Report Of The 3rd ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture-Related GMOs

August 13 – 15, 2003
Amari Watergate Hotel
Bangkok • Thailand

ASEAN FOUNDATION

ILSI International Life Sciences Institute

Ministry of Agriculture and Cooperatives, Thailand

Health Canada
Food Standards Australia New Zealand

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International Life Sciences Institute (ILSI) Southeast Asia Region
ASEAN Foundation, Indonesia
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REPORT OF THE

3RD ASEAN-ILSI TRAINING WORKSHOP ON SAFETY AND RISK ASSESSMENT OF AGRICULTURE-RELATED GMOS

AUGUST 13-15, 2003
Bangkok, THAILAND

Organized by
ILSI Southeast Asia Region

National Bureau of Agricultural Commodity
and Food Standards,
Ministry of Agriculture and Cooperatives, Thailand

With the support from
ASEAN
The ASEAN Foundation / ASEAN-Japan Solidarity Fund

In collaboration with

Health Canada

Food Standards Australia New Zealand

ILSI International Food Biotechnology Committee

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WELCOME REMARKS

Dr Ruben Umaly
Executive Director, ASEAN Foundation

Excellencies, Distinguished Participants, Ladies and Gentlemen, it is a great pleasure for me to be here this morning, to take part in the opening ceremony of the 3rd ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture-Related GMO's.

I would like to express our gratitude to the Ministry of Agriculture and Cooperatives, Thailand for hosting such an important event. I also would like to express my appreciation to the ASEAN Secretariat and International Life Sciences Institute (ILSI), for their efforts in initiating this project.

GMO is considered to be one of the most sensitive issues in the global society. With the rapid development and commercialization of GM crops, there is a need for stakeholders such as regulatory scientists, administrators and decision makers, particularly in ASEAN, to understand the scientific issues relating to the use of GMO.

The ASEAN Foundation was established primarily to contribute in the elevation or acceleration of functional cooperation, an area that has always been an important part of the mission of ASEAN. The Framework for Elevating Functional Cooperation adopted at the 29th ASEAN Ministerial Meeting in Jakarta on 20 July, 1996 cites the theme for functional cooperation to be a shared prosperity through human development, technological competitiveness, and social cohesiveness.

The ASEAN Foundation has a unique, fundamental mission as stated in the Memorandum of Understanding on the Establishment of the ASEAN Foundation. The Foundation has been mandated to promote greater awareness of the ASEAN culture and greater interaction among the ASEAN people. It also aims to increase participation in ASEAN activities and enhance development cooperative projects aimed at alleviating poverty and improving the socio-economic status of the people.

Furthermore, we all acknowledge the critical importance of the development of the region's human resource. The ASEAN Foundationis, therefore, mandated to implement human resources development programs to promote the growth of a productive and technologically competent ASEAN regional workforce which is very vital to the progress of ASEAN.

In view of the precedent, the ASEAN Foundation supports this undertaking whole-heartedly.

During these three days, you are to actively participate in this training workshop aimed at addressing the directive of the ASEAN Ministers of Agriculture and Forestry for manpower training and capacity building, particularly, for key regulatory scientists, administrators and decision makers from the ASEAN member countries. It is expected that all of you will be able to share your new acquired knowledge and experience with your colleagues when you return to your respective countries.

This workshop will, no doubt, bring you the opportunities to learn the latest scientific developments related to safety assessment of GM plant foods. Personally, as a former molecular biologist, I myself feel the benefit of having such knowledge and experience.

This workshop is not only to support the development of human resources, but also to further enhance the cooperation and solidarity among people in the ASEAN region. I hope that you will return to your country not only with new knowledge and experience, but also with new friends and co-workers in the field of GMO.

The ASEAN Foundation acknowledges with much gratitude the generous help that the Government of Japan has given to the Foundation in the form of the ASEAN-Japan Solidarity Fund. This cooperation, which has been with us for the last three and a half years, has borne us concrete and beneficial results. Participation of ASEAN delegates to this course has been made possible through financial support from this Fund.

I am truly glad to share with you another accomplishment in the life of the ASEAN Foundation, a life of helping the people of ASEAN to make our region more progressive, more developed and more prosperous.

With this, I wish each and every one of you attending the 3rd ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture-Related GMO's much success, and a wonderful stay in this beautiful city of smiles and angels - Bangkok.

Thank you.

OPENING ADDRESS

Dr Ampon Kittiampon
Director, Bureau of Agricultural Commodity and Food Standards
Thailand

Dr Umaly, ASEAN Secretariat representative, Mrs Yeong, Distinguished ASEAN participants, facilitators, speakers, ladies and gentlemen,

I am very honored that Thailand is chosen as the host for the 3rd ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture-Related Genetically Modified Organisms. On behalf of the National Bureau of Agricultural Commodity and Food Standards, which is the co-organizer of this meeting, I would like to extend my warmest wishes and welcome to Dr Ruben Umaly, ASEAN representatives, ILSI organizers and all the participants.

As we know the background of this training workshop was that at the 21st Meeting of the ASEAN Ministers of Agriculture and Forestry (AMAF) in 1999, the ASEAN Ministers endorsed the ASEAN Guidelines on Risk Assessment of Agriculture-Related Genetically Modified Organisms (GMOs). This means that the AMAF was aware of the significance of biotechnology in increasing the productivity of agriculture and recognized the important impact of GMOs on our future development, especially the safety of the consumers. Hence, a better common understanding of GMOs among the ASEAN member countries are crucial and there are needs to further study the approach to undertake the scientific evaluation of applications for the release of agriculture-related GMOs in their countries. As a result, a series of training workshops was approved to be held in 4 ASEAN countries, beginning with Singapore in 2001, followed by Malaysia in 2002, Thailand at the present time and Indonesia in 2004. For this reason, participants from various related fields, both from the public and private sectors are invited right here to perceive and share the development of GMOs as well as to pool our experiences and ideas for more effective biosafety evaluation and risk assessment. To enhance the completeness of the workshop, a case study on Insect Resistant Corn (MON810) will be used to highlight the risk assessment process. Thailand will also share a case study on Papaya GMOs, and the program will also include a poster display session and field visit.

It is my sincere hope that the discussions among the researchers and experts from various disciplines will lead to the significant results and practice of risk assessment. In the mean time, the training for trainers, as one of the capacity building purposes of this workshop, will produce more ASEAN resource persons to further continue ASEAN's

Program for Public Awareness on GMOs. I also believe that our common ultimate goal is that the 4th series of the workshop brings the suitable guidelines on biosafety for protecting consumers and the environment. Additionally, it will serve as the basis for formulating measures, laws, regulations, and mutual understanding between the countries to facilitate better trade practices.

Finally, I would like to thank the International Life Sciences Institute Southeast Asia Region for co-organizing this workshop in Thailand. I would like also to convey my deep thanks to Health Canada and Food Standards Australia New Zealand, and the Department of Agriculture and BIOTEC of Thailand for their efforts and support in making this workshop possible. And to the most important supporters for this workshop, in terms of organization, as well as fund allocation, I wish to express my deep gratitude - the ASEAN Secretariat, ASEAN Foundation and ASEAN-Japan Solidarity Fund.

Ladies and gentlemen, may I take this opportunity to wish all of you a successful and fruitful workshop, an enjoyable welcome river cruise dinner on the 14th night, and a pleasant stay in Bangkok.

Thank you.

INTRODUCTION

Mrs Yeong Boon Yee
Executive Director, ILSI Southeast Asia Region

Dr Ampon Kittiampon, Secretary General, Bureau of Agricultural Commodity and Food Standards, Thailand

Dr Ruben Umaly, Executive Director, ASEAN Foundation

On behalf of the organizers, the Bureau of Agriculture Commodity and Food Standards, Ministry of Agriculture, Thailand, and the International Life Sciences Institute, under the auspices of ASEAN SOM-AMAF, we extend a very warm welcome to you, distinguished speakers, ASEAN delegates, colleagues and guests to this 3rd ASEAN Training Workshop on the Safety and Risk Assessment of Agriculture-Related GMOs in Bangkok, Thailand.

This 3rd ASEAN-ILSI workshop follows the previous two, held 2001 in Singapore and 2002 in Malaysia respectively, where some of you may have attended. The two previous workshops completed successfully with a thorough review of the safety assessment of Glyphosate Tolerant Soybean GTS 40-3-2 as a case study. This workshop will embark on a new case study on Insect Resistant Corn MON 810.

We would like to acknowledge the continuing support and collaboration provided by Health Canada and Food Standards Australia New Zealand (FSANZ) to facilitate this capacity building workshop series. We are also grateful for the participation of our guest speaker from Japan to share an update on their regulatory development, and the facilitation assistance from Biotec Thailand for the workshop series.

Headquartered in the USA, ILSI is a non-profit scientific organization with branches throughout the world. Its mission is to improve food safety and nutrition for the well-being of the general public. 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 standard setting. It assists with the scientific exchanges 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 the information are readily accessible to those that have the expertise and experience to transform them into

easily understandable information to the non-specialists and the public.

ILSI has, for over the last twelve years, brought a balanced approach to facilitate activities related to the safety assessment of biotechnology-derived plants and foods. Since 1998, on an international level, ILSI has helped facilitate scientific meetings on the safety assessment of GM foods in more than 20 countries in Asia, Australia, Europe, Latin and N America and the Middle East, and published a substantial number of reports and proceedings for use as reference. These meetings address issues such as understanding the concept of risk assessment, substantial equivalence, method development for the detection of GMOs in the food chain, labeling guidelines, assessment of allergenic or toxic effects, and how the scientific information is used to make decisions about safety.

More recently, ILSI facilitated workshops on nutrition and biotechnology, bringing experts together to identify nutrition issues that may be addressed through a better understanding of and utilization of gene technology.

We are pleased to have this opportunity to work with our ASEAN colleagues and the ACFS, Ministry of Agriculture, Thailand and to collaborate with other regional and international scientific organizations in our scientific and education endeavors to build capacity for the regional countries.

We hope this seminar and workshop, will provide you with the relevant information and practical tools to further 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 like to thank the organizing committee of Thailand and the ASEAN Secretariat for working closely with us to ensure the success of this meeting series. We appreciate the assistance of the local organizer in coordinating the field visit to Kasetsart University's Central Laboratory Greenhouse Complex to observe the transgenic papaya research and field trial. Finally, we acknowledge the generous support of the ASEAN Foundation through the Japan-ASEAN Solidarity Fund that made possible the participation of several representatives from each of the ASEAN countries to attend this workshop.

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

Thank you.

WORKSHOP OVERVIEW - FRAMEWORK AND OBJECTIVES

Dr William Yan, Health Canada, Canada

The purpose of the workshop is to share the latest information on guidelines, regulations and experience in GM food safety assessment by regulatory agencies from Australia, Canada and Japan, as well as updated international safety assessment procedures for GM foods by Codex, FAO/WHO and OECD. Moreover, current information on the biosafety policy options within ASEAN will be presented to give an overview and share other challenging issues in the development of biosafety legislations, guidelines and human resource development in the region. The development of a GM viral resistant papaya in Thailand will be shared.

The focus of the workshop will be the hands-on experience in food safety assessment of a genetically modified, insect-resistant corn variety (MON 810). It will also incorporate an overview of the environmental safety assessment considerations for GM plants.

The purpose of the hands-on exercise is to guide the participants on how to critically analyze scientific data and how to use this data to evaluate the safety of GM food plant based on the concept of "substantial equivalence." The participants will be divided into groups and they are to discuss the scientific information presented and draw conclusions on the safety aspect of the GM corn case study.

The participants are encouraged to consider the key factors in the safety assessment, as each individual country would have its own dietary exposure and environmental issues.

PLENARY SESSION - PRESENTATIONS

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

Dr Paul Brent, Food Standards Australia New Zealand, Australia

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The safety of conventional food is based on the history of safe human consumption. An explicitly cautious approach is applied for novel foods without an established history of safe human consumption, such as foods produced using gene technology. Novel foods including genetically modified (GM) foods must undergo a mandatory pre-market safety assessment in Australia and New Zealand.

Food Standards Australia New Zealand (FSANZ) is the bi-national organization responsible for developing food regulatory measures for Australia and New Zealand, in accordance with the Food Standards Australia New Zealand Act (FSANZ Act) 1991, with the objective of ensuring a high standard of public health protection throughout Australia and New Zealand. The pre-market assessment and approval process aims to ensure that food derived from biotechnology is as safe as conventionally produced foods, based on internationally recognized risk-based approaches and the best scientific information. Thus far, no evidence has been found of safety concerns that are not shared by their conventional counterparts with a long history of safe human consumption. Todate, FSANZ has completed and released full safety assessments on 22 GM foods for public comment. Of these, 21 have been approved for sale in Australia and New Zealand by the Ministerial Council.

FSANZ requires labels for GM foods that have been significantly changed with respect to composition or end use. Currently, labeling is required where novel DNA and/or protein is present in the final food or when foods have altered characteristics compared to their conventional counterparts. Under the labeling division of the Standard, an ingredient is allowed to contain up to 1% of unintended presence of GM product without requiring labeling.

Canadian Regulation of Novel Foods

Mr Brian Harrison, Health Canada, Canada

The Novel Food Regulations under the Canadian Food and Drugs Act require a pre-market notification in Canada for all novel foods, including food developed using biotechnology. Petitioners are required to notify Health Canada prior to the sale or advertisement of a novel food. This permits Health Canada to conduct a thorough safety assessment to determine whether the food is safe for consumption in Canada, and can be marketed for sale.

The definition of a novel food is categorized into three components: foods without a safe history of use, foods that have been developed using a novel process and genetically modified foods. The Canadian Novel Foods Regulation requires manufacturers of novel foods to notify Health Canada before market release of the product. Health Canada is required to respond within 45 days of receipt of the notification should the product be considered unacceptable for sale. If the novel foods have been established as safe for consumption, the manufacturer or importer will be notified in writing and foods may enter the market place in the same manner as traditional food products and remain subject to the same post-market standards applicable to all foods in Canada.

The specific criteria for the safety assessment of novel foods are outlined in the Health Canada publication, Guidelines for the Safety Assessment of Novel Foods. The safety assessment involves determining how the food was developed; how its composition and nutritional quality compares to non-modified counterpart foods; and what potential the food has for being toxic or causing allergic reactions. Health Canada's safety assessment process is based upon principles developed through international expert consultations carried out by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations, and the Organization for Economic Cooperation and Development (OECD).

Labeling would be required for novel foods where safety concerns are identified, such as allergenicity and compositional or nutritional changes. In this situation, special labelling would be used to alert consumers or susceptible groups in the population.

Biosafety Policy Options and Capacity Building Related to GMOs in the Food Processing Industry of ASEAN

Dr Sakarindr Bhumiratana, National Center for Genetic Engineering and Biotechnology, Thailand

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The ten member countries of ASEAN can be divided into two groups based on their GM and biosafety policy options.

The first group comprises those that have yet to develop a policy on GMOs. This group includes Cambodia, Lao PDR, Myanmar, Brunei Darussalam and Vietnam. Among these countries, Lao PDR is setting up the National Biosafety Framework and the government has designated the Science, Technology and Environment Agency as the national focal point. Brunei is establishing the National Authority on Genetic Modification (NAGM) to oversee the regulatory control of GMOs. Vietnam has formed a working group and drafted the Biosafety Bill, which is being approved by the Ministry of Science, Technology and Environment. As for Cambodia, the Cambodian Import and Export Inspection and Fraud Repression Department of the Ministry of Commerce is of the view that, as long as the safety of GM food has been substantiated by scientific evidence, Cambodia sees no need to develop a restriction policy on GMOs. In Myanmar, due to limitations on the infrastructure and regulatory framework, the government has yet to take up the issue.

The second group comprises countries that exercise regulation over GMOs, either through their existing systems or new regulations. Several of these countries, including Indonesia, Malaysia, Philippines and Thailand, are expected to have their Biosafety Legislation enforced soon. The Philippines published its Biosafety Guidelines in 1991, which covers laboratory approval and environmental release.

In Singapore, the control of GMOs imported into the country and the commercial release of GMOs for culture and cultivation or for agriculture production are through the existing Acts administered by the Agri-Food and Veterinary Authority of Singapore (AVA), formerly known as the Primary Production Department. Once approval is granted, the product (GMO) will be registered with the Genetically Modified Advisory Committee (GMAC). As for commercial and academic research, the project managers are required to seek clearance from GMAC before any research is done using GMOs and vectors not in the positive list.

Malaysia and Indonesia have drafted national guidelines for the release of GMOs into the environment. Indonesia is the only country to have the legal provisions on biosafety

of genetically engineered agricultural biotechnology products released under the Ministerial Decree No. 85/kpts/HK330/9/1997.

As for policy options, there are five policy areas in which the governments of developing countries can either support or discourage GM crops: intellectual property rights, biosafety, trade, food safety, and public research and investment.

ASEAN members are at different embryonic stages of development with regards to biosafety. The countries, Brunei, Cambodia, Lao PDR and Myanmar that have not yet initiated any policy on biosafety should give highest priority to establish such policies. As for Malaysia, Philippines, Singapore, Thailand and Vietnam, the adoption of biosafety protocol into law should be set as the first priority and then a clear-cut plan of implementation should also be established. The policy on the national biosafety legal framework is vitally important and, most if not all ASEAN members do not have laws or lack legal mechanisms to support the protocol. ASEAN needs to focus on capacity building to fully implement the biosafety policy. As a strategy for consumer protection, it must develop the capacity to conduct risk assessment, risk management and field trials. Many ASEAN countries also do not have the capacity to develop biosafety clearing house mechanisms. ASEAN should quickly develop coordination among governments on biosafety, the capacity for data management and information sharing and strengthen the research network system. ASEAN should thus work together and develop expertise to strengthen capacity in the following areas:

- policy and decision making process
- develop a legal framework for biosafety
- develop a framework for industrial production and usage of GMOs
- provide training in and implementation of risk assessment
- data management and information sharing
- technology upgrade and preparedness to implement a biosafety regulatory framework
- develop biosafety clearing house mechanisms to facilitate cooperation among ASEAN member countries

Regulating Genetically Modified Foods and Food Additives in Japan

Dr Hiroshi Kamada, Tsukuba University, Japan

The Ministry of Health and Welfare (MHW) first established the guidelines for the safety assessment of GM food additives in 1996. However, the mandatory requirement for the safety assessment of GM foods and food additives was not enforced until 2001, under the Food Sanitation Law. The Subcommittee on Biotechnology, set up under the Ministry of Health, Labour and Welfare (MHLW) is responsible for establishing concepts and procedures for the safety assessment of GM foods and food additives. In the actual assessment, a working group of the Subcommittee review and evaluate the scientific safety data submitted by companies. However, the approval for market release is still under the jurisdiction of MHLW. The principle of safety assessment in Japan is based on the internationally accepted concept of "substantial equivalence." The general scientific information required for the safety evaluation of GM foods are as follows:

- newly obtained characteristics by genetic modification
- allergenicity of the gene products
- toxicity of the gene products
- effects on metabolic pathway of the gene product
- differences between host and the GM organism
- living and proliferating ability of the GM organism in the field
- inactivating method of GM organism
- permission and consumption information in various countries of the GM organism
- methods for production, breeding and cultivation of the GM organism
- seed production and storage methods

Future challenges of GM food safety assessment include:

1. The consideration for the safety of stack strain produced by cross-pollination between GM and non GM
2. Developing a new concept on the safety assessment of GM foods that cannot be judged by "substantial equivalence"
3. Assessment of the safety of newly developed GMOs and cell fusion products over a family
4. Risk communication

The Food Safety Commission, established in 2003, under the new Food Safety Basic Law is responsible for the risk assessment of foods, including GM foods and food additives. For the approved GM foods (except for GM food additives), labeling on GM products in the market is mandatory (MHLW and MAFF) if the proportion is over 5% (in each event) in the product.

Environmental Safety Assessment of Plants with Novel Traits

Mr Brian Harrison, Health Canada, Canada

The Canadian Food Inspection Agency (CFIA) is responsible for the regulation of plants with novel traits (PNTs) in Canada in regards to environmental safety. The trigger for regulatory oversight is the novelty of the product rather than the methods used in its production. PNTs may be produced by recombinant DNA technology, mutagenesis or traditional breeding. A PNT is defined as a plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated species of seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change.

Environmental release in Canada of PNTs requires authorization. Authorizations are issued, with or without conditions, only after an environmental risk assessment has been conducted by the CFIA, under the Seeds Act. Environmental release applications are considered for releases under either confined conditions, as in research field trials, or on an unconfined, unrestricted basis.

The use of confined field trials is intended to give developers the opportunity to evaluate PNTs under controlled conditions. Confined field trials are designed in a manner to mitigate any potential environmental impact of PNTs and to prevent their introduction into feed and food systems until full assessments have been completed.

When a developer wishes to release into the environment a PNT under unconfined conditions, i.e. towards marketing the PNT, information required to undertake a full environmental safety assessment must be provided to the CFIA. Detailed information about the novel trait, the method used to introduce the novel trait into the plant and any risk of adverse environmental effects resulting from the release of the plant into the environment, must be provided. Potential adverse effects could include the plant becoming a weed of agriculture or invasive of natural habitats; novel traits passing to wild relatives through gene flow; the plant or its gene products adversely effecting non-target organisms (including humans); and the plant's impact on biodiversity.

Currently, the Canadian government requirements for PNT's commercial release are assessments for the environment, food / feed safety, and variety registration. In addition, detection methods and identification techniques for each PNT must be made available to the CFIA.

The future challenges for environmental assessment are the possibility of environmental problems stemmed from agronomics, same / different herbicide tolerance traits in different / same species, and the complex interactions of PNTs with other species for forest trees.

Concepts and Principles of Food Safety Assessment of Agriculture-Related GMOs: International Perspective

Dr Paul Brent, Food Standards Australia New Zealand, Australia

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Various international organizations, particularly the OECD countries and the United Nations FAO/WHO expert consultations, have harmonized on the agreed approaches to evaluate the safety of genetically modified (GM) food. The Codex Alimentarius Commission (Codex), recognized as the body for setting international food standards, has developed the guidelines for the safety assessment of foods derived from GM plants and GM microorganisms. The approach used in most countries to assess the safety of foods produced by genetic modification draws on concepts and principles developed by Codex. The key principles of safety assessment are:

- scientific and risk based methods
- assessment conducted on a case-by-case basis
- considerations of both intended and unintended effects of genetic modification
- comparison made to conventionally produced foods

The safety assessment of GM foods includes evaluation of:

- host and donor organisms
- nature of genetic modification
- toxicological and allergenicity issues
- nutritional issues

Other issues, where the impact on human health from potential transfer of novel genetic material (including antibiotic resistance genes) to cells, including microorganisms, in the human digestive tract is also considered. Consensus documents that provide guidance on critical parameters of food safety and nutrition for each GM food crop have been developed by OECD.

The concepts and principles developed by OECD, FAO/WHO and Codex have been pratically applied by countries assessing the safety of GMOs and food derived from biotechnology. It is likely that in the future, genetic modification will be more complicated. The challenges for regulation of GM food require new criteria for assessing other foods, including GM animals and nutritionally enriched or therapeutic GM crops. Initiatives to identify and address such future needs have began, including the safety considerations of novel foods and feeds that are not derived through genetic modification.

Thai Transgenic PRSV- Resistant Papaya

Dr Suchirat Sakuanrungsirikul, Department of Agriculture, Thailand

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The regulatory agencies for transgenic products in Thailand involve the Ministry of Agriculture and Cooperatives (MOAC), National Biosafety Committee (NBC) and the Food and Drug Administration (FDA).

Papaya (Carica papaya L.) is one of the major stable food crops in the rural communities of Thailand. However, the yield for papaya production has drastically decreased, particularly in the Northeastern part of Thailand due to the "Papaya Ring Spot Virus". The infection area by the virus increases every year limiting the cultivation of the papaya. As a strategy to control PRSV, the Department of Agriculture and Cornell University jointly developed the transgenic PRSV-resistant papaya using three different plant cell lines. Excellent lines have now been carried through three generations and one excellent line of Khak Nuan (R3-181-KN) and Khak Dam (R2-300 KD) has been identified.

An environmental assessment was conducted using the established guidelines of Thailand's National Biosafety Committee (NBC). The studies focused on the possible effects the transgenic papaya has on its ecological context such as microflora of the soil, beneficial insects, and the natural glow of transgenic CP genes to non-modified papaya and other related plant species.

The food safety assessment of the transgenic papaya is currently being studied based on the guidelines established by NBC. In consideration, descriptive information on the introduced genetic material and its expression product and acceptable levels of inherent plant crop, plant toxicants and nutrients must be submitted for the evaluation of "substantial equivalence."

One of the novel GM products recently approved in Canada is the viral resistance papaya that has also been already approved in the US. However, in the US GM papaya, the viral protein is being expressed in the GM plant. As Canada does not grow plants such as papaya due to the cold climate, approval of GM papaya does not require environmental safety data.

BREAKOUT SESSIONS - CASE STUDY

Risk Assessment of Genetically Modified Corn with Insect-Resistant Trait

The approval for the food use of insect resistant (protected) corn line MON 810 was given by Health Canada in 1997 and by FSANZ in 2000. The decisions were made by both regulatory authorities following a comprehensive assessment of MON 810 based upon internationally accepted principles for establishing the safety of food derived from genetically modified plants. The data and information used in the case study have been summarized for training purpose from parts of the food safety submission that was assessed by FSANZ and Health Canada, and should not be considered a complete safety assessment.

The breakout sessions provided unique opportunities for workshop participants to discuss and share views on the safety data of the genetically modified insect resistant corn (MON 810) as provided in the case study.

The participants were designated into four working groups of 12 each, with mixed representation from different academic areas. The topics addressed by the working groups included evaluation data on: the host organism, donor organism, transformation system, molecular characterization of the inserted DNA, genetic stability of the introduced trait, expressed material / effect, toxicity, allergenicity, and nutrition. Each group reviewed the information and data provided and was guided by the facilitators, who introduced the topics and raised important issues to stimulate discussions. At the end of the session, each group reported on their critical evaluation and conclusions.

Development and Production of GM Insect Resistant Corn Line MON 810

The Host Organism

The history of the host organism can provide information that is important to the assessment of a GM food. A thorough knowledge of the host plant, processing and properties of the final food products is important in order to establish appropriate data for comparison with the GM food. Any endogenous traits that may adversely impact human health must be described (e.g. production of allergens or toxins).

Corn is grown on every habitable continent since its original cultivation over 8000 years ago in Mexico and Central America. It is consumed as a staple food and used widely in many different food products.

Participants generally agreed that corn is a safe diet staple and that food derived from this crop has a long history of safe food use. Although there are no endogenous toxins associated with corn, the participants requested more information on potential allergens.

The Donor Organism: Bacillus thuringiensis and its history

Information about the donor organism(s) is required to determine if it exhibits characteristics of pathogenicity or toxin production, or have other traits that affect human health.

The cryIA(b) gene inserted into MON 810 originates from a Bacillus thuringiensis var. kurstaki., Bacillus thuringiensis has been used in commercially registered microbial pesticide formulations for over 40 years and is ubiquitous in many soils throughout the world. From data submitted, B.t. toxicity has been found to be insect specific based on information presented on the molecular toxicity mechanism of the delta endotoxin crystal.

Concerns were raised on the closeness of Bacillus thuringiensis var. kurstaki (or Bt)'s to other pathogenic cereus and B. anthrax. More information on the toxicity and allergenicity of the Cry IA(b) protein (addressed later in the case study) and the possible pathogenicity of Bacillus thuringiensis var. kurstaki is needed. In the genetic modification chapter of the case study, it is shown that only limited and well-characterized DNA fragments are used to construct the plasmid vector.

The New Corn Variety MON 810

Information on the characteristic of corn variety MON 810 was described. Its intended uses are for an animal feed, but possible use as human food is expected. The company also details information on the corn line development and the back-crossing process.

Concerns raised by the groups were that the step-by-step description of the back-crossing process were ambiguous and unclear. A question was raised on the intended use of line MON 810 as the parental line or hybrid line.

Genetic Modification

It is important to have a detailed understanding of the methods that introduce novel traits into the host plant because it determines, in part, the information requirements for the assessment of the molecular biology of the plant. A commercial corn line was transformed by particle acceleration or biolistic transformation. Information describing the genetic elements (source, identity and expected function) that make up the two plasmid vectors used in the transformation process was reviewed by participants. Together, these plasmids contain the cry1Ab, epsps, gox, and nptII genes, the regulatory components necessary for the expression of these genes, and origins of replication. A consideration of all genetic material that could be potentially delivered to the corn plant is critical to the evaluation of molecular biological data generated for the modified plant.

Transformed plant cells were selected for glyphosate tolerance and regenerated to whole plants.

During the discussions, participants raised strong points about the lack of detailed description of the selection process. The facilitators explained that the glyphosate tolerance trait used for selecting purposes was originally present at a different locus in the transformed plant but it was segregated out during back-crossing.

Characterization of the Genetic Modification

In order to provide clear understanding of the impact on the composition and safety of foods derived from genetically modified organisms, a comprehensive molecular and biochemical characterization of the organism is carried out. The information and data to be provided includes: a detailed characterization of all inserted DNA; the number of insertion sites; the gene product and its function; and the level and site of expression.

Workshop participants evaluated the molecular characterization data generated by the

developer. This data demonstrated that MON 810 contains one integrated DNA segment found on a 5.5 kb NdeI fragment. Further analysis determined that this one insert contains the E35S promoter, maize hsp70 intron and the cry1Ab gene. The epsps, gox, and nptII selectable markers were not detected in the MON 810. The stability of this insertion was demonstrated through seven generations of crossing.

A number of issues were discussed relating to the quality of some of the blots. These were mainly due to photocopying of the case study material but it was pointed out that the data presented by developers must be of the quality expected when submitting to a peer review scientific journal. Each lane on the blots must be labeled. The blots must have appropriate positive and negative control lanes, and the position of molecular size standards must be clearly labeled. The participants also discussed a few discrepancies in the molecular size of bands observed on two blots. A petitioner should address these types of discrepancies. In this case, they were within the expected deviation range in resolution of the applied technique.

Modified Plant Expression

This section of the case study dealt with the assessment of information related to the expression of new substances in the modified organism. The expression of the cry1Ab gene was detected at very low levels in various corn tissues derived from MON 810. This is to be expected since this gene is regulated by the E35S promoter that is constitutively expressed and is not tissue specific. Therefore the Cry1Ab protein is expected to be present in all plant tissues during the life of the plant. Although the gox and epsps genes were not detected in MON 810, the developer also tested for the presence of these gene products in MON 810. As expected, the EPSPS and GOX proteins were not detected.

The discussion groups generally agreed with the data provided. However, more data were requested on the following:

- accumulative trend of Bt toxin in the grain
- better quality gel pictures
- more details on the segregation experiments to determine gene stability
- more information on the residual peptides on trypsin digested protein cleavage

PRODUCT INFORMATION

Toxicity

Toxicological assessment is required for new substances expressed in a GM organism. Since the Cry1Ab protein is the only new protein expressed in MON 810, this protein was the focus of the toxicological assessment. Data was evaluated from acute oral toxicity studies, digestibility studies, and amino acid sequence comparisons to known protein toxins.

In general, the participants agreed that Cry IA (b) protein is not toxic to humans because:

- the trypsin resistant core of the Cry1Ab protein was shown to rapidly degrade in simulated digestive fluids
- an acute mouse toxicology study demonstrated that the Cry1Ab protein is not toxic to animals
- the Cry1Ab protein expressed in MON 810 has no homology to known protein toxins except for other Bt proteins.

It was agreed that further information is needed to clarify some of the concerns:

- more data on toxicity using primate as the animal model
- more details on how the simulated digestion fluid was conducted
- nature of antibody used in detection of degraded proteins
- more references be cited on protocol used
- concerns on proper experimental designs particularly in acute gavage toxicity
- rational using tobacco budworm as target pest not European Corn Borer

Allergenicity

The potential allergenicity of newly introduced proteins in a GM food is an important consideration of the food safety assessment. Since there is no direct method to test whether a protein is an allergen, a weight of evidence approach is used. Participants reviewed data presented by the developer to determine if the Cry1Ab protein had a potential to be a food allergen. Based on this review, participants concluded that:

- the Cry1Ab protein has no amino acid homology with known allergens
- the protein degrades rapidly in simulated digestive fluids
- Cry1Ab has a history of safe exposure based on the use of Bt in microbial pesticides for over 40 years

The participants agreed with the data provided that there is no scientific evidence for Cry IA (b) to be an allergen. However, concerns were raised over the development of an animal testing model in this area.

Nutrition

Compositional and nutrition data enabled participants to determine the potential unintended effects arising from the insertion of DNA sequences into the plant genome. An important step in the safety and nutritional assessment of the modified food is a comparison of its composition with its appropriate counterpart. To determine whether there are any significant differences, the major constituents of the food must be analysed, that is, macronutrients and their component parts, as well as individual micronutrients and other bioactive substances.

After reviewing the data presented in this section, the participants generally agreed that the nutritional components of corn MON 810 are no different to their conventional counterpart. Compositional data for protein, fat, ash, carbohydrates, calories, moisture, amino acids, fatty acids, anti-nutritional factors, and natural toxins were comparable to data for control corn lines and within published ranges for commercial corn varieties.

However, the participants requested further information on:

- complete statistical analysis to determine similarity or difference
- antinutrients in corn

DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

The insect-protected corn line MON 810 was evaluated by workshop participants based upon internationally accepted principles used in the safety assessment of GM foods. The assessment process involved an extensive analysis of the nature of the genetic modification together with a consideration of general safety issues, toxicological issues and nutritional issues associated with the new GM food. This approach established whether or not a food produced from GM corn is as safe and nutritious as food produced from non-GM varieties.

The detailed information available on the genetic modification used to produce MON 810 indicated that no unintentional changes have taken place at the molecular level and that the novel genetic material is stably inserted and maintained over several generations.

Data on the potential toxicity and allergenicity of the protein encoded by the transferred gene were reviewed, and indicated that the new protein expressed in insect-protected corn is non-toxic and unlikely to have allergenic effects.

Compositional analysis demonstrated no significant differences between insect-protected corn and its conventional counterparts. This constituted further evidence that no unintentional effects have occurred as a result of the genetic modification.

Based on the totality of the data presented, the participants were able to conclude that food derived from MON 810 is as safe as food from other traditional commercial corn varieties.

A number of the deficiencies raised by the group would normally be addressed in a full submission. Much of the information presented in this case study has been reduced to summaries and the data presented is only a subset of the data actually submitted to regulatory authorities. Additional information and clarification would be requested from applicants should a submission be incomplete or have inadequate data.

QUESTIONS & ANSWERS DISCUSSION

A selection of the questions fielded during the presentations to the facilitators are highlighted below for reference purposes:

Question: *How can FSANZ reduce the regulatory barriers further with the new system?*
Answer: FSANZ has just recently completed the review of the food standard codes by making it less descriptive so that the application can be broader. This would open more opportunities for international trade. Furthermore, FSANZ also opened more channels of communication and consultation with the industry and have the industry associations involved in the standard setting process to reduce the regulation burden as much as possible.

Question: *What is the definition of "Zero Tolerance"?*
Answer: Australia has a "Zero Tolerance" policy on unapproved GM seeds coming into the country whether it is unintended contaminant or intended importation. This means all GM seeds or food products must not contain any GM material not approved for consumption.

Question: *How do you detect GM seed or material?*
Answer: FSANZ does not work on GMO detection, but we will advise the relevant agencies involved such as AQIS (Australian Quarantine Inspection Service) to handle this aspect.

Question: *At what stage is the present mechanism of resistance where no viral protein is expressed in the GM-plant?*
Answer: There have been reports that the inhibition of viral production is mRNA-mediated, which has been shown to be more effective than protein-level mediation.

Question: *How much public consultation is involved and how much information is provided to the public?*
Answer: Currently, the public is not involved in the decision-making process. This is because it involves technical evaluation, while most of the questions from the public are social and non-scientific issues. Both Australia / New Zealand and Canada plan to set up a separate forum to gather public opinion.

Question: *Is the submission for safety assessment free of charge?*
Answer: Australia is now charging a fee for all the submission for approval. Canada currently has no cost recovery for food safety assessment.

Question: *How can a company be expected to know exactly what type of safety data is required for submission to the regulators?*
Answer: Companies usually learn by experience (trial / error). Currently, Canada does not have workshops to educate companies. FSANZ has also received feedback from companies that there are no clear criteria as to what information is needed.

Question: *How do you handle criticisms on conflicting interest of the regulators when they to try to assist with the approval of a product?*
Answer: Regulators are government employees so they must perform their job in the ethical manner to review the data, ensure that the data is correct and that the product is safe for commercial release as food.

Question: *This is more an environmental question. Has there been new developments on insect pest species due to the release of GM corn MON 810?*
Answer: There are no scientific reports on new species of insect pests developed, or if a new pest has developed due to the release of the corn MON 810.

Question: *Do you expect the Thai GM papaya to benefit the small stakeholders and rural villagers?*
Answer: An MOU was signed between Cornell University and Ministry of Agriculture allowing the release the GM papaya to the villagers following the completion of all safety assessment procedures. If commercialization is to be considered, a royalty fee will be charged.

APPENDICES

RESOURCE INFORMATION

A guide to a list of international documents and scientific publications on plant biotechnology and the safety assessment of food products derived from plant biotechnology (including general food safety, protein safety, allergy assessment, and substantial equivalence) is available at http://www.ilsi.org/misc/biotech/frontmaster.pdf. This guide is updated on a regular basis.

Safety Assessment of Genetically Modified Corn

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As a special initiative of ASEAN Leaders, the main objectives of the **ASEAN Foundation**, established in 1997, are to generate greater awareness of ASEAN, and promote greater interaction and participation by member countries in ASEAN activities. Additionally, the ASEAN Foundation carries out human resource development efforts to enable the people of the region to realize their full potential and capacity towards progress as productive and responsible members of society. The Foundation is also directed at the evolution of a development cooperation strategy aimed at providing mutual assistance and equitable economic development, and alleviating poverty. Activities under the Foundation are funded by member countries and through donations from various sources. The government of Japan, through the **ASEAN-Japan Solidarity Fund**, contributes a major portion of these funds to support capacity building projects on science, technology, social development, culture and information within ASEAN.

The **Ministry of Agriculture and Cooperatives, Thailand** is responsible for all agricultural affairs including economics, irrigation, fisheries, livestock, forestry, land development and cooperatives. It consists of 13 departments and offices, and 7 state enterprises. The **National Bureau of Agricultural Commodity and Food Standards (ACFS)**, established in 2002, serves as the focal point for the Ministry of Agriculture and Cooperatives. The mission of ACFS is to set standards for agricultural commodities, semi-processed and processed foods; monitor food safety; build inspection and certification systems throughout food chains; negotiate and cooperate in the world forum on agricultural and food standards; and develop databases for agricultural and food standards.

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 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 the industry, government, and foundations.

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