Report of the
2nd ASEAN-ILSI
Training Workshop on Safety and Risk Assessment of Agriculture-Related GMOs

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Malaysia

Organized by:

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Ministry of Agriculture Malaysia

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WELCOME REMARKS

Y. BHG . Dato' Ismail Ibrahim,
Director General ff Agriculture, Malaysia

Issues on GMOs are of great concern and being debated in various fora all over the world. GMOs have now reached our doors and tables, and whether we like it or not, we have to address this issue rationally and scientifically. With this rationale, Malaysia is taking a positive step towards hosting this second workshop.

I would like to take this opportunity to thank our Deputy Secretary General of the Ministry of Agriculture who, on behalf of the Secretary General,will officiate the opening ceremony

I would like to welcome our distinguished delegates, guests and participants to this 2nd ASEAN-ILSI Training Workshop on the Safety and Risk Assessment of Agriculture-Related Genetically Modified Organisms (GMOs).

The idea of having a series of workshops was conceived at the 21st Meeting of the ASEAN Ministerial Agriculture and Forestry (AMAF) in 1999. GMOs are said to offer enormous benefits, particularly in medicine and agriculture. In some aspects, GM technologies may be able to help poor farmers by providing new varieties that are resistant to pest, drought or cold weather. Recently, however, even developing countries have become concerned about GMOs because of perceived possible threats to humans and the environment.

The first training workshop was held in Singapore last year with a case study approach to the safety and risk assessment of agriculture-related GMO systems. As a follow-up, this second workshop will provide participants with a hands-on exercise in the safety and risk assessment of agriculture-related GMOs. The third and fourth training workshops will be held in Thailand and Indonesia, respectively.

Fourteen overseas participants and 40 local participants are here to attend this workshop. The overseas participants are from Singapore, Thailand, Indonesia, Brunei Darussalam and the Philippines. Among us today are scientists, administrators, and decision makers from the universities, research agencies and other government agencies, which deal directly with GMOs.

We hope that, at the end of the workshop, participants will have a better understanding of GMOs, risk assessment and most importantly be able to evaluate and make decisions on safety regarding GMOs.

I would like to thank ILSI as co-organizer of this workshop, particularly in providing financial support to enable participants from each country to attend this workshop.

I would also like to thank Health Canada, Food Standards Australia New Zealand, and the Ministry of Health, Labour and Welfare of Japan for their support in allowing their experts to attend this workshop, and to share with us their experience on approaches in evaluating GMOs.

Lastly, I would like to express my appreciation to the organizing committee for their hard work in ensuring the success of the workshop.

Thank you.

OPENING ADDRESS

Mr. Mohd Zulkifli Abdul Rauf
Deputy Secretary General, Ministry of Agriculture, Malaysia
(As SOM-AMAF Leader, Malaysia)

I wish to thank the organizing committee for giving me the privilege to say a few words and officiate this workshop. On behalf of the Government of Malaysia I would like to extend our warmest welcome to our distinguished delegates, guests and participants to this 2nd ASEAN-ILSI Training Workshop on the Safety and Risk Assessment of Agriculture-Related Genetically Modified Organisms (GMOs). My thanks to the speakers, Mr. Brian Harrison and Mr. Luc Bourbonnière from Health Canada, Dr. Paul Brent from Food Standards Australia New Zealand, and Dr. Go Tanaka, from the Ministry of Health, Labour and Welfare, Japan who have kindly taken time off their from busy schedules to speak and share their experiences at this workshop. The sharing of your vast experiences in the various fields on the safety and risk assessment of agriculture-related GMOs will, no doubt, bring much enlightenment to participants of this workshop. I am confident that you will provide us with up to date information on safety and risk assessment of GMOs that will stimulate capacity building in these fields in the region.

I was informed that this training workshop program would be held in four different ASEAN countries over a period of 2 years. The objective of the workshop is to address issues such as understanding the concept of risk assessment, substantial equivalence, testing and labeling, assessment of allergenic or toxic effects and the use of scientific information to facilitate decision-making with regards to safety.

I also understand that the Calgene's delayed-ripening tomato became the first genetically modified food crop to be produced and consumed in 1994. Since then, more research and field release have been conducted on GMOs including soybean, maize, canola, cotton and potato. In the developed world, there is clear evidence that the use of genetically modified crops has resulted in significant benefits. These include higher crop yields, reduced farm costs, increased farm profits, increased nutritional traits and as well as improvement of the environment. Recognizing the benefits of genetically modified (GM) crops, several countries have since contributed to more than a 20-fold increase in planted area of GM crops globally. These countries are Argentina, Australia, Bulgaria, Canada, China, France, Germany, Mexico, Romania, Spain, South Africa, Ukraine and the USA. The area planted with genetically modified crops has increased tremendously from 1.7 million hectares in 1996 to 43 million hectares in 2000.

Most GM crops are being developed for pest resistance, herbicide resistance, viral disease resistance, stress tolerance, improving nutritional quality, ripening delay and so on. However, the emergence of genetically modified plants, animals and microorganisms with superior genetic traits and their subsequent release into the environment have currently raised concern among the public at large particularly on safety-related issues. The potential risks include the following:

i) the danger of unintentionally introducing allergens and other anti-nutrition factors in foods. An example of this case occurred in 2001 where Starlink corn, a variety of genetically engineered corn not approved for human consumption due to its potential to cause allergy to humans was accidentally introduced to the global food supply. This resulted in extensive food recalls in the United States and Japan, costing millions of dollars in loss of profit for the farmers, food processors and the grain industry. Besides the loss in profit, more than US $1 billion was spent within a period of six months to eradicate the Starlink corn in the field.

ii) the likelihood of transgenes escaping from cultivated crops into their wild relatives. For example in Mexico, one of the world's oldest varieties of maize has been contaminated by GMOs causing potential threat to genetic diversity.

iii) the possibility that transgenic crops carrying antibiotic genes may generate antibiotic resistance in livestock or humans.

iv) the potential for pests to develop resistance to the toxins produced by GM crops e.g. Bt cotton on control of boll weevil.

v) the risk of these toxins affecting non-target pests.

The potential risks concerning 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 GM crops and foods as well as the fact that many countries are still skeptical of their effects on food and human health, most regulating authorities of member countries in ASEAN are in the process of reviewing and where appropriate, strengthening their existing national legislation with a view to incorporating provisions for regulating and managing GMOs. However, the developed countries have already had in place stringent regulations including testing of GM crops and foods against associated risks to agriculture, environment, animals and human health. Recently the EU importation banned Canadian honey because of the inability of the Canadian honey producers to guarantee the absence of pollen from GM plants. In order for ASEAN's regulating authorities to effectively regulate

and manage GM crops and foods, there is an urgent need to develop capacity building, as well as to develop infrastructure and facilities to evaluate the presence of GMOs.

Due to persistent concerns about genetically modified crops, the development of GMOs globally has remained mostly in the hands of a handful of multinational companies who had purchased or teamed up with companies that were specialists in this technology. These multinational companies are also responsible for bringing GM crops to this region. In the ASEAN region, for example, Bt corn has been introduced in Indonesia and Thailand, and Bt cotton in the Philippines. The trend of GM in foods is spreading so rapidly that it has become almost impossible for consumers to avoid them. In this respect, some countries are regulating GM products in the market through labeling to ensure transparency and provide for informed consumer choices.

Recognizing that trade in GMOs is expected to increase exponentially in future, concern for the safety of GMOs to human and animal health, and the environment cannot be ignored. Biosafety procedures for genetic modification and release are well established in most developed countries, reflecting the level of biotechnology activities undertaken. However, in a developing country like Malaysia, research in genetic modification is limited. Currently it is being performed on rice and papaya for resistance to tungro virus disease and papaya ring spot virus disease, respectively. This research is being carried out on a small scale in Government funded research institutions and universities.

Nevertheless, there will be field release of GMOs envisaged in the future. Taking this into consideration, there is an urgent need for Malaysia and other ASEAN countries to develop biosafety procedures and increase capacity building in the area of safety assessment on agriculture-related GMOs.

The training workshop which begins today, is appropriate and most timely, as the adoption of the Cartagena Protocol on Biosafety in Montreal in January 2000 requires all parties to implement their obligations to regulate the trans-boundary movement, handling and use of GMOs resulting from modern biotechnology. In addition, while the science of biotechnology has advanced in this region over the years, expertise in risk assessment and management of GMOs are generally lacking. I hope this training workshop will assist in providing an opportunity for regulatory authorities, scientists, administrators and decision makers from ASEAN to learn the latest scientific developments related to safety assessment of agriculture-related GMOs. I believe this workshop will be a fruitful one and will be able to come up with certain workable action plans for regional cooperation for the year 2002 and beyond.

At this juncture, I would like to congratulate ILSI and the Department of Agriculture, Malaysia for organizing this timely and important workshop. I would

also like to thank the organizing committee for the hard work they have put in to ensure the success of this workshop.

To our foreign participants, please take this opportunity to visit our friendly and beautiful country. There are so many exciting and interesting tourist destinations and shopping complexes that await your visit.

On this note, ladies and gentlemen, I am pleased to declare open this 2nd ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture-Related GMOs.

Thank you and have a good and fruitful workshop.

INTRODUCTION

Mrs. Yeong Boon Yee
Executive Director, ILSI Southeast Asia Region

On behalf of the organizers, the Ministry of Agriculture, Malaysia and ILSI, under the auspices of the ASEAN SOM-AMAF, we extend a very warm welcome to you, distinguished guests, ASEAN delegates, speakers and colleagues to this 2nd ASEAN training workshop on Safety and Risk Assessment of Agriculture-Related GMOs in Kuala Lumpur, Malaysia.

As shared at the first workshop held a year ago, in July 2001, hosted by the Agri-food and Veterinary Authority (AVA) of Singapore, the coming together of this safety assessment training program series sprang from the recognition of such need, as identified in early 1999 by several of the key regulatory bodies within ASEAN. It gained the Ministerial approval in November 2000 at the special SOM-AMAF meeting in Brunei in which four workshops were proposed to be held in Singapore, Malaysia, Thailand and possibly Indonesia.

We would like to thank Health Canada and Food Standards Australia New Zealand (FSANZ) for their continuing support and collaboration to facilitate this capacity building workshop series. We are also grateful for the participation of our guest speaker from the Ministry of Health, Labour and Welfare, Japan to share updates on their regulatory development and the assistance of Biotech Thailand for this workshop.

As part of its mandate to address new and emerging scientific issues, ILSI works with international agencies such as FAO and WHO in the process of scientific consensus building, and in the harmonization of standards setting. It assists in the scientific exchange among scientists by convening workshops, symposia, conferences and expert panels to examine the scientific basis for issues critical to improving human and environmental health. The objective is to ensure that the latest and most comprehensive scientific information is available to those who are responsible for health and safety decisions, and that information are readily accessible to those that have the expertise and experience to transform them into easily understandable information for the non-specialists and the public.

ILSI has for over the last twelve years, brought a balanced approach through activities related to the safety assessment of biotechnology-derived plants and foods. Since 1998, internationally, ILSI has facilitated scientific meetings on the safety assessment of GM foods in more than 20 countries in Asia, Australia, Europe, Latin and North America and the Middle East, and published a substantial number of reports and proceedings for use as reference materials.

The workshops addressed issues such as understanding of the concepts of risk assessments, substantial equivalence, method development for the detection of GMOs in the food chain, labeling guidelines, assessment of allergenic or toxic effects, and how scientific information is used to make effective decisions about safety.

Scientists throughout the world understand that just as with conventional foods, there may be some unanswered questions and uncertainties associated with the development, deployment and consumption of biotechnology-derived foods. Knowledge and understanding are ever changing and that confidence accrues with experience. With experience come better-informed questions that stimulate more research, yielding new information. This dynamic process brings challenges and opportunities, and yet is essential to all scientific and technological development.

ILSI and its partners have and will continue to play a significant global role in generating and disseminating scientific information about food biotechnology.

The ILSI Southeast Asia Region branch, headquartered in Singapore, was established in 1993 and now serves the ASEAN countries, Australasia and the Pacific Islands.

We are pleased to have this opportunity to work with our ASEAN colleagues and the Ministry of Agriculture, Malaysia, and to collaborate with other regional and international scientific organizations in our scientific and educational endeavors to enhance capacity building for the regional countries.

We hope this two-and-a-half day workshop, with its further deliberation on the case study on Glyphosate Tolerant Soybean GTS 40-3-2 will provide you with pertinent information and practical tools to aid in your understanding of the process of safety assessment of GM food crops, and that it will be beneficial to your work and your country. We would like to thank the organizing committee of Malaysia and the ASEAN Secretariat for working closely with us to ensure the success of this meeting.

Without further ado, we wish you a fruitful and enjoyable workshop.

Thank you.

Workshop Overview - Framework and Objectives

Mr. Brian Harrison
Health Canada, Canada

The purpose of the workshop is to share Australia's, Canada's and Japan's experiences in the regulation and safety assessment of genetically modified (GM) foods based on international developments in GM foods by Codex, FAO/WHO and OECD.

The highlight of the workshop is the presentation of a case study to provide a hands-on exercise in the food safety assessment of a GM soybean variety (GTS 40-3-2) and also to present environmental considerations for the safety assessment of GM plants.

The workshop participants will be given an overview of GM foods, GM plants and novel foods and related activities as carried out in Australia, Canada, New Zealand and Japan through presentations. Following that will be breakout sessions using GTS 40-3-2 for the hands-on exercise on the safety assessment of GM foods. Each group will present its findings and inference at the end of the sessions.

Team effort is greatly emphasized. This workshop will see a team of evaluators – toxicologists, nutritional scientists, molecular biologists, microbiologists and chemists working together to determine that soybean variety GTS 40-3-2 is safe for consumption.

PRESENTATIONS

Concepts and Principles of Food Safety Assessment of Agriculture-related GMOs – An International Perspective

Dr. Paul Brent, Food Standards Australia New Zealand, Australia
Mr. Brian Harrison, Health Canada, Canada

Currently, there are no internationally agreed regulatory requirements for foods derived from biotechnology, either in relation to assessing the potential human health impact of the foods or for providing information about production methods. However, international discussion between OECD countries, and with the FAO and WHO expert consultations have resulted in a consensus on specific safety issues that should be considered when evaluating a novel food. Many countries recognize the Codex Alimentarius Commission (CODEX) as the appropriate body for setting international food standards, including those that apply to GM foods. The Codex Ad Hoc Taskforce on Foods Derived from Biotechnology recently finalized its recommendations on guidelines for the safety assessment of foods derived from biotechnology (now at Step 8 of the Codex procedure).

Novel foods, including GM foods, undergo a mandatory pre-market safety assessment in some jurisdictions (for example, Australia, Canada and Japan). The approach used in most countries to assess the safety of foods produced by genetic modification draws on the concepts and principles that have been developed internationally. Foods derived from biotechnology are subject to case-by-case assessment of safety. The benchmark for an acceptable level of safety is generally conferred by the conventionally produced food. Safety assessment of GM foods are undertaken according to the following key principles:

- safety assessments use scientific, risk based methods;
- safety assessments are conducted on a case-by-case basis;
- both the intended and unintended effects of genetic modification are considered;
- where appropriate, comparisons are made to conventionally produced foods.

A key component of international harmonization and capacity building in the safety assessment of GM foods is the sharing of information about GM food

safety assessments. This should be a priority for all regulatory agencies involved in the regulation of GM foods and for international standard setting bodies such as Codex. Better use of existing information and mechanisms for information exchange are vital as a first step towards the broader objective of international mutual recognition of assessment on GM foods and adoption of broad regulatory principles of operation such as transparency and public consultation and participation.

Discussion

Saturnina C. Halos: The issue of possible accumulation of damage over time has been raised. How should this issue be addressed? What kind of questions should a regulator ask?

Answer: Regulatory authorities such as FSANZ and Health Canada consider the potential for long-term effects during the safety assessment of a GM product. The pre-market assessment ensures that no new toxins or allergens are introduced into the marketplace. If a new protein is found to have characteristics associated with toxicity or allergenicity, long-term studies would be required to demonstrate safety. To this point, no products of biotechnology have required long-term assessment.

Yahya Muhamad: What is the expert view regarding assessment of unknown compounds in GMO and what are the analytical capabilities to identify these compounds?

Answer: The potential for the production of unknown effects in GMOs are no different to that of conventionally produced foods provided the regulator gets complete information on molecular characterization, compositional analysis, potential for allergenicity and toxicity. There is no scientific reason to believe that a new protein, other than the novel protein expressed by the novel gene, will be produced. This also applies to the production of new toxins and allergens. New analytical capabilities such as proteomics and metabolomics may help in future but much more work needs to be done in these emerging fields before they are able to be used as tools to facilitate the comparative approach. For example, comprehensive data will need to be obtained on the appropriate comparator plant, not just the GMO.

Lorelie Agbagala: What is the level of GM in food allowable before safety assessment is required?

Answer: If the plant has been genetically modified, most countries require that the plants undergo safety assessment. Related to this is the labeling of

GM foods. In different countries there are different labeling laws. In some countries like Japan, Thailand and Australia, the labeling laws have a threshold for unintended contamination that triggers labeling.

Lorelie Agbagala: How is sampling of imported GM food done before it goes to the market?

Answer: In Canada, sampling is the responsibility of the Canadian Food Inspection Agency as part of their enforcement of the Canadian Food and Drugs Act. Manufacturers and importers must be aware of the regulations in a country they choose to import to with regard to GM products. If they do not comply in Canada, they are in contravention of the Canadian Food and Drugs Act and Regulations and can be fined or imprisoned.

Overview of GMO Safety Assessment and Labeling in Japan

Dr. Go Tanaka
Ministry of Health, Labour and Welfare, Japan

In April 2001, Japan made it mandatory for the safety assessment of foods produced by recombinant DNA technology, referred to as genetically modified foods (GM foods) under the Food Sanitation Law. This is to prevent the domestic distribution of GM foods that are not proven safe. Currently, GM foods and products using GM foods as ingredients that do not undergo safety assessment are banned from import and sale. Quarantine stations monitor GM foods to determine if imported GM foods have undergone safety assessment.

The safety for individual GM foods is evaluated on various detailed items, based on the standards for the safety assessment of foods and food additives produced by recombinant DNA techniques, following the recommendations of the Pharmaceutical Affairs and Food Sanitation Council, which serves as an Advisory Committee under the Ministry of Health, Labour and Welfare.

As of July 2002, 43 types of foods and 10 types of food additives have undergone safety assessment. GM foods are also subject to evaluation by the Ministry of Agriculture, Forestry and Fisheries. The evaluation includes environmental effects when GM agricultural products are cultivated, as well as its safety assessment as feeds.

For GM foods that have undergone safety assessment, the Japanese government established new labeling standards, making it mandatory last year (April 2001). Foods covered by the labeling legislation include five agricultural products: soybeans, corn, potato, rapeseed and cottonseed, and 24 kinds of processed foods derived from them in which recombinant DNAs or protein produced thereby are detected after the manufacturing process.

Discussion

Yeang Hoong Yeet: GM products in Japan are exempted from mandatory labeling if the proportion of each ingredient is less than 5% by weight. If a product contains 5 ingredients and each has 4% GM by weight, the total proportion of GM ingredients would be 20%. Would this product be exempted from the regulation since the proportion of GM in a food product should not exceed 5%?

Answer: It is exempted because it is less than 5% for each ingredient in the product.

Ghazali Zakaria: In Japan, quarantine stations monitor GM food to determine if imported GM foods have undergone safety assessment. For inspection of GM food, they are subjected to qualitative and quantitative tests. What are the facilities you provide at your quarantine stations to monitor GM food?

Answer: There are two laboratories in Kobe and Yokohama, respectively, which carry out qualitative and quantitative tests by using real time PCR and ELISA. These laboratories carry out screening for quarantine pests and diseases.

Wong Wan Cheng: What are the enforcement actions undertaken by the quarantine inspectors if non-approved GM foods are detected as in the case of potato and papaya?

Answer: If non-approved GM foods are detected, then the action taken by the quarantine authority in Japan will be to either I) destroy the product, or ii) send it back to the country of origin.

Norrakiah Abdullah Sani: To what extent is recombinant bacteria used in food?

Answer: Food additives should not contain any recombinant bacteria. As in the case of yogurt, cheese and natto (Japanese tempe), they may contain living GM microorganisms and will be assessed under a different food safety assessment scheme. Such safety assessment on GM microorganisms is currently being developed by CODEX.

An Overview of Environmental Assessments of Plants with Novel Traits in Canada

Mr. Luc Bourbonnière
Health Canada, Canada

In Canada, a genetically engineered plant is considered to be a plant with a novel trait (PNT). Plants falling into this category are regulated on the basis of the characteristics of the product, not the specific process by which the product is made. The primary trigger of the regulatory process is the novelty of the plant species, its characteristics or traits and use, in the Canadian context. Therefore, products of traditional breeding or mutagenesis as well as the products of recombinant DNA technology may be considered novel and regulated.

The Safety Based Model for the regulation of PNTs is based on the concepts of familiarity and substantial equivalence. Familiarity applies to the knowledge of the characteristics of a plant species and experience with the use of that plant species. Substantial equivalence refers to the determination of potential alteration of environmental interactions, in comparison to an appropriate comparator, and considers the following criteria:

- Potential to become a weed of agriculture
- Potential to be invasive of natural habitats
- Potential gene flow to weedy relatives that may become weedy or invasive
- Potential to become a plant pest
- Potential impact on non-target species
- Potential impact on biodiversity

Risk management is applied to confined field-testing by the imposition of terms and conditions to the field tests. For an unconfined environmental release, any identified risk is minimized by placing specific conditions on production and use. An example of this would be the imposition of a pest resistance management plan on an insect tolerant crop engineered to produce an insecticidal toxin.

Discussion

Nurlianie Bermawie: Reproductive isolation and post-harvest land use are applied during confined field trials, not after being released or through unconfined release. How do we prevent gene flow if such regulations are no longer applied?

Answer: When an unconfined release assessment is performed, the issue of gene transfer is addressed as part of the requirements for granting full release authorization. Based on the biology of the host (especially its reproductive biology) and on the nature of the trait and other factors, a determination is made to determine the likelihood of that gene transfer to occur and also its significance. Based on this, a decision will be reached.

Saturnina C. Halos: What is the basis for imposing post-harvest land use restriction?

Answer: The main reason is the potential for the survival of the transgenic crop after the growing season. The survivors or volunteers would be difficult to detect if the crop planted is of the same species as that of the previous year. Crop rotation permits detection and destruction of volunteer crops. The example in Canada is canola.

Ahmad Parveez Ghulam Kadir: 1) What is isolation distance? 2) In the case of the GMO plant, which requires an isolation distance of 5 – 10 km and is grown over a wide area in the country, the isolation distance is not practical to be fulfilled. In this case, will the applicant be granted a confined release? Does bagging individual flowers help to get the application granted?

Answer: 1) Isolation distance (ID) is the distance between the plot where the GM plant is grown and any other plot. It is also called the buffer zone. 2) I agree that ID would be impractical in the situation you described. The decision to grant or refuse is based on the outcome of the confined trial assessment. Based on the biology of the plant, they will determine the best way to achieve reproductive isolation. This will be done on a case-by-case basis, depending on the plant. If it can be shown that bagging will effectively lead to reproductive isolation, then approval could be granted. If not, it could be refused.

Marina P. Natural: What is the best method for disposal of GM plant material?

Answer: There is no prescribed methodology to dispose off plant material after a confined trial. It is the responsibility of the petitioner to ensure that the material does not enter the food or feed chain and they should destroy the material or segregate it until the plant is approved (for food, feed etc). The method of disposal would be based on the fact that it would render the material non-viable such as incineration and composting.

Norshahidah Khairullah: Are post-release monitoring and post-marketing monitoring the same? Whose responsibilities are they?

Answer: On post-release monitoring, petitioners have the responsibility to gather information on the plants even after approval. If they become aware of any information, which could change our assessment, they must provide us with it. Post-marketing monitoring deals more with long term effects. At Health Canada, there is a feasibility study that will try to see if monitoring such effects is possible. In Canada, this responsibility lies with the government. It is still in an embryonic stage.

Regulating Genetically Modified (GM) Foods in Australia and New Zealand

Dr. Paul Brent
Food Standards Australia New Zealand, Australia

The Food Standards Australia New Zealand (FSANZ) (formerly ANZFA) is responsible for developing, varying and reviewing national food standards through a legislative decision-making process. The FSANZ Board approves new standards or variations to food standards that are then accepted by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), a council made up of Commonwealth, State and Territory, and the New Zealand Health and Agricultural Ministers. If the Council accepts the changes recommended by FSANZ, the food standards are automatically adopted by reference under the food laws of Australian States and Territories and New Zealand.

To-date, FSANZ has received 23 applications for GM foods covering soybeans, corn, canola, potato, sugar beet, and cotton. All but one of these is related to the introduction of genetic traits designed to improve production characteristics, such as pest and disease resistance or tolerance to herbicides. The other application relates to changes in the oleic acid content of a soybean, which improves the cooking characteristics of the oil, and may also provide potential health benefits to consumers. FSANZ has completed and released full safety assessments on 21 GM foods for public comment. Of the 21 commodities whose assessments have been released in the two rounds of public consultation, 20 have been approved for sale in Australia and New Zealand by the Ministerial Council, and the remaining one is in the process of assessment. Two applications have been withdrawn by the applicants because they have not continued commercialization.

In July 2000, the Ministerial Council agreed to the adoption of new labeling requirements for GM foods. Labeling is now required where: novel DNA and/or protein are present in the final food; and/or the food has altered characteristics when compared with its conventional counterparts. Exemptions apply to:

- highly refined food where the effect of the refining process is to remove novel DNA and/or protein;
- processing aids and food additives except those where novel DNA and/or protein is present in the final food;
- flavors which are present in a concentration less than or equal to 0.1% in the final food; and
- food prepared at the point of sale.

Discussion

Nurlianie Bermawie: In Indonesia all data from the applicants are treated confidentially. In Australia, what sort of data is treated as confidential and what is open to public especially when these are related to identification process (IP) handling?

Answer: Confidentiality of information is applied for by applicants under the FSANZ Act. FSANZ will grant permission only for a very small amount of commercially sensitive information such as the sequence of the gene insert. All other information, including raw data is available to the public.

Canadian Regulations of Biotechnology Derived Foods

Mr. Brian Harrison
Health Canada, Canada

International consultations held by the OECD, FAO and WHO support the conclusion that food safety considerations regarding foods derived from genetic modification are basically of the same nature as those that might arise from other ways of altering the genome of the organism, such as conventional breeding, and the techniques of modern biotechnology do not introduce risks which are different from those already associated with the food supply. The Canadian approach to safety assessment is based upon principles developed through expert consultation with the OECD, FAO and WHO.

Under the Canadian Food and Drugs Act and Regulations, there are a number of regulatory mechanisms to control the sale of food in Canada. These mechanisms include pre-market notification, pre-market approval and food standards. Pre-market notification is the proposed approach that would be applied to foods derived through genetic modification. This approach requires the submission of information regarding the product in question to the Health Products and Food Branch of Health Canada so that a determination can be made with respect to its acceptability as food prior to sale.

A Novel Foods Regulation has been promulgated under the Canadian Food and Drugs Act that requires manufacturers of novel foods, including foods developed using genetic modification, to notify Health Canada before the sale of the product in Canada. This permits Health Canada to conduct a thorough safety assessment. Each safety assessment of food developed using genetic modification considers the process used to develop it; compares its characteristics to and that of its traditional counterpart; its nutritional quality; the potential for the presence of any toxicants or anti-nutrients; and the potential allergenicity of any proteins introduced into the food. Health Canada is required to respond within 45 days of receipt of the notification should the product be considered unacceptable for sale. Additional information may be requested to review the product and if this is the case, the manufacturer is not permitted to sell or advertise his product until the additional information is reviewed. Once reviewed, these foods enter the marketplace in the same manner as traditional food products and remain subject to post-market standards applicable to all foods in Canada.

To date 50 GM plants have completed the regulatory process in Canada.

In addition to the proposed Novel Food Regulations, the Health Products and

Food Branch has issued Guidelines for the Safety Assessment of Novel Foods (1994).

These guidelines establish the safety assessment criteria that assist developers in the collection of information required to demonstrate the safety of novel foods.

In Canada, Health Canada and the Canadian Food Inspection Agency (CFIA) share the responsibility for food labeling policies under the Food and Drugs Act. Health Canada's responsibilities for food labeling falls within the Department's mandate for health and safety issues. Mandatory labeling is required for GM foods where safety concerns such as allergenicity and compositional or nutritional changes are identified. Voluntary labeling of foods derived from biotechnology is permitted under the current legislation as an option for food companies to meet market place demands.

The CFIA is responsible for protecting consumers from misrepresentation and fraud with respect to food labeling, packaging and advertising, and for prescribing basic food labeling and advertising requirements.

Discussion

Ho Haw Leng: What is the number of applications for novel foods which were unapproved by Health Canada?

Answer: Health Canada conducts a rigorous assessment of all novel foods before they can enter the food supply. A novel food cannot be sold until all the safety assessment criteria outlined in the guidelines are addressed by the petitioner. While Health Canada has not rejected any application to date, some novel food submissions applications have outstanding deficiencies that have prevented certain products from being approved for sale.

Determination of Environmental Safety of Glyphosate Tolerant Soybean (*Glycine max* L.) GTS 40-3-2

Mr. Luc Bourbonnière
Health Canada, Canada

Health Canada does not conduct environmental assessments on GM plants. Environmental assessments on GM plants are performed by the Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA). This presentation is based on the CFIA's Decision Document for Glyphosate Tolerant GTS 40-3-2, taking into consideration Canada's weather and agricultural practices.

Unconfined release assessment include the molecular characterization of the PNT and biology and interactions of the PNT such as:

- Potential to become a weed
- Potential for gene flow
- Potential to become a plant pest
- Potential impact on non-target species
- Potential impact on biodiversity

In terms of molecular characterization, there are two insertion points, one with a functional copy of the glyphosate tolerance gene and one with a partial insert. The insertion is stable and the gene is expressed in leaves and seeds. The protein expressed is not glycosylated, nor has it undergone post-transcriptional modifications. The protein is not heat stable and is easily digested.

Agronomic performance: GTS 40-3-2 is substantially equivalent to unmodified varieties for these characteristics. No competitive advantage was conferred by the insertion of the novel gene, other than tolerance to the Roundup® herbicide. The line was tested under various environment conditions and showed no obvious differences in agronomic performance when compared to unmodified counterparts under the same conditions.

Weediness: Soybean is not weedy, nor is it invasive of unmanaged habitats in Canada. Soybean is not wind-pollinated and is mostly self-pollinated. It does not survive under cool wet oil conditions in Canada. GTS 40-3-2 was determined not to be different from its counterparts in this respect. If volunteer plants should arise, they can easily be managed by mechanical means and other chemical controls. In Canada, glyphosate is not used in normal crop

rotation cycles, so resistance is not a concern in weed management control. To conclude, GTS 40-3-2 and its progeny have no altered weediness or invasiveness potential compared to current commercialized soybean varieties.

Potential for gene flow: *G. max* has a wild annual relative, *G. soja*. Natural hybridization can occur between these relatives. *G. soja* is not naturally occurring in Canada and although it can be cultivated in experimental plots, there have been no reports of its escape from such plots to unmanaged habitats. In Canada, the potential for transfer of the glyphosate tolerance trait from the transgenic line to soybean relatives through gene flow is negligible in managed ecosystems.

Plant pest potential: Soybean is not a plant pest in Canada. The intended effect of the novel traits is unrelated to plant pest potential. Agronomic characteristics, qualitative and quantitative composition of GTS 40-3-2 were shown to be within the range of values displayed by currently commercialized soybean varieties. As such the plant pest potential of this line is not altered.

Potential impact on non-target organisms: The novel gene and resulting enzyme do not result in altered toxic or allergenic properties. The enzyme is ubiquitous in microorganisms, fungi and plants. It is rapidly inactivated in mammalian stomach and intestinal fluids by enzymatic degradation and pH-mediated proteolysis. GTS 40-3-2 is substantially equivalent to traditional varieties in terms of anti-nutritional factors such as trypsin inhibitor, lectins, isoflavones and urease. Protein profiles, amino acid and fatty acid compositions were equivalent to those of the unmodified counterpart. To conclude, the GTS 40-3-2 line will not result in altered impacts on interacting organisms, including humans. However, if the novel trait were to relate to a protein with known toxicity to certain species, then the non-target requirements would be more extensive to address this issue.

Potential impact on biodiversity: The introduced EPSP synthase was determined to be safe to non-target organisms. The GTS 40-3-2 line has no novel phenotypic characteristic which would extend its use beyond the current geographic range of soybean production in Canada. The novel trait will not be transferred to unmanaged environments. Therefore the potential impact on biodiversity is equivalent to that of currently commercialized soybean lines.

CFIA has concluded that neither the novel gene nor its resulting gene product and associated novel trait confer any intended or unintended ecological advantage, or environmental impact to GTS 40-3-2. In Canada, there is no potential for transfer to wild relatives. Unconfined release into the environment, and other *G. max* lines derived from it, but without the introduction of any other novel traits is therefore, considered safe.

Discussion

Ahmad Parveez Ghulam Kadir: How detailed should a submission be for a food safety assessment or for an environmental risk assessment?

Answer: The company will have to provide all the raw data to be evaluated to ensure that the data was generated properly. It is the responsibility of the company to generate appropriate data, as per regulatory guidelines, for the regulatory agencies to conduct their assessment of the plant. For confined field trials, the information requirement will not be as extensive, as confinement precludes the necessity of a full environmental assessment.

Saturnina Halos: What criteria do you use for the selection of test organism/ test insects?

Answer: Generally it is a case-by-case approach and each country will have to determine its own set of test organisms. As for Bt toxin, it is very specific to certain insects and not toxic to humans. An appropriate suite of non-target test species would include other insects that would also be exposed to the toxin, as well as mammalian and bird test organisms. A lot of information is already available on Bt toxins.

Yong Lee Ming: Do you receive any feedback from the organic plant growers for the acceptance of GM food? What is the acceptance level of GM crop in organic farming?

Answer: Yes. A lot of feedback has been received from the organic farmers especially in the use of Bt. They are concerned with gene flow and the potential contamination that might occur. In Australia, the tolerance level for GM plants by the organic farmers is zero. There are various proposals to curb the advance of GMOs into their respective areas such as to create GM free zones. In Japan, the labeling laws are clear in that organic products cannot contain GM genes.

Koh Cheng Lek: Please comment on 'horizontal gene transfer' from GM plants or foods to other organisms.

Answer: The regulatory authorities always take into consideration the potential for horizontal gene transfer (HGT) in their safety assessment. A study in Australia has shown that there is a very small amount of gene flow from GM canola into its weedy relatives. A study using marker genes also has shown that there is no risk from ingestion of marker genes. There is international consensus that the likelihood of HGT contributing to human antibiotics resistance from ingestion of GM plants that contain antibiotic resistance marker genes is effectively zero.

Lorelie Agbagala: What are the conditions for confined field trial?

Answer: For confined field trial, the applicant will have to demonstrate complete reproduction isolation of the trial plots; they are not allowed to put the product into the food or feed chain; they are not allowed to relocate the trial (unless another confined field trial application is approved); and they will have to have the plant materials destroyed completely or rendered completely unviable.

Hypothetical Deficiencies Encountered During the Safety Assessment of GM Foods

Dr. Paul Brent
Food Standards Australia New Zealand, Australia

Most regulatory systems worldwide have a statutory timeframe under which an assessment for approval of a food application (including GM foods) has to be completed. FSANZ has a period of 12-18 months to assess and make a decision to either approve or not approve an application. A detailed discussion with the applicant during the planning and development stage of the product is desirable so that the applicant is familiar with the regulatory requirements before submitting the application.

It is desirable to undertake a thorough examination of the data submitted by the applicant before accepting the application, if possible, in order to identify the completeness of the data package and any deficiency. Deficiencies in the data submitted by the applicant will normally result in the following process in Australia:

- contact and discussion with the applicant;
- agreement on action to be taken;
- sending of an official stop-clock deficiency letter to the applicant detailing the data required if the matter is unresolved;
- a timeframe for supply of the data;
- failure to comply will usually result in the rejection of the application and a better alternative would be for the applicant to withdraw the application if the data requirements cannot be met.

Hypothetical deficiencies in the data submitted that may result in a deficiency letter and/or rejection of the application include but is not limited to:

1. General

- Experiments not conducted under GLP, and audited or generally conducted poorly.
- For toxicology and allergenicity studies, only summaries of studies are submitted without supporting raw data.
- Inadequate background information on host and donor organisms, role of plant in the diet (i.e. which part of plant is eaten, if it is consumed by particular population groups, levels of natural toxins, etc).

2. Statistics

- Lack of appropriate arguments supported by evidence in relation to statistically different changes in compositional parameters between GM and non-GM controls.

- Inappropriate sampling of data points for robust statistical analysis (i.e. number of plants to be sampled, sampling of crop area; trials and growing seasons, etc).
- No information on historical ranges supplied on commodity for comparison with GM and non-GM foods.
- Lack of appropriate statistical analysis.
- Sample sizes too small for proper statistical analysis.
- Tabulated results not clear (i.e. missing (n) values, (P) values, error calculations, etc).

3. Molecular characterization

- Southern, northern, western blots that are not clear, or do not have molecular markers or proper controls.
- Incomplete nucleotide sequence data.

4. Genetic Stability

Traits must be demonstrated to be expressed and inherited stably through several generations consistent with laws of inheritance.

5. Expressed Material

- Incomplete information on protein and its function.
- Level and site of expression of protein (seed, leaf, oil).
- Comparison of plant and bacterial expressed proteins not adequate; plant protein used in analysis not from plant line being commercialized but from another line expressing same protein.
- Methodologies to detect protein.

6. Nutritional Considerations

Incomplete compositional analysis; often data on vitamins and minerals missing.

7. Toxicology and Food safety

- Lack of compositional and metabolite data on sprayed and unsprayed plants for herbicide tolerant-plants.
- Testing for equivalency between bacterial and plant expression systems not adequate.
- Bioinformatics data not adequately supported by discussion of results.
- Gastric and intestinal model systems analysis not well conducted (e.g. studies at 37 C).
- Oral toxicity studies not adequate; results not explained; summaries with no raw data.
- Levels of natural toxins and anti-nutrients not done.

8. Allergenicity

- Protein levels should be measured in each food fraction, including oils and sugars.
- Inadequate discussions on implications where amino acid sequence homology comparisons are borderline (e.g. 6 contiguous matches and greater).

9. Conclusion

Assessment of overall deficiency is on totality of data package. A decision must always be made on a case-by-case basis.

BREAKOUT SESSIONS

Case Study: Novel Food Safety Assessment of a Genetically Modified Herbicide Tolerant Soybean

For the hands-on training on the safety and risk assessment of Agriculture–related Genetically Modified Organisms (GMOs), breakout sessions were held using the case study 'Novel Food Safety Assessment of a Genetically Modified Herbicide Tolerant Soybean' as the framework for discussion. This case study used excerpts from the applications for the food safety assessment submitted by Monsanto to the regulatory authorities in Canada, the United Kingdom and the United States for the genetically modified soybean and its progeny.

There were four working groups, each comprising about 12 participants. Each group was assisted by a workshop facilitator to discuss and assess the data in the case study.

The breakout sessions were divided into two parts:

- **Development and Production of Modified Soybean**
- **Product Information**

At the end of the sessions, the working groups met to present their findings.

Development and Production of Modified Plant (Soybean)

Host Organism

For the host plant, the history of safe use as a food product included information on:

- Origins of the food crop
- How the plant is typically cultivated, transported and stored
- Any special process to make the plant edible
- The plant's role in diet:
  - *what part is used as the food source*
  - *consumption by a particular subgroup*
  - *macro– and micro-nutrient contributions to the diet*
- genotype and phenotype relative to its safety, including known toxicity and allergenicity. These included plants used in the breeding and modification of the plant and related species.

All groups generally agreed that information on the origin and history of safe use as food by humans is sufficient. It was noted that the host organism, soybean *(Glycine max)* had a long history of more than 4,500 years, used as food and has been extensively cultivated and consumed by humans.

The participants raised concerns that the data and information for the safety issues and risks in eating soybean such as information of the presence of antinutrients such as trypsin inhibitors, hemaglutinin, phytic acid and phytoestrogens, as well as the presence of low molecular weight carbohydrates should be included.

However, they agreed that the assessment for the safety evaluation of genetically modified soybeans has to ensure that the levels of antinutrients fall within the range of natural variation found within the foods produced using the traditional soybeans.

Participants highlighted the lack of information on the exposure and consumption patterns. Questions were raised to include information on mode of ingestion, i.e. consumed in processed form and never eaten raw. It was commented that heat processing would destroy antinutrients.

Donor Organism

Information on naturally occurring toxins, antinutrients and allergens for microorganisms, information on pathogenicity and relationships to known

pathogens should be included in the assessment of the host organism.

If the donor organism contains known allergens, particular caution must be exercised. When the genetically engineered food contains genes from other sources, it must be assumed that the novel gene product is allergenic unless proven otherwise.

In this case study, the participants concluded there was no safety concern on donor organisms and inserted genes. It was commented that the inserted genes of the donor organisms had no history of hazardous effects to humans, i.e. it is not linked to pathogenicity traits or other harmful characteristics and have been widely used based on linkage data. It is also noted that experimental evidence is required for the safety assessment.

However, some questions were raised by other groups on reasons for gene construction made with two EPSPS genes and initial selection with GUS that disappeared in the subsequent generation. Information is lacking for the DNA sequence alignment and amino acid alignment. The participants were informed later that such information is normally provided and for the purpose of this workshop, where left out.

The participants also noted that *Agrobacterium* is a naturally occurring soil bacterium and is well characterized.

Transformation System

A detailed description of the methods for introducing new genetic material into plant cells is important as it will determine the information requirement for the assessments of the molecular biology of the plant. The two principal methods for introduction are microparticle bombardment and Agrobacterium-mediated transformation.

Information on genetic construct should include:

- size, identity and function of all DNA components
- listing of all regulatory components
- markers (trait selection)
- labeling of restriction enzyme sites

Generally, most of the participants agreed that information on the method of transformation, i.e. biolistic or microparticle bombardment is sufficient. They also noted that the vector carrying the gene for transformation is well characterized to allow for proper interpretation of subsequent experiments for molecular characterization. The genetic element (restriction enzymes) used were also listed and are sufficient for assessment.

Molecular Characterization of the Inserted DNA

Molecular characterization of a transgenic plant provides information about the composition and integrity of the inserted DNA; the number of copies of the inserted DNA; the number of sites of insertion; and the level of expression of the novel protein(s) over time and in different tissues; and characterization of DNA insertions in plant genome resulting from genetic modification.

A petitioner can use various methods to achieve this characterization:

- Southern blots
- PCR
- Gene sequencing

A detailed molecular characterization may be able to address issues related to positional effects, pleiotropic effects, and gene silencing. However, in the absence of other empirical data, such analyses are unlikely to predict unforeseen effects on the concentrations of key nutrients, antinutrients, or endogenous toxins.

Participants concluded that the information is generally adequate, but the following concerns should be addressed:

- The difficulty to read and interpret some copies of the gel from the Southern Blot Analylses and PCR:
  - *The molecular markers are not well-separated*
  - *Extra bands that need further explanation*
- The disappearance of the selectable marker, GUS, in GTS40-3-2 needs to be explained
- More emphasis on the protein rather than DNA because safety issues arise on the effect of the protein

Genetic Stability of the Introduced Trait

The novel traits that are expressed and inherited in a manner that is stable through several generations are consistent with laws of inheritance. The inheritance and stability of each introduced trait that is functional in the transformed plants must be determined.

Serological techniques are generally used to measure trait expression either quantitatively (e.g. enzyme linked immunosorbent assay ELISA), radio-immunoassay, or qualitatively (e.g. ELISA, Western immunoblotting).

In this case study, the data shows the presence of the same-sized DNA insert up to the 6th generation and the Mendelian segregation indicating a dominant trait showing the genetic stability of the glyphosate tolerance.

The participants concluded that the trait is conditioned by one dominant gene, hence the gene encoding CP4 EPSPS is genetically stable over six generations.

Introduction to Product Information

Expressed Material/Effects

Hazard identification requires knowledge of which introduced genes are expressed, the characteristics, concentration and localization of expressed products and the consequences of expression.

Some concern over inconsistencies in the presentation of the results was raised. More data are required for experimental design and results.

A concern was also raised regarding information on how samples were collected. The expression test should also be conducted on a wide variety of soybean products such as soybean drink, tofu, soy sauce and soybean meal. The participants found no information from any common processing of soybean for human consumption.

However, the participants generally agreed that only CP4EPSPS was expressed and that no additional CP4EPSPS immunoreactive proteins were detected.

Toxicity

A key consideration of the toxicological assessment was the protein expression product(s) of the inserted gene(s). The inserted DNA is not of concern with respect to ingestion of genetically modified plants or their products. In humans, dietary intakes of RNA and DNA vary widely but are typically in the range of 0.1 to 1.0 g per day (Doerfler & Schubert 1997), in particular the part(s), which will be subjected to processing prior to consumption. Any concern over the presence of novel DNA in a genetically engineered food consumed in the human diet must take into consideration that this DNA would represent less than 1/250,000 of the total amount of DNA consumed. In view of this and the digestibility of dietary DNA, the probability of transfer of genes from genetically engineered foods (or any food) to mammalian cells, or gut microorganisms, is infinitely small.

The genetic material inserted into food crops is frequently derived from microorganisms that have not previously been present in the human diet to any extent, and the corresponding gene products are considered to be novel with respect to human consumption. In determining which data would be required, it should first be established whether the novel protein(s) will be expressed in the edible tissue and if present, whether the anticipated processing conditions will result in the removal or denaturation of proteinaceous material. Information should be provided concerning which transgenic expression

products will be present in the modified crop, the expression levels of the relevant proteins in various plant tissues, in particular the part(s) which will be subjected to prior consumption of the product. If a concern remains, then data is required to address the safety of the novel protein.

Introduced genes are often derived from microorganisms that do not have a history of significant consumption by humans. However, in some cases the protein product of introduced genes has been consumed in significant amounts such as viral coat proteins from transgenic potatoes, papaya and squash.

An assessment of potential toxicity of a novel protein should consider the following factors:

- prior history of safe human consumption or is sufficiently similar to proteins that have been safely consumed in food;
- comparison of amino acid sequences to known toxins and antinutrients;
- stability to heat or processing methods;
- degradation in representative gastric or intestinal model systems;
- Any indication of potential toxicity would require the need for additional studies on a case-by-case basis.

For this case study, the participants raised concerns over the following issues:

- Results given but raw data not included
- Further details of methodology needed
- Reference/ industry data needed
- Specific type of tissue for toxicity testing not indicated
- Number of mice used was not given
- Method of obtaining dosage rate

Participants commented that digestion studies showed that rapid degradation occurs in simulated gastric juice and small intestine juice. In conclusion, participants agreed that there were no significant health and safety concerns regarding the toxicity of the novel protein.

Allergenicity

Due to the absence of definitive tests to determine potential allergenicity, international organizations have developed a decision tree and weight of evidence approaches to the allergenicity assessment of GM foods. The decision tree was developed by IFBC and ILSI in 1996 and was elaborated upon by the FAO/WHO in 2000.

The decision tree strategy involves the following:

- Gene source
- Physiochemical properties (molecular weight, heat and processing stability digestive stability)
- Amino acid sequence homology
- Prevalence in foods
- Immunological analysis (RAST)

An initial assessment is performed where:

- The source of the novel gene (protein) is considered
- Amino acid sequence homology is compared
- Pepsin resistance is determined

In the event that the source is a known source of allergens, or if there is a match to an allergen in an amino acid sequence analysis, then testing in immunological assays should be performed where sera are available.

For allergenicity analysis, the following factors should be considered:

- Source of the gene (protein)
- Amino acid sequence homology
- Degradation in gastrointestinal fluids
- Heat stability
- Prevalence of the protein in the food product
- Specific serum screening

Participants commented that there is no reaction on serum screening. It was mentioned that physiochemical properties were not typical of an allergen. Therefore, it was concluded that CP4 EPSPS is not a potential allergen.

Nutritional Data

One of the most important aspects on food assessment is to consider the potential for any change in nutritional composition, especially in key elements that have significant impact on the diet and for any change in the bioavailability of key nutritional components. Genetic engineering could alter the nutritional value of plants or lead to unexpected or unintended changes in concentrations of various natural toxicants or antinutrients.

It was generally agreed that there were no significant or unintended changes in the composition of nutrient and antinurients between GTS40-3-2 and its parental line. However, issues such as method of sampling where soybean samples were collected in two different years could affect the stability of nutrients over a period of time. Therefore, data are needed on storage conditions and time.

Inconsistencies and incomplete data were the main concern of the participants and more information is needed before any assessment can be made.

An issue on religious connotation and ethic was also raised.

CLOSING REMARKS

In her concluding remarks, Ms. Asna Booty Othman, chairperson of the organizing committee, expressed her gratitude to the faculty members for their continuous guidance and diligence, to ILSI for providing financial support and to the participants for their active participation. She expressed the need for the ASEAN region to be convinced of the need to harmonize risk assessment on agriculture-related GMOs.

Mrs. Yeong Boon Yee, Executive Director of ILSI SEA Region expressed her appreciation to the Ministry of Agriculture, Malaysia for hosting the workshop and thanked the speakers from Health Canada, FSANZ, Japan Ministry of Health and Biotec Thailand for sharing their expertise and experience, and for facilitating the discussions. The outcome of this workshop, she added, would be useful for the development of future workshops. Other than to achieve harmonization, it is envisaged that the workshop series will achieve a step further in enhancing capacity building in the field of safety and risk assessment of agriculture-related GMOs for the region.

APPENDICES

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The **International Life Sciences Institute (ILSI)** is a nonprofit, worldwide foundation based in Washington, DC established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. ILSI branches include Argentina, Brasil, Europe, India, Japan, Korea, Mexico, North Africa and the Gulf Region, North America, North Andean, South Africa, South Andean, Southeast Asia Region, the Focal Point in China, and the ILSI Health and Environmental Sciences Institute. ILSI also accomplishes its work through the ILSI Research Foundation (composed of the ILSI Human Nutrition Institute and the ILSI Risk Science Institute) and the ILSI Center for Health Promotion. Established in 1993, **ILSI Southeast Asia Region**, located in Singapore currently serves as the regional office for the coordination of scientific programs, research and information dissemination in ASEAN, Australia, New Zealand and the Pacific. By bringing together scientists from academia, government, industry and the public sector, ILSI seeks a balanced approach to solving problems of common concern for the well-being of the general public. ILSI receives financial support from industry, government, and foundations.

The **Ministry of Agriculture (MOA) Malaysia** is the policy-making body for the agriculture sector in the country. The MOA plans, formulates and designs programs and projects for the implementation of policies and strategic directions of the Third National Agricultural Policy (NAP3). The objectives of the MOA are to: increase the income of farmers, livestock breeders and fishermen by increasing output from agriculture, livestock and fishery activities through efficient utilization of the nation's resources; increase the production of food for domestic consumption and for export as well as diversifying agricultural, fishery and livestock activities including downstream activities in line with market opportunities, both domestic and abroad; monitor, evaluate and coordinate the implementation of project/programs executed under the Integrated Agricultural Development Projects (IADP) as well as non-IADPs; provide economic and analytical services inclusive of collation, analysis and storage of statistics and making them available to end-users; ensure the participation of the MOA in international programs, and serve as a one-stop agency to the private sector for the provision of advisory and expert services in the agricultural sector.

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- ILSI Southeast Asia Region Task Force on Biotechnology
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- Ministry of Agriculture, Malaysia
- Health Canada
- Food Standards Australia New Zealand

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