittee under NBC
1998	Establishment of Microbial Biosafety Subcommittee under NBC
1998	Trade dispute between Thailand and some EU countries over detention of tuna in oil
1999	from Thailand. Other trade dispute cases follow suit.
	Subcommittee for Policy on Trade of Biotechnology Products set up under the
1999	Committee for International Economic Policy
	Amendment of the 1964 Plant Quarantine Act to strengthen regulation of transgenic
1999	plants
	A report "Status of GMOs in Thailand" published by BIOTEC
September 1999	First public hearing on GMOs organized by Department of Agriculture (DOA) held in
September 1999	Bangkok
	First survey in Bangkok by BIOTEC on public awareness and attitude towards GMOs
October 1999	Inauguration of Thailand Biodiversity Center (TBC) as the potential national focal point
December 1999	for the Cartagena Protocol on Biosafety (Thailand has not yet signed the protocol). NBC's secretariat (including subcommittees) moved to TBC.
	Establishment of DNA Technology Laboratory (former part of DNA Fingerprinting
2000	Unit), with a mandate to detect GMOs on service basis, among other tasks.
	Establishment of two separate GMOs detection laboratories in DOA and Department of
2000	Medical Science (DMSc)
	Thailand Food and Drug Administration (FDA) commissioned a workgroup to consider
2000	labeling method for GM foods
	Ministry of Agriculture and Cooperatives (MOAC)'s declaration on import prohibition
March 2000	of 40 transgenic plants (revised) with exceptions for grains of GM corn and soybean

... To be continued

Continuation

Date	Events
April 2000	Trade dispute between Thailand and Kuwait/Saudi Arabia over tuna in oil (suspected to be made from GM soybean)
October 2000	A National Subcommittee on Biosafety Policy proposed to the National Committee on Conservation and Utilization of Biodiversity (NCCUB), with TBC as secretariat office.
January 2001	Trade dispute between Thailand and Egypt over tuna in oil reached its peak. Both party agreed to sign Memorandum of Understanding (MOU).
February 2001	A draft of GMOs policy approved by the Subcommittee for Policy on Trade of Biotechnology Products
March 2001	BIOTEC starts a series of consultation meeting with stakeholders on GMOs issue
April 2001	A controversial resolution by the Cabinet to halt MOAC's large-scale field trials according to a request from a pressure group, until a biosafety law is finished.
August 2001	BIOTEC concluded consultation series.
May 2002	Ministry of Public Health adopts GM food labeling law.

8. THAILAND (2)

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INTRODUCTION

During the last few decades very rapid development has occurred in modern and high technologies, e.g., computer, communication, material sciences and especially in biotechnology. An early use of biotechnology was plant tissue culture technology, which enabled the micro-propagation of important plants in enormous numbers. This has led to a new way of mass-production and commercialization in the seed industries whereby synthetic seeds have been used in many countries.

Somaclonal variation has then became familiar to the plant tissue culturists and was added as a good tool for developing new types of plants with special characteristics such as flower form, color, salt tolerance and disease as well as insect tolerance. In potato, somaclonal variation has been proven to be useful to significantly increase resistance to virus attack and scab disease (Evans, 1989).

Plant protoplasts, or naked plant cells, have also provided a new innovation for studying plant physiology in more detail and has provided a way to study gene transfer, firstly with the expression of the plant virus in the protoplast system. Furthermore, gene pooling by protoplast fusion then became useful because it allowed scientists to produce novel plants through organelle transfer and particularly somatic hybridization. Though intergeneric hybrid through protoplast fusion has not succeeded, it has opened the gate to interspecific hybrid production, which is now in commercial use.

Many problems have been solved by the previously named technologies, however certain problems still remain unsolved even while new challenges have arisen for scientists to take on. With increasing understanding of recombinant DNA technology, gene cloning and *in vivo* genetic manipulating it has become possible to manipulate DNA and transfer gene components between species in order to encourage the replication of desired traits. Genetically engineered plants and animals as well as microbes have been developed but with their development has come the fear that such technologies could accidentally create uncontrollable monsters, such as super weeds in the case of plants. This fear has led to debates on what human health and environmental effects might be created after genetically modified organisms (GMOs) have been released or consumed worldwide.

Thailand has led the world in ornamental flowers, such as orchids, and in many processed fruits and vegetables, such as canned pineapple, fruit juices and concentrates, and canned baby corn. Furthermore, Thailand also exports various animal products and grains. So, the name “Kitchen of the World” might be appropriate for Thailand. Thus the problems on GMO crops and foods are a “hot issue” for the Thais.

GMO SITUATION IN THAILAND

Compared to other developing countries, Thailand still has a weak base in biotechnology, but it has been strengthened by many government programs. Recombinant DNA technology was introduced to Thailand around mid-1980 and has rapidly become established in many parts of the country, mostly in the universities and the public organizations. The leading institution in Thailand for the study of biotechnology is the National Center for Genetic Engineering and Biotechnology, previously known as NCGEB now known as BIOTEC. BIOTEC is not only a funding agency but is also actively doing research on GMO detection and evaluation and is involved in planning and surveillance of the Thai biotechnology policy. Major work with the GMOs in Thailand are as follows:

1. ***Tomato***

A coat protein (CP) transformation has been made for controlling tomato yellow leaf curl virus. At present, the transgenic plants are already obtained and tested under contained greenhouse conditions.

2. ***Papaya***

A CP transformation has been made for solving the papaya ring spot virus problem. At present, the transgenic plants with mature fruits are in contained greenhouses awaiting field testing. Besides the CP gene, the delayed ripening gene has also been transformed into papaya.

3. ***Chili Pepper***

Chili vein-banding mottle virus is an important disease of chili pepper. CP and replicase genes have been used in the transformation for the control of the virus. The transgenic plants with mature fruits are in contained greenhouses.

4. ***Yard-long Bean***

A CP gene has been transformed into these plants for the control of cowpea aphid-borne mosaic virus. However, the transformation process for yard-long beans has been more difficult than other plant transformations and little progress has been made.

5. ***Cotton***

A local cotton variety has been transformed using *Bacillus thuringiensis (Bt)* genes, CryI Ab and CryI Ac. This project is undertaken by the University of Ottawa, Canada with collaboration of French Agricultural Research Centre for International Development (*Centre de cooperation Internationale en Recherche Agronomique pour le Developpement* [CIRAD])/CA and Kasetsart University. The transgenic plants are still in the laboratory.

6. ***Orchid***

The gene controlling color expression is now under study and some progresses have been obtained at the laboratory level. However, many steps needed to be solved before getting real transgenic plants.

Thailand has also allowed importation of certain GMOs for field trails but only under strict regulation and supervision of the authorities involved. The imported GMOs are listed in Table 1.

MONITORING OF FIELD TESTS

Though a number of transgenic plants have been introduced to Thailand (Table 1), they were limited to only five crops: maize (23 cases); cotton (15 cases); tomato (three cases); papaya (two cases); and rice (one case), and only limited numbers have been tested in the field as reported by Attathom and Sriwatanapongse, 1994; and Sriwatanapongse, *et al*., 1996.

Flavr Savr Tomato

In 1993, the Calgene Fresh Company requested permission to conduct a field test on seed production of genetically engineered Flavr Savr tomato in Thailand. Permission was granted in 1994. The proposed parental lines had all been tested in the U.S. under the permit process in the U.S. that was later relaxed to a notification process for tomatoes and five other crop species (Animal and Plant Health Inspection Service [APHIS], 1993). The National Biosafety Committee (NBC) at the time considered the case in accordance with the Biosafety Guidelines and permitted the field trials with some conditions. It was specified that Calgene should collaborate with a local company and with a plant pathologist from a university as a collaborating expert. Since this was the first of such studies in Thailand, testing was performed under a strictly contained environment (i.e., a netted house) to prevent insect pollination. Subsequently, in 1995-96, the Flavr Savr tomato from DNA Plant Technology (DNAP) was approved for field testing in an open field in the Northeast of the country.

Table 1. Imported GMOs in Thailand during 1995 and the Present

Common Name	Trait	Variety Name/ Pedigree	Importing Agency	Import Date
Tomato			Thai Variety Company	
Tomato	PQ-prolong shelf life		Upjohn Company	5 Sept. 1995
Tomato			Thai Variety Company	
Cotton	IR-insect resistance (lepidopteran)		Monsanto	
Cotton	IR-insect resistance (lepidopteran)	NU COTN 33B	Monsanto	
Maize	IR-insect resistance	6TO27×2N984 *Bt*	Novartis	4 Dec. 1996
Cotton	IR-insect resistance	NU COTN 33B	Monsanto	22 Apr. 1997
Cotton	IR-insect resistance	NU COTN 33B	Monsanto	22 Apr. 1997
Cotton	IR-insect resistance	NU COTN 33B	Monsanto	22 Apr. 1997
Papaya	VR-resistance to papaya ring spot virus		Horticultural Crops Research Institute	1997
Cotton	HT-herbicide tolerance	1445, 1698	Monsanto	
Maize	IR-insect resistance	Pioneer 33VOB	Pioneer	15 Sept. 1997
Maize	IR-insect resistance	Pioneer EF2GMBI	Pioneer	15 Sept. 1997
Maize	IR-insect resistance	Pioneer HM2HGB	Pioneer	15 Sept. 1997
Maize	Insect resistance		DEKLAB	
Rice	BR-*Xanthomonas sp.*	Dawk Mali 105	Rice Research Institute	25 Aug. 1997
Maize	IR-insect resistance		Monsanto	
Maize	HT-herbicide tolerance		Monsanto	
Cotton	HT-herbicide tolerance	Cotton line 1445	Monsanto	
Maize	HT-herbicide tolerance	GA-21	Monsanto	18 May 1998
Maize	HT-phosphinothricin	DLL25	Charoen Grain Crop Ltd.	
Maize	IR-insect resistance	Mon 810	Monsanto	3 June 1998
Maize	IR-insect resistance	CHAW 9703 *Bt*	Cargill	5 Oct. 1998
Maize	IR-insect resistance	Q810002	Novartis	7 Dec. 1998
Maize	IR-insect resistance	Q810001	Novartis	8 Dec. 1998
Maize	Insect resistance	Q810034	Novartis	9 Dec. 1998
Maize	Insect resistance	Q810055	Novartis	10 Dec. 1998
Maize	Insect resistance	Q824560	Novartis	11 Dec. 1998
Maize	Insect resistance	Q824562	Novartis	12 Dec. 1998
Maize	Insect resistance	6TO27×2N984 *Bt*	Novartis	5 Nov. 1998
Cotton	Insect resistance	MEDM-9801	Monsanto	28 Jan. 1999
Cotton	Insect resistance	MEDM-9803	Monsanto	29 Jan. 1999
Cotton	Insect resistance	MEDM-9806	Monsanto	30 Jan. 1999
Cotton	Insect resistance	MEDM-9807	Monsanto	31 Jan. 1999
Cotton	Insect resistance	MEDM-9808	Monsanto	1 Feb. 1999
Cotton	Insect resistance	MEDM-9810	Monsanto	2 Feb. 1999
Maize	Herbicide resistance	GA-22	Monsanto	19 Apr. 1999
Cotton	Herbicide resistance	Cotton line 1445	Monsanto	28 Jan. 1999

... To be continued

Continuation

Common Name	Trait	Variety Name/ Pedigree	Importing Agency	Import Date
Maize	Insect resistance	Mon 810	Monsanto	29 June 1999
Maize	Herbicide resistance	CHAW 9703 RR	Cargill	
Papaya	Disease resistance		Plant Genetic Engineering Unit	
Cotton	Insect resistance	NU COTN 33B	Monsanto	28 June 1996
Maize	Herbicide resistance	C919-604	Monsanto	
Maize	Insect resistance	C-919 *Bt*	Monsanto	

Note: * Data from Biodiversity Group, BIOTEC, Thailand, 2002.

Monsanto *Bt* Cotton

The application to field test this *Bt* cotton was made in 1995 and it took some time for the NBC and Department of Agriculture (DOA), Institutional Biosafety Committee (IBC) to grant permission. Since the case involved genes producing a protein that is toxic to certain group of insects, careful consideration had to be made. Finally, it was recommended that *Bt* cotton had to be planted in a netted screen house to protect insects. Tests were also made for the survival of beneficial insects under the same containment as the *Bt* cotton. The experiment was performed in the Northeast beginning in March 1996 and repeated in open fields in the rainy season. Approval was granted to test the materials in open fields at the DOA's experimental stations and in farmers' fields in 1997. Results from the field tests indicated that there would be no risk involved in the planting of *Bt* cotton. At present, the case is under consideration for deregulation for commercial production.

***Bt* Corn**

The third transgenic crop undergoing field tests is Novartis *Bt* corn. Again the test is being performed in netted houses in Takfah, Nakhon Sawan at the Company's experiment station.

BIOSAFETY GUIDELINES IN THAILAND

In order to cope with the requests of the researchers and the needs of the private companies that would like to either conduct the research or imported the existed GMOs from the other countries, the Thai Government has set up the "Biosafety Guidelines for the Laboratory and Field Trial" (Napompeth, 1993, for more detail see Damrongchai's paper). Under that regulation, the NBC and IBC have been set up and have worked as the body guiding activities on recombinant DNA technologies and related areas. Workshops and training courses on the biosafety and handling of the GMOs have been conducted in many institutes and have helped increase public understanding and awareness of GMOs. BIOTEC is the major body taking care of these activities and the universities act as the technology transfer agencies.

BIODIVERSITY POLICY AND GMOs

Much debate and discussion on the impact of GMOs on native genetic resources has taken place among policymakers, NGOs, scientists and the regulatory bodies. Results from those activities have led to the proper measures to include in an environmental impact assessment on GMOs, the passage of laws and regulations on their import and export, and the education of the public about their pros and cons. The policy, which will be in effect between 2003-07, would also keep an eye on invasive alien species of plants, animals and microorganisms which are not native and can emulate local species and damage crops. The new policy and a list of projects related to biodiversity will be submitted to the Cabinet for budget approval upon completion. As part of this process, the Ministry of Agriculture and Cooperatives has announced a list of 40 GMO crops, such as rice, corn, soybean, potato, etc. as being prohibited from import into Thailand except for the purpose of research. There are eight GMO crops which are still under an experimental stage and controlled by the

Ministry of Agriculture and Cooperatives, such as cotton, tomato and corn. Unconfined planting of GMO crops has not been allowed in Thailand since 2000.

FUTURE OF GMOs IN THAILAND

The research and analysis on GMOs and the issuance of certificates for non-GMO crops and products are an important agenda item for the Cabinet. At present, BIOTEC through the DNA Technology Laboratory has a well-developed capability and uses high standards in investigating the presence of GMO products from both plant materials and foods. The DOA, the Ministry of Agriculture and Cooperatives also has the potential to detect GMOs and is expected to upgrade the standardization on GMOs to an international standard within two years.

GREENPEACE and Green Net recently identified seven food products with GMOs in Thailand and urged the government to initiate a labeling policy to protect consumers' rights. These seven products were among 30 items from Thailand that the two groups sent to a Hong Kong-based laboratory for genetic testing – although manufacturers of the items here said there was no GMO material in their products. One big problem for Thailand and other developing countries is that consumers are caught between contradicting scientific explanations on GMOs. After the environmental groups released their statement, for example, the manufacturers of the seven items responded by issuing statements saying that their products are GMO-free. Though labeling seems to be a good way out at the moment, environmentalists say only consumer pressure can successfully see this through, since there is no law prohibiting GMO food in Thailand right now. Because many questions and much uncertainty still exist among the Thai people, some would say, "It makes me feel unsure about the future. We never know how much protection we have. If GMOs really turned harmful, what will happen to us in the future?"

All of the questions are in the hands of the scientists, who need to have a strong ethical responsibility. Adding these issues to the curriculum in all levels of the education system is also needed. At present, only the high school and university levels have these topics in the curriculum. Moreover, public education is also a special responsibility of the scientists who have the best knowledge of technology. In this way, the public could have the ability to balance benefits and risks of GMOs products.

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INTRODUCTION

Vietnam is an agricultural country with a total area of 331,000 km^2 and a population in the year 2000 of 77.7 million, 76 percent of whom live in rural areas. Vietnam agriculture compares extremely well with the growth performance of developing countries. Growth has been sustained at a level of 4.5 percent per year and in 2000; agriculture contributed a 20.8-percent share in GDP (80.4 percent by cultivation, 17.1 percent by animal husbandry, and 2.5 percent by service).

In 2000, cultivation of various crops contributed to the total production as follows: food crops (rice, maize, cassava, sweet potato), 63.2 percent; industrial crops (rubber, coffee, tea, cashew, pepper, sugarcane), 7.6 percent; and other crops, 1.8 percent. Recently notable export crops of Vietnam have consisted of rice, coffee, rubber, cashew nuts, pepper and some fruit crops.

The new policies on agriculture and rural development of the government since renovation and the important roles of science and technology activities are two main factors contributing to such achievements. However, in coming years, Vietnam will face and have to overcome challenges in agriculture and rural development such as the following problems: high frequency of natural disaster (flood, drought, storm, salinity, etc.); a high percentage of poverty (8.5 million or 11.4 percent); high production cost; low product quality; and severe competition in the world market.

Looking to the future rapid development of agriculture, the Vietnam Government has invested in science and technology with special priority for biotechnology. However, there have also been concerns on the efficiency and interactions of biotechnology, especially on the safety of genetically modified organisms (GMOs) and their products to the environment, public health and other areas.

As a result of debates and meetings of various scientists and managers in agricultural and environmental fields on biotechnology, many suggestions have been made on the important role of biotechnology in the economic development of an agricultural country such as Vietnam. Depending on the genes transferred into the targeted plants, the genetically modified (GM) plants have better quality, higher productivity or are more resistant to diseases, insects and adverse conditions. However, they must be approved in advance of large-scale production.

Vietnamese scientists have cooperated closely with international organizations in biotechnology and transgenic plant development. However, until now Vietnam has not yet created a legal framework for regulation of GMOs and their products. Based on the International Convention on Biological Diversity and the Biosafety Protocol including exchange and transport of GMOs for international trade, a proposed regulation for GMOs and their products was prepared with contributions by special experts, related ministries, branches, institutes, universities, etc.

SOME RESULTS OF RESEARCH ON TRANSGENIC PLANTS

In the Rice Plant

Gene resources (pMON, pRQ6, Bar gene, Xa.21) used for gene bombardment have been transformed in *Escherichia coli (E. coli)* host cells and stored as glycerol culture. Agrobacterium/plasmids have been used for Agrobacterium-mediated transformation. Cry/Ti-plasmid cloning has been started for Agrobacterium-mediated rice transformation purposes. The gene bombardment procedure using Corbo-PIG gun has been established. The Bacterial Leaf Blight (BLB)-resistant gene Xa.21 has been bombarded into callus from Vietnamese varieties (CR203, C71, Xuan 2, DR1) and regenerated transformants have been obtained. Transgene Xa.21 presence in the transformants has been confirmed by Polymerase Chain Reaction (PCR) techniques using the primer for partial Xa.21 sequences. Southern hybridization analysis of transformants is ongoing. Putative transgenic plants are planted for the BLB test in artificial conditions.

An efficient rice transformation system has been developed utilizing mature seed-derived callus and an inexpensive particle bombardment device. The bombardment technique widely used for rice transformation resulted in recovery of fertile transgenic rice plants from immature zygotic embryo in several rice genotypes. Le Tan Duc, *et al.* (1998) have used mature seed-derived callus as targets for bombardment as an alternative system to immature embryos. The indica genotypes, Bengal, calli M202, were bombarded using an inexpensive particle inflow gun. It makes rice transformation technology accessible to laboratories which do not have the financial resources to obtain more expensive particle bombardment instruments. Genes encoding hygromycin resistance (hph), β-glucuronidase (Gus) and bialaphos resistance (bar) driven by CaMV 35S promoters were used for bombardment. Molecular and biochemical analyses were performed to confirm the integration and expression of the introduced genes.

Indica rice transformations containing soybean tripsin inhibitor (SBTI) gene were conducted by the Food Crop Research Institute in 1997.

Introduction of the hph, Gus, and Xa-2 genes into japonica Taipei 309 and Vietnamese indica VL 901 rice varieties have been done by the Agricultural Genetics Institute (AGI) in cooperation with the International Laboratory of Tropical Agricultural Biotechnology (ILTAB), U.S.A.

Agrobacterium tumefaciens has been used for transformation of rice varieties by T. B. Lan, N. L. Hoa, *et al.* in 1997 at AGI. Immature seeds (7-10 days old) and embryogenic callus (three weeks old) induced from mature seeds of DT10, DT13 were involved in the transformation. The vector used was *Agrobacterium tumefaciens* strain LBA 4404 containing pCAMBIA-1300 and pCAMBIA-1301 carrying the hygromycine resistance gene and the Gus construct in the T-DNA region. Hygromycine-resistant calli were subcultured once, and DNA extraction was carried out to check with PCR using primers specific to the hygromycine resistance construct. Those calli that gave positive results were transferred to the plant regeneration medium MS-R.

In Other Crops

Transfers of Gus A, Bar and hph genes into tomato (*Lycopersicon esculentum*) and soybean (*Glycine max* L.) using the electroporation method have been achieved by the National Center for Natural Science and Technology (NCST) and the Institute of Tropical Biology (ITB) in Ho Chi Minh city, Vietnam.

Transfer of the *Bacillus thuringiensis (Bt)* gene, the Bar gene and the Gus A gene into eggplant (*Solanum melongena* L.) using *Agrobacterium tumefaciens*-mediated transformation has been carried out by N. T. Thanh, L. T. Duc, *et al.* in 1998. Cotyledons of eggplant were co-cultivated with *Agrobacterium tumefaciens* strain ERA 105 (pITB 1) harboring a synthetic CryI A(b) gene from *Bt*, a Bar gene and a Gus A gene. Strong Gus activity was detected in the selected putative calli and shoots by chemical assay. The presence of the *Bt* gene will be determined by PCR and tests of insect resistance will be done in the glasshouse.

Agrobacterium tumefaciens-mediated transformation of mung bean (*Vigna radiata* L.) using mature cotyledons was implemented by NCST and ITB, Ho Chi Minh city in 1998. The transgenic plants were tested in the glasshouse.

Transfer of synthetic CryI A (B and C), Bar gene and Gus A gene into the commercial tobacco variety K.326 via *Agrobacterium tumefaciens* has been conducted by N. H. Ho, *et al.* at NCST and ITB, Ho Chi Minh city. The transgenic plants have been identified and tested in the glasshouse.

ORIENTATION OF BIOTECHNOLOGY AND USE OF GMOs

Biotechnology has a positive impact on food security and can contribute to the sustainability of modern agriculture. It may be able to reduce some of the negative impacts of current agricultural practices and it may help stave off impending agricultural and environmental crises. However, the use of biotechnology to address constraints in agricultural production brings with its questions regarding the potential of GMOs to cause unacceptable impacts on human health and environment. Use of biotechnology and its products must be practiced in a safe and sustainable manner that minimizes the possibility of adverse effects.

In Vietnam, biotechnology is one of the key elements in the strategy of economic, scientific and social development confirmed in the government policies during 2000-10. However, under Vietnam's conditions, the investment in manpower, facilities and new policies (including support by law and regulations), the emphasis for biotechnology is in manpower development. Every year, under bilateral and multilateral agreements with national and international organizations, many Vietnamese scientists are sent abroad for studying and training in the field of biotechnology.

In considering the use of GMOs to solve problems one must consider not only the crops to be transformed, but also all the distinct characteristics available from GMOs in order to construct a suitable solution to a specific situation (Table 1). Most current GMOs are herbicide-tolerant, insect-resistant or tolerant to abiotic stresses. The technology therefore offers possibilities for a wide range of products including some which can result in a reduction in use of dangerous pesticides, herbicides. Other new varieties under development can withstand environmental stresses. GMOs can be directly used in research, development or production. For plant breeders, GMOs offer significant opportunities for improving genetic materials in their breeding programs.

Table 1. Types of Genetically Modified Organisms

Characters	Examples	Rationale
Consumer or industrial qualities	Long shelf-life tomato, high-starch maize	Development of new foods or sources of industrial products
Herbicide tolerance	Various crops tolerant to specific herbicides	More efficient herbicide use and/or use of safe herbicides
Disease or insect resistance	Bollworm-resistant cotton, virus-resistant tobacco	Reduction in pesticide use
Tolerance to abiotic stresses	Research on drought-tolerant maize	Improved production in marginal areas (but involves polygenic modifications; more difficult than other GMOs)

Source: Adapted from Robert Tripp, 1998.

The main crops of economic interest for study on the application of biotechnology are rice, maize, rubber, coffee, vegetable and some main fruits. Other crops with a high level of effort include ornamental plants, forest plants and some industrial plants (cotton, rubber). At the present time, GMOs in food crops and medicinal plants which affect human health directly have been restricted to laboratory and glasshouse testing. Field testing is not allowed for such GMOs (Table 2).

Table 2. Permitted Categories for Trial and Use of GMOs in Vietnam

Target Plants in GMOs	Laboratory and Greenhouse Testing	Field Trial	Production
Food and vegetable plants (rice, maize, soybean, potato, tomato, etc.)	++	–	–
Industrial crops (rubber, cotton)	++	++	+
Ornamental plants (orchids, rose, cut-flowers, etc.)	+++	++	+
Forest plants	+++	+	+
Medicinal plants	++	–	–

Remarks: "–" = Not acceptable; "+" = little; "++" = medium; and "+++" = high.

DRAFTING BIOSAFETY REGULATION IN VIETNAM

Working Group and Principles to Establish Draft Biosafety Regulations

The Vietnam Government established and instructed an integrated working group to draw up biosafety regulations for GMOs and their products. The working group included experienced and well-qualified experts from different ministries in which the major roles are played by the Ministry of Science and Technology (MOSTE) and the Ministry of Environment. Other members included: Ministry of Agriculture and Rural Development (MARD), Ministry of Public Health (MPH), Ministry of Fishery and Aquatic Products (MFAP), Ministry of Commerce and Ministry of Justice. The working group considered policies appropriate to Vietnam situations and referred to the experiences of Japan, Australia, China and international organizations, especially from Asian countries.

Vietnam biosafety regulations will be the framework for ensuring the safe use and realization of the benefits of GMOs and their products. The biosafety regulations are based on the following principles:

* Biosafety regulations should be based on sound science and be appropriate for the management system Vietnam. The regulations are intended to provide the data necessary to conduct a rational risk analysis.
* The final products are regulated rather than the process by which they are created. GMOs and their products should be regulated according to the same criteria as any other products. In principles, they must be treated the same as products of conventional technology.
* Risk assessment should be carefully conducted on a "case-by-case" basis with full consideration of the experiences and scientific data accumulated in the world scientific community.
* There should be a gradual reduction of oversight for categories which have been determined to pose a low risk.
* Implementation of regulations and procedures shall be amended and improved as experience dicates.

Since 2000, the draft biosafety regulation for GMOs and their products has been sent to various institutions, legislative agencies, selected ministries, NGOs and government enterprises, to collect their comments and suggestions. In 2002 the draft will be submitted to the Prime Minister. Official biosafety regulation for GMOs and their products may be issued in early 2003.

Objectives of Draft Biosafety Regulation

* To ensure the safe transboundary movement and use of GMOs and their products
* To provide a common framework for national biosafety activities
* To set up mechanisms for the release GMOs and their products in Vietnam
* To assess risks of GMOs and their products.

The scope of biosafety regulations covers organisms and their products that contain genetic materials which have been altered in a way which does not occur in mating or natural recombination. These organisms and their materials include: (1) plants; (2) microorganisms; (3) microorganisms living in or on animals; (4) microorganisms as live vaccines; (5) animals (vertebrates, not including fish); (6) fish and aquatic organisms; (7) invertebrates; (8) organisms for biological control; (9) organisms for bioremediation; and (10) organisms to be consumed as food.

Procedures for Notification

* All GMOs and their products brought into Vietnam by the proponent for release should comply with existing Vietnam biosafety regulations.
* Before the release of any GMOs and their products in Vietnam the proponent is required to submit a proposal to the relevant ministries of Vietnam
* The broad classifications of information required in the proposal include:
    - species of organisms
    - eventual use of the GMOs and their products
    - location of release site
    - habitat and ecology information about the release site

– data from contained experiments and studies
– experimental procedures, monitoring and contingency planning
– other assessments.

ROLE AND RESPONSIBILITIES OF REGULATORY AGENCIES

1. ***Ministry of Agriculture and Rural Development***

* To manage and to implement biosafety activities in agriculture
* To develop biosafety policies for agriculture
* To formulate, review or amend the policies of biosafety regulations, guidelines in agriculture, and to guide risk assessments of agricultural biotechnology
* To publish the protocols of risk assessments and relevant criteria for GMOs and their products in agriculture.

The MARD will establish a biosafety advisory committee for GMOs and their products in the field of agriculture. The Ministry will monitor biotechnology activities through its quarantine services.

2. ***Ministry of Science, Technology and Environment***

MOSTE is a major contributor to the setting up of biosafety regulations for GMOs and their products. The Ministry has an important role in monitoring the implementation of the biosafety regulations in research and development, especially those regulations related to environmental issues.

3. ***Ministry of Public Health***

GM food, products, and drugs are regulated by the MPH, although the MARD deals with the same responsibilities.

4. ***Ministry of Fishery and Aquatic Products***

The MFAP manages all biosafety activities relating to aquatic GMOs and their products.

5. ***Ministry of Industry (MI)***

The MI covers biosafety activities related to the implemention and registration of processed GMOs (and their products) in the industrial field.

Each Ministry has its own biosafety committee to oversee their responsibilities and collaborations. Main issues that need to be addressed are:

* organization mechanisms
* regulatory authority
* scope of regulation
* regulatory approaches
* procedures for application of GMOs
* information to be included in applications of approval of agricultural products of biotechnology such as: the name and contact information of the applicants; academic degree(s) of the person(s) dealing with GMOs; the scientific name and common or commercial names of the GMOs; information on human or animal health and safety; environmental protocols for field trials; evaluation of agronomic performance, etc.
* procedures for review for agricultural products of biotechnology and for the review of information resulting from tests.
* processes for application such as “ when, where to apply”.

Major Difficulties in the Implementation of Biosafety Regulations

Vietnam institutions have attempted to prepare draft biosafety regulations for GMOs and their products. However there are many difficulties to face in implementing them. These include:

* the need to have new equipment for GMO testing, analysis and identification in laboratories, glasshouses and the field.
* the lack of experienced, qualified experts to review, and conduct risk assessment
* the lack of funds for biosafety activities.

There are diverse comments and opinions on the following issues which need to be resolved in drafting biosafety regulations:

* The structure of the biosafety system
* The scope of the system
* The roles and responsibilities of regulatory agencies, and the national biosafety advisory committee
* The lack of protocols for risk assessment.

CONCLUSION

Biotechnology has been rationally developed in Vietnam and some Vietnamese institutions have made advancements in the genetic modification of plants for food crops. However various constraints, such as the establishment of satisfactory regulations, have been challenges to the development and use of GMOs and their products.

GM food crops and medicinal plants have been tested in the laboratory and in glasshouses. At present field testing is not allowed for such GMOs.

Formulation and implementation of biosafety regulations for GMOs and their products in Vietnam should be based on sound science and take into account the Vietnamese situation. Biosafety reviews are conducted on the basis of scientific principles and take into account experiences in developing countries.

Due to the rapid changes in the science and application of biotechnology products, Vietnam biosafety regulations for GMOs and their products should be periodically reviewed and updated.

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2. PROGRAM OF ACTIVITIES

(19-23 November 2002)

Date/Time	Activity
Mon., 19 Nov.	
Forenoon	Opening Ceremony
Afternoon	Presentation and Discussion on Topic: *Recent Developments and Achievements in Agricultural Applications of Biotechnology* by George B. Fuller, Ph.D. Presentation and Discussion on Topic: *Production of GM Foods/Products: Implications on Food Safety* by Dr. Shu-Kong Chen
Tue., 19 Nov.	
Forenoon	Presentation and Discussion on Topic: *Benefits and Costs of Commercialization of GM Technology* by Dr. George Kuo Presentation and Discussion on Topic: *Environmental Impacts of GM Crops: Assessing the Risks of Application of Coat-Protein Gene Transgenic Papaya in Taiwan* by Dr. Shyi-Dong Yeh Presentation of Country Report
Afternoon	Presentation of Country Reports
Wed., 20 Nov.	
Forenoon	Presentation and Discussion on Topic: *Regulation and Policy on GMO Detection/ Traceability* by Dr. Akihiro Hino Presentation and Discussion on Topic: *Public Communication: Consumer's Perspective of GMO/GM Foods* by Dr. Fu-Sung Frank Chiang Presentation of Country Report
Afternoon	Presentation of Country Reports
Thurs., 21 Nov.	
Forenoon	Presentation and Discussion on Topic: *Developing Appropriate Mechanisms for Regulating the Use of GMOs: Japan's Experience* by Dr. Keiji Kainuma Presentation of Country Report
Afternoon	Workshop Discussions
Fri., 22 Nov.	Field Trip: visit Asian Vegetable Research and Development Center (AVRDC) and Taiwan Salt Industrial Corporation (TSIC)
Sat., 23 Nov.	
Forenoon	Summing-up Session Closing Ceremony