

# **BIOSAFETY**

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# **NEWSLETTER**

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**Malaysian  
Biosafety Act 2007**

**NRE-UNDP-GEF  
Biosafety Project**

**Risk Assessment  
Workshop**



**INAUGURAL ISSUE**

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## Message from Dato' Zoal Azha bin Yusof

*Secretary General  
Ministry of Natural Resources and Environment*

The National Policy on Biological Diversity, launched in April 1998, calls for the sustainable utilization of our biological resources among others through biotechnology. The government recognises the role of modern biotechnology for the promotion of human well-being, particularly in meeting needs for food, agriculture and health care. In view of its potential, biotechnology has been identified as a new engine of growth for the nation as reflected in the National Biotechnology Policy and the Ninth (9th) Malaysian Plan.

As Malaysia embarks on its drive to pursue biotechnology as one of the new income sources of the nation, biosafety and the safe transfer, handling and use of Living Modified Organisms (LMOs) has become increasingly important. Being a megabiodiverse country, Malaysia has great concern to ensure that the nation's biological resources are well safeguarded. Biosafety ensures the potential adverse impact of modern biotechnology is minimised and managed in a manner that does not have a negative impact on biodiversity and human health.

Cartagena Protocol on Biosafety was adopted on 29 January 2000. Since its adoption, the Protocol has received remarkable support and steady progress in its implementation. The number of parties to the Protocol continues to grow, and currently stands at 153. Malaysia signed the Protocol on 24 May 2000 and subsequently ratified it on 3 September 2003. Malaysia has consistently been playing an important role in finding consensual solutions in many critical areas of biosafety and has been well recognised by the international community for her efforts.

At the national front, the Biosafety Act has been passed by the Parliament in July 2007 and subsequently the Biosafety Core Team has been formed in April 2008 to pave way for the full implementation of the Protocol through the Biosafety Act.

It has been well recognised that successful implementation of the Protocol is contingent on the development of continuous biosafety capacity building activities in par with the technology which is growing and evolving very rapidly. To keep pace with the developments in the field of biotechnology as well as associated safety concerns, capacity building for various stakeholders in different areas becomes important. Keeping this in view, the Ministry of Natural Resources and Environment has implemented a United Nations Development Programme - Global Environment Facility (UNDP-GEF) project since 2007 for capacity building on biosafety which focuses on institutional strengthening, information dissemination and training.

I am pleased to introduce the first issue of this newsletter which is part of the UNDP-GEF project activities. This newsletter will be published three times a year with the objective of disseminating information to the various stakeholders as well as to report on the project activities. I hope that it will play a significant role as an avenue to share information and raise awareness about biosafety issues and activities.

**Dato' Zoal Azha bin Yusof**



## Message from the Chief Editor Mr. Letchumanan Ramatha

*Head, Biosafety Core Team  
Ministry of Natural Resources and Environment*

The Biosafety Act 2007 (the Act) has been passed by the Malaysian Parliament in July 2007 and many activities have been initiated by the Ministry of Natural Resources and Environment (NRE) to work towards implementation of the Act. However, many are still in the dark about biosafety and the Biosafety Act itself, the status of biosafety around the region as well as its impact to research and the industry. This is clearly seen through the queries and presumptions from various stakeholders that have been expressed through formal letters, verbal communications in meetings and events. The ministry sees the need to disseminate accurate information about the Act and biosafety in general to all stakeholders and public in general.

The Cartagena Protocol on Biosafety (CPB) recognises the crucial role of information sharing, gathering and dissemination for the successful implementation of the Protocol. Article 23 of the CPB on public awareness and participation emphasises the need and importance for parties to engage in the promotion and facilitation of public awareness, education and participation regarding the biosafety of living modified organisms.

Therefore, information sharing through the form of a newsletter will be a useful communication tool to convey accurate information about the Act as well as the CPB, and biosafety in general for the purpose of raising awareness and giving unbiased information to all stakeholders and the public. The newsletter will also be a reliable reference point to get updated information on activities and current issues on biosafety to build confidence, ensure transparency and open communication to relevant stakeholders and public and ensure a smooth transition towards implementation of the Biosafety Act.

I am positive that the Biosafety Newsletter will be able to do exactly the same and serve as an effective communication tool for the ministry.

In this inaugural issue of the newsletter, among others, attention has been given to present the Biosafety Act 2007, the Core Team that was set up by NRE to implement the Act, an insight into the efforts of the government to help build capacity through the NRE-UNDP-GEF Biosafety Project on capacity building, approved events and products in Malaysia and research on genetically modified plants in Malaysia. Readers can look forward for more news on the preparedness of the ministry to enforce the Biosafety Act 2007 in the next issue.

A handwritten signature in black ink, consisting of a large, stylized 'L' followed by several horizontal strokes and a small 'h' at the end.

**Mr Letchumanan Ramatha**

# The Biosafety Core Team

It was indeed a significant landmark event when the Malaysian Biosafety Act was passed in the Parliament on 11 July 2007 and received the Royal Ascent on 29 August 2007. Even though it has been a rugged journey for this Act to be a reality, it is a positive and promising beginning for Malaysia to take a proactive approach towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology as well as fulfill Malaysia's obligation under the Cartagena Protocol on Biosafety.

Under the Act, the Ministry of Natural Resources and Environment (NRE) has been given the mandate to set up a National Biosafety Board (NBB) that will be responsible to regulate the release, importation, exportation and contained use of any living modified organism derived from modern biotechnology and products of such organisms. The Chairman of the NBB is the Secretary General of NRE and the composite membership is represented by six other relevant ministries. The Biosafety Core Team has been formed under NRE to implement the Biosafety Act through the NBB. This team will be the lifeline of biosafety regulatory activities for Malaysia.

The Head of the Core Team also holds the position of Secretary of the NBB. This team will comprise of 25 personnel and is based at NRE. The main components of the Core Team are the Processing and Certification Unit, Evaluation and Research Unit, Policy and Communication Unit and Enforcement and Monitoring Unit. Holding on to the vision "To be an excellent focal point for all biosafety activities towards promoting safe use of modern biotechnology", this team is set to work on the following core business:

- Enforce the Biosafety Act and ensure compliance.
- Monitor activities relating to modern biotechnology.
- Establish mechanism to facilitate the collection, storage and dissemination of data relating to biosafety.
- Secretariat for the NBB and Genetic Modification Advisory Committee (GMAC).

- Provide a platform for consultations on all issues relating to biosafety.
- Increase public awareness on biosafety.
- Coordinate activities on biosafety between federal government and the states, non-governmental organisations (NGOs) and the industry.
- Build cooperation between relevant local agencies and external agencies and organisations.
- Fulfill Malaysia's obligations arising from biosafety related international agreements, conventions and treaties.

The *modus operandi* of this team is interactive, transparent and timely. In order to enable this, a website has been developed specifically for biosafety ([www.biosafety.nre.gov.my](http://www.biosafety.nre.gov.my)) as well as an open communication channel through [biosafety@nre.gov.my](mailto:biosafety@nre.gov.my). Biosafety regulatory activities (which replaces a former voluntary system) and public awareness will become more visible in Malaysia through this team. The team is committed to work towards achieving the qualities of a first class public sector organisation by providing top-notch customer services as a one stop centre in being an operational arm of the Biosafety Act.



Seated (L to R): Letchumanan Ramatha and Mary Tiong.  
Standing (L to R): Emmy Farhany, Poniah, Noor Ridzuan,  
Noor Izwani and Raja Nursyamimi.

# Malaysian Biosafety Act 2007

*".....while Malaysia is aware that biotechnology holds much promise, we are also concerned that biotechnological products should not pose any threat to the environment, or to human health and safety."*

*Rt.Hon.Prime Minister of Malaysia.*

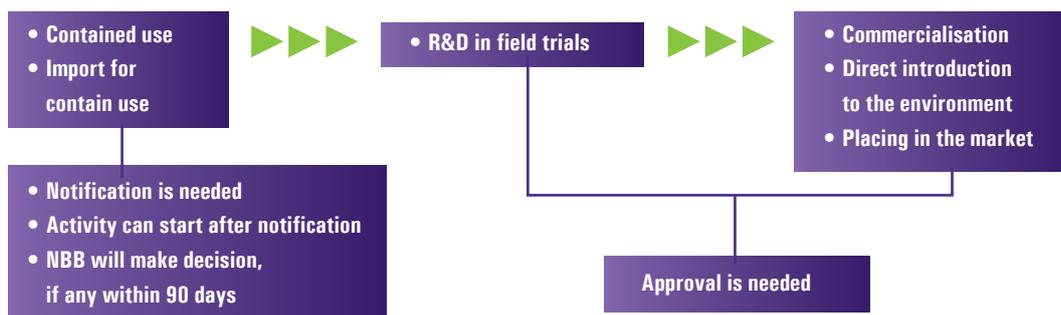
*24 January 2005, Paris*

The Malaysian Biosafety Act 2007 was developed in consultation with all stakeholders, such as representatives from the relevant Ministries and agencies, biotechnology industry, local researchers, Non-Governmental Organisations and also foreign embassies. This Act is drafted to be in line with the National Biodiversity Policy (1998) and the National Biotechnology Policy (2005) and covers only modern biotechnology activities. The objective of the Act is to protect the health and safety of people, animals, plants, the environment and biological diversity by regulating the release, importation and contained use of Living Modified Organisms (LMOs) and/or the release of products of such organisms. The Act is an enabling law where most of the operational issues will be spelt out within the Regulations.

## Main Parts of the Act

- Part I Preliminary**
- Part II National Biosafety Board (NBB)**
- Part III Approval for Release & Import**
- Part IV Notification for Export, Contained Use and Import for Contained use**
- Part V Risk Assessment & Risk Management & Emergency Response Plan**
- Part VI Enforcement**
- Part VII Miscellaneous**

## Biosafety Act - From Bench to Market



## Establishment of National Biosafety Board

A board by the name National Biosafety Board (NBB) is established under the implementation of the Biosafety Act 2007.

### Functions of NBB

- (A) Decide on all applications and matters under Approval for Release and Import (Part III) and Notification for Export, Contained use, and Import for contained use (Part IV).
- (B) Monitor activities relating to living modified organisms and products of such organisms.
- (C) Promote research, development, educational and training activities relating to biosafety.
- (D) Establish mechanisms to facilitate the collection, storage and dissemination of data relating to living modified organisms and products of such organisms and biosafety; and
- (E) Perform or provide for the performance of the obligations arising from agreements,

conventions or treaties relating to biosafety to which Malaysia is a party where such agreements, conventions or treaties relate to the purposes of this Act.

### The NBB consists of the following members who are appointed by the minister:

- Secretary General of the Ministry of Natural Resources and Environment as the Chairman.

### A representative from the

- Ministry of Agriculture & Agro-based Industry,
- Ministry of Health,
- Ministry of Plantation Industries & Commodities,
- Ministry of Domestic Trade & Consumer Affairs,
- Ministry of International Trade & Industry,
- Ministry of Science, Technology & Innovation,

and not more than four other persons who have the knowledge or experience or both in any of the disciplines or matters relevant to this Act.

## The Establishment of Genetic Modification Advisory Committee (GMAC)

The function of GMAC is to provide scientific, technical and other relevant advice to the minister or the NBB. The chairman of GMAC will be appointed by the minister and other advisory members will be appointed by the NBB. Members of GMAC consist of experts from various science-based and other relevant disciplines.

## Approval for Release Activities and Import of Living Modified Organisms

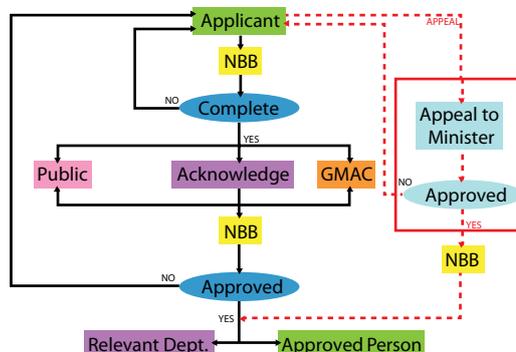
All release and import of LMOs and products of such organisms is prohibited unless approved by the NBB. The release activities as spelt out in the 2nd schedule of the Act are:

1. Research and development purposes in all field experiments.
2. Supply or offer to supply for sale or placing on the market.
3. Offer as gift, prize or free item.
4. Disposal.
5. Remediation purposes.
6. Any other activity which does not amount to contained use.

## The Application Process

1. An application for approval must be completed and submitted to the Director General (DG) in the prescribed manner, together with the prescribed fees, and be accompanied with:
  - a) a risk assessment and a risk management report,
  - b) an emergency response plan, and/or
  - c) other information as may be specified by NBB.
2. Upon receiving the application the DG shall:
  - a) Refer it to GMAC for its recommendations.
  - b) Refer it to relevant government agencies for specific matters.
  - c) Invite public participation for purpose of public disclosure.
3. GMAC shall forward its recommendation whether or not the application should be approved and the terms and conditions to be imposed by NBB, if any, after the assessment.
4. After having considered the recommendations of GMAC, the comments of the relevant department or government agency, the views of members of the public, if any, and any additional

information, particulars or documents furnished pursuant to a request, NBB may grant the application by issuing a certificate of approval or refuse the application.



*"The international community has recognised the potential hazards and risks of genetic engineering. The principle of precaution underpins the Cartagena Protocol on Biosafety as well as its parent convention, the CBD."*

*Rt.Hon.Prime Minister of Malaysia.*

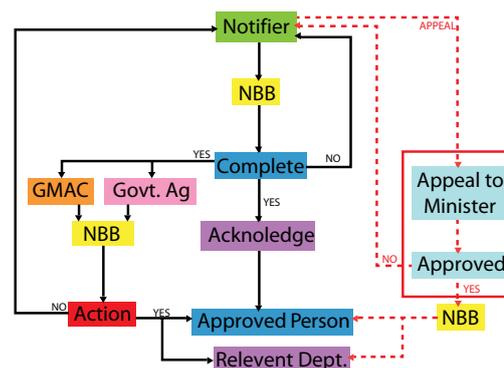
*- 24 January 2005, Paris*

## Notification for Export, Contained Use and Import for Contained Use

1. An application for notification must be completed and submitted to NBB in the prescribed manner, together with the prescribed fees accompanied with:
  - a) an emergency response plan, and
  - b) specific measures for the contained use activity.
2. The DG shall issue an acknowledgement of receipt of a notification submitted. Upon receiving the acknowledgement, the notifier may undertake the activities relating to the notification.
3. The DG shall refer the notification to GMAC and relevant government agencies for their recommendations.
4. GMAC will later forward its recommendation on the notification to NBB.
5. Upon having considered the recommendations of GMAC, NBB may make no order, issue a cessation order, impose such terms and conditions, order the approved person to make rectifications or make any other order as NBB sees fit in the interest of biosafety.

*The Malaysian Biosafety Act 2007 is available at bookshops that sell Law books. It is also available at Percetakan Nasional Malaysia Berhad at RM11.50*

*You can download the Act from [www.nre.gov.my](http://www.nre.gov.my)*



# NRE-UNDP-GEF Biosafety Project

## Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety and the Malaysian Biosafety Act



With increasing emphasis on biotechnology, the Government of Malaysia in 1997 demonstrated its commitment to biosafety by producing a set of voluntary National Guidelines for the release of Genetically Modified Organisms (GMOs) into the environment. A Genetic Modification Advisory Committee (GMAC) was set up to assist the Ministry of Natural Resources and Environment (NRE) on biosafety matters. This was followed by the drafting of a Biosafety Act. After Malaysia signed the Cartagena Protocol on Biosafety (CPB) on 24 May 2000, the Biosafety Bill was re-drafted to harmonise with the CPB. Malaysia ratified the CPB on September 2003 and the Biosafety Act was passed in Parliament in July 2007.

NRE and other government agencies are not well equipped to successfully implement the Biosafety Act as there are insufficient capacities in risk assessment and risk management, administrative and regulatory implementation. This project will help Malaysia build capacity to undertake these tasks as well as to build channels for information dissemination and public participation.

### Goals & Objectives

The overall goal of this project is to assist Malaysia to fully implement the obligations under the CPB related to the transboundary movement of living modified organisms (LMOs). This includes the assessment, management and long term monitoring of the potential risks to the sustainable use of biodiversity and to human health posed by the introduction of LMOs.

The objective of this project is that at the end of the three years, there will be sufficient capacity in the country and effective coordination between the responsible agencies to assess and manage risks associated with the transboundary movement of LMOs. This will be achieved through the strengthening of the national biosafety framework with the necessary regulations, enhanced technical capacity and enforcement and monitoring capacities as well as an effectively managed information and coordination network.

### Main Activities of this Project

1. Support Malaysia to establish legal and regulatory framework that permits effective implementation of the Biosafety Act 2007.
2. Enhance scientific, socio-economic and institutional capacities for risk assessment.
3. Increase capacity for developing and implementing a risk management programme.
4. Develop capacity for long-term regime building maintenance.
5. Develop institutional coordination and sharing of information.
6. Raise public awareness relative to the transboundary of LMOs and promote participation of stakeholders.

### Administration of the Project

The Project Steering Committee (PSC), chaired by the Secretary General of NRE as the National Executing Agency, reviews the project on a quarterly basis. NRE implements the project and adheres to UNDP rules and procedures for national execution of projects. The Project Team, comprising of the National Project Coordinator and Project Assistant administers the project and is in charge of overall project management and co-ordination among different agencies.

The Project Management Unit meets monthly and is chaired by the National Project Director from NRE. This provides transparency and accountability in the implementation of the project. UNDP Malaysia monitors the financial activity of the project as well as supports and monitors the progress towards achieving results.

### Project Partners and Stakeholders

- Government agencies - Ministry of Science, Technology & Innovation, Ministry of Health, Ministry of Agriculture & Agro-based Industry, Ministry of Domestic Trade & Consumer Affairs, Ministry of International Trade & Industry, Ministry of Information, Ministry of Higher Education, Economic Planning Unit, Ministry of Plantation Industries & Commodities, Chemistry Department, Forestry Department.
- Research institutes & local universities.
- Private corporations - Malaysian Biotechnology Corporation, Federation of Malaysian Manufacturers (FMM), Malaysian Bio-Industry Organisation (MBO)
- NGOs - Malaysian Nature Society, Third World Network (TWN)

## Seminar On Biosafety Awareness Roles and Obligations of Researchers, Research and Academic Institutions Under The Biosafety Act 2007 12 June 2008, Crystal Crown Hotel, Petaling Jaya

The Ministry of Natural Resources and Environment (NRE), the United Nations Development Programme – Global Environment Facility Project (Capacity Building Activities on implementing the Cartagena Protocol on Biosafety) and the Centre for Research in Biotechnology for Agriculture (CEBAR) jointly organised a half day seminar on Biosafety Awareness – Roles and Obligations of Researchers, Research and Academic Institutions under the Biosafety Act 2007. This event was held at Crystal Crown Hotel, Petaling Jaya on 12 June 2008.

This initiative is part of the efforts of NRE to raise awareness on the implementation of the Act among all levels of society on the key elements of the Act. This seminar was targeted at all researchers involved in the field of modern biotechnology especially in the development and application of Living Modified Organisms (LMOs). The aim of the seminar was to outline the role of all organisations undertaking research in modern biotechnology once the Biosafety Act is enforced. This seminar also aims to elucidate and give guidance to the researchers on their obligations and compliances under the Act.

A total of 132 researchers from various research facilities participated in this seminar. There were 62 participants from public universities, 19 participants from research institutes, 11 participants from government agencies, 24 participants from private colleges and universities, 4 participants from NGOs and 12 participants from private companies.

The seminar was officiated by Datuk Fatimah Raya Nasron, the then Deputy Secretary General 1 of NRE. Datuk Fatimah informed the participants that NRE took a participatory approach in developing the Act, where researchers from public universities and research institutions played an active role to ensure that minimal burden put on the researchers will not impede innovation in the field of modern biotechnology. The purpose of the regulations under the Act is to ensure that research in modern biotechnology is done with adequate safety measures. It will complement and strengthen existing Good

Laboratory Practices and ensure safe handling in laboratories and contained areas of research.

There were 3 main presenters in this seminar. **Mr K Nagulendran** from the Conservation and Environmental Management Division, NRE who gave a presentation on the **Overview of the Biosafety Act 2007**. The second presenter was **Assoc Prof Dr Norihan Mohd. Saleh** from the Faculty of Biotechnology & Biomolecular Science, University Putra Malaysia who spoke on the **Role of Universities and Research Organisations in Implementation of Biosafety Act 2007**. The final speaker, **Prof Dr Rofina Yasmin Othman** from CEBAR, University of Malaya delivered a presentation on the **Obligations of Researchers under the Malaysian Biosafety Act**.

After the presentations, a session for questions and answers was facilitated by Prof Dr Norzulaani Khalid, University of Malaya. Participants took the opportunity to seek clarifications on what type of research will be regulated under the Notification process and the possibility of any exemptions granted under the Act for Notification. Other issues that were brought up included the implementation date of the Biosafety Act 2007, expected timeline to receive approvals, deadlines for setting up Institutional Biosafety Committees (IBCs) and the expected quantum of fees.



Panel discussion (L to R): Mr Nagulendran, Assoc Prof Dr Norihan Mohd Saleh, Prof Norzulaani Khalid, Prof Rofina Yasmin Othman.



Participants at the seminar.

# Risk Assessment Workshop on Transgenic Insects 13-15 November 2008 PJ Hilton

This workshop was jointly organised by UNDP, CEBAR University of Malaya and NRE from the 13-15 November, 2008. Its objectives were to review the current model for risk assessment of transgenic insects and build capacity of scientists and regulators in risk assessment and management to facilitate decision making process under the Biosafety Act. A total of 70 participants from local universities, research institutes and government agencies who are conducting research and development on genetically modified organisms actively participated in this workshop.

The organising committee was fortunate to have very experienced scientists and regulators to make the workshop effective and meet its objectives. Dr. J. Nagaraju, Head of Laboratory of Molecular Genetics at the Centre DNA Fingerprinting and Diagnostics (CDFD), India, shared his knowledge with the participants on transgenic silkworm for viral resistance by RNA interference (RNAi). The participants also found it useful to interact with him as he has experience in biosafety from a molecular genetics perspective, and is also a member of India's regulatory body Review Committee on Genetic Manipulation (RCGM). The participants also experienced another perspective from Dr. Robert Rose, formerly from the US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) and the Environmental Protection Agency (EPA). His experience as a regulator and APHIS reviewer for the first genetically modified pink bollworm field trial in the USA was invaluable. He also shared with the participants the draft of USDA's Environmental Impact Statement on Genetically Engineered Pink Bollworm and Fruit Flies. Experiences in the use of transgenic insects for human health were delivered by Dr. SS Vasan, a visiting Research Fellow at Oxford

University and Head of Public Health at Oxitec, a company founded and part-owned by Oxford University, and Ms. Camila Beech, a regulator from the United Kingdom. The participants had the opportunity to get a first hand perspective of the Malaysian Biosafety Act 2007 from Mr. Letchumanan Ramatha, the Head of the Biosafety Core Team of the NRE. Prof. Dr. Rofina Yasmin Othman, head of CEBAR, University of Malaya, gave an insight to researchers present at the workshop on their role with respect to the Act. The following topics presented were equally effective and interesting:

1. Overview of the Malaysian Biosafety Act 2007 and the Cartagena Protocol on Biosafety.
2. Role of R & D Organisations in the implementation of the Biosafety Act 2007.
3. Transgenic insects and their importance to public health and agriculture.
4. Risk Assessment, Risk Management, and Ethical-Social-Cultural Issues.
5. Stages Leading to Programmatic Use of Transgenic Insects: Contained, Confined and Open Field Trials.
6. Methods, molecular characterization and demonstrating proof of principle in insect genetic engineering.
7. Commercial use, genotypic stability, phenotypic stability and other safety issues involving insect genetic engineering.

It was followed by case studies on environmental impact assessment on the use of transgenic pink bollworm, fruit fly and *Aedes Aegypti*. The participants found the case studies very useful as it helped them to think and view Biosafety from a wider perspective by their interactions and exchange of ideas with the resource people and other participants from various agencies.



(L to R) Dr. SS Vasan, Saraswathy, Dr. Robert Rose, Camilla Beech, Dr. Nagaraju.

### The following are some pointers from the workshop

When doing risk assessment, it is important not to assess all transgenic insects into one group. Each transgenic insect strain will have a different risk profile, and therefore requires different risk management strategies. Every risk posed by a transgenic insect can be managed by avoiding, transferring, mitigating or accepting the risk. Accepting the risks and finding ways to mitigate them are all part of the risk assessment and management procedures.

There is no end to the list of all the information one can evaluate. Therefore risk assessment of transgenic insect must be conducted:

- by distinguishing what is necessary to know from what will be nice to know.
- with a specific and measurable end point in mind (e.g. We will do studies L and M for N months to satisfy ourselves about this particular risk).
- by comparing the particular transgenic insect with an appropriate comparator (usually the unmodified wild type insect).
- by comparing risks of available alternative solution(s) for the problem we are trying to solve by using this transgenic insect.
- by weighing the risks versus benefits on a case by case basis.

The risk assessment workshop on Transgenic Insects is the first in the series of workshops scientists and regulator can look forward to in the future organised by the NRE-UNDP-GEF Biosafety Project in collaboration with CEBAR University of Malaya.



Participants discussing animatedly during case study break-out sessions.

# Fact Sheet on Approved Events and Products in Malaysia

## 01 Event: Roundup Ready™ Soybean for FFP\* Purposes in Malaysia

Crop: *Glycine max* – Soybeans Applicant: Monsanto Company

### Description:

Herbicide (Glyphosate) tolerant soybean variety was produced by inserting a modified *CP4 5-enolpyruvylshikimate-3-phosphate synthase* (EPSPS) encoding gene from the soil bacterium *Agrobacterium tumefaciens* into the soybean. EPSPS is an enzyme involved in the biochemical pathway for the production of the aromatic amino acids needed for protein synthesis, which is required for plant growth and maintenance. Glyphosate, selectively inhibits the activity of the EPSPS enzyme, thus shutting off the aromatic amino acid synthesis. Application of this broad spectrum, non-selective herbicide on Roundup Ready Soybean, kills all the emerged weeds with no harm to the crop itself.

### Safety Assessment:

The nutritional equivalence and wholesomeness of Roundup Ready™ soybeans compared to conventional soybeans was demonstrated by the analysis of key nutrients, including proximates, amino acid and fatty acid composition, as well as anti-nutrients. The nutritional equivalence of Roundup Ready™ soybeans to conventional soybeans was confirmed in numerous feeding studies with rats, cows, pigs, broiler chickens, fish and quail. The environmental impact of Roundup Ready™ soybeans is also comparable to conventional soybeans. Study results show that Roundup Ready™ soybeans are as safe as conventional soybeans with respect to food, feed and environmental safety.

## 02 Event: NK603 Roundup Ready™ Maize for FFP\* Purposes in Malaysia

Crop: *Zea mays* - Maize Applicant: Monsanto Company

### Description:

Maize tolerant to the herbicide glyphosate was produced through the introduction of a modified gene encoding *CP4 5-enolpyruvyl shikimate-3-phosphate synthase* (EPSPS), an enzyme involved in the shikimic biochemical pathway for the production of the aromatic amino acids. The mode of action is similar to that of the Roundup Ready™ Soybean.

### Safety Assessment:

NK603 has nutritional equivalence to conventional maize. *CP4 EPSPS* protein digests rapidly and lacks toxicity and allergenicity. The environmental impact of NK603 is also comparable to conventional corn with respect to food, feed and environmental safety.

## 03 Event: MON 810 YieldGard™ Maize against Corn-Borer for FFP\* Purposes in Malaysia

Crop: *Zea mays* - Maize Applicant: Monsanto Company

### Description:

Mon 810 YieldGard™ is a variety of maize that was produced by inserting a truncated form of the *cry1Ab* gene (which codes for the production of the insecticidal protein) from *Bacillus thuringiensis* subsp. *kurstaki HD-1*. The genetic modification affords resistance to attack by the European corn borer (ECB), *Ostrinia nubilalis*, the southwestern corn borer (SWCB, *Diatraea grandiosella*) and the pink borer (*Sesamia cretica*).

### Safety Assessment:

MON 810 improves grain quality by reducing insect (only Lepidopteran insects) damage to ears. The *Cry1Ab* protein has selective toxicity and is harmless to humans, fish, wildlife and beneficial insects. Tests have shown that the *Cry1Ab* protein is present at very low levels in the grain and food but rapidly degraded in simulated gastric fluids; shows no similarity to known allergens and shows no harmful effects to animals when fed at very high levels. The forage and grain of MON810 plants are as safe and nutritious as conventional maize varieties.

## 04 Event: MON 863 YieldGard® Rootworm+ + Maize for FFP\* Purposes in Malaysia

Crop: *Zea mays* - Maize

Applicant: Monsanto Company

### Description:

Maize resistant to corn root worm (*Diabrotica virgifera*) produced by inserting the Cry3Bb1 gene from *Bacillus thuringiensis* subsp. *kumamotoensis*. This gene encodes for the insecticidal protein Cry3Bb1 which is toxic only to Coleopteran insects.

### Safety Assessment:

Results of biochemical analyses of the grain and forage demonstrate the compositional equivalence of MON 863 to conventional corn varieties. The Cry3Bb1 protein is degraded rapidly, not stable in heat, not glycosylated and has no biologically relevant amino acid sequence similarity to known allergens and toxins. As for environmental safety, the Cry3Bb1 protein has no adverse effects on non target species. Food and feed products derived from MON 863 are safe and nutritious for consumption as those derived from conventional maize varieties and pose no risk to the environment.

## 05 Product Name: ISP type III HPLC 12 Glacein™ - Ice-Structuring Protein (ISP) in Food

LMO source: *Recombinant Baker's Yeast* Applicant: Unilever Malaysia

### Description:

ISP is a copy of a protein found in ocean pout (fish). However, no fish components are used in the derivation or manufacture of ISP. ISP is used as a processing aid in frozen products at a level <0.005%. It is used to control ice crystal size, shape and growth by Unilever in the preparation of ice-cream.

### Safety Assessment:

The outcome of safety testing in ISP shows that there is no evidence of (i) a potential to induce or elicit allergic reactions, (ii) genotoxicity/mutagenicity or (iii) any adverse effects in 13-week rat study. The yeast cells used for the commercial manufacture of ISP is recombinant baker's yeast and uses standard industrial-scale biotechnology processing and food-grade material. The recombinant yeast is separated from the final product (ISP) and it is GMO and DNA free.

Note: FFP represents food, feed and processing.

# Research on Genetically Modified Plants in Malaysia

Prepared by Prof. Dr.  
Rofina Yasmin Othman

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Research on genetic modification of plants in Malaysia has been reported since the early 90's with the initial projects driven by international cooperative programmes with bodies such as the **Australian Centre for International Agriculture Research (ACIAR)**, **International Service for the Acquisition of Agri-biotech Applications (ISAAA)** and the **Rockefeller Institute**. A subsequent focus on biotechnology funding in Malaysia has allowed for the rapid development of projects focusing on indigenously important crops and traits. This report is based on literature of various types and from several sources, including organisation reports, conference abstracts and peer reviewed scientific publications.

Reports on transgenic research include development of processes such use of explants, constructs and delivery methods. These are mainly contained or laboratory research carried out in public institutions including research institutions and institutes of higher

learning. More recently private institutions of higher learning have initiated research in this area. While the initial traits reported focused on crop improvement including disease resistance and postharvest quality, current research has moved into areas such as nutritional improvement and biopharmaceutical production. Biotechnology-derived papaya developed for resistance to Papaya Ringspot Virus (PRSV) and improved postharvest qualities have completed a first contained field evaluation trial while transgenic rubber is also known to have been grown in restricted contained trials. Pineapple developed for resistance to fruit black heart disorder has also been evaluated for proof-of-concept. Other biotechnology-derived food crops are at various stages of gene cloning and transformation and evaluation. Table 1 summarizes selected published information obtained based on crop type or traits and processes developed. Several of these processes have been patented. (Please refer to Table 1 on page 14)

**Table 1: List of plants, traits & processes in transgenic research in Malaysia**

Plant	Trait/Process	
Banana cv Berangan <i>Musa acuminata</i>	Transformation Protocols/ early flowering	Wong W.C <i>et al.</i> (2009), Transgenic Plant Journal (in press)
Banana cv Berangan <i>Musa acuminata</i>	Fusarium resistance	Sreeraman <i>et al.</i> (2006) Scientia horticulturae , Vol. 108, (4), pp. 378-389
Chilli pepper <i>Capsicum annum</i> L	CMV coat protein	Zarina Zainuddin <i>et al.</i> (2002) Malaysian Journal of Science, Vol 21 (1 & 2): 25-30. ISSN 1394-3065
Chilli pepper <i>Capsicum annum</i>	Development of transformation process	I. Ismail <i>et al.</i> (2005) Malaysian Journal of Biochemistry and Molecular Biology, Vol 12: 1-7 <a href="http://ejum.fsktm.um.edu.my/ArticleInformation.aspx?ArticleID=604">http://ejum.fsktm.um.edu.my/ArticleInformation.aspx?ArticleID=604</a>
Eggplant <i>Solanum melongena</i> L	Transformation protocol	Z.Ramli (1997) in Abstracts, 5th International Congress of Plant Molecular Biology (no.1414.) ed J.F.D.Dean
Mangosteen <i>Garcinia mangostana</i> L	Early flowering genes	Summary available at: <a href="http://www.nbbnet.gov.my/research/exe%20project/exe%20summary/Adrain.htm">http://www.nbbnet.gov.my/research/exe%20project/exe%20summary/Adrain.htm</a>
Oil palm <i>Elaeis guineensis</i> Jacq.	Polyhydroxyalkanoates	Abdul Masani Mat Yunus, <i>et al.</i> (2008), Asia Pacific Journal of Molecular Biology & Biotechnology, 16 (1):1-10. <a href="http://www.msmbb.org.my/apjmbb/html161/161a.pdf">http://www.msmbb.org.my/apjmbb/html161/161a.pdf</a>
Oil palm <i>Elaeis guineensis</i> Jacq.	BT gene	Lee Mei Phing <i>et al.</i> (2006) Electronic Journal of Biotechnology, 9 (2). ISSN 07173458 <a href="http://www.ejbiotechnology.info/content/vol9/issue2/full/3/BIP/index.html">http://www.ejbiotechnology.info/content/vol9/issue2/full/3/BIP/index.html</a>
Oil palm <i>Elaeis guineensis</i> Jacq.	Transformation protocols	Parveez A. (2003) MPOB Information Series MPOB TT No 189 ISSN1511-1871 N.Abdul Majid <i>et al.</i> (2007) Asia Pacific Journal of Molecular Biology & Biotechnology, 15 (1):1-8. <a href="http://www.msmbb.org.my/apjmbb/html151/151a.pdf">http://www.msmbb.org.my/apjmbb/html151/151a.pdf</a>
Orchid <i>Dendrobium</i> sp.	Transformation Process	Ong, A. <i>et al.</i> (2000) Asia Pacific Journal of Molecular Biology & Biotechnology, 8 (1). pp. 85-94.
Orchid /tulips <i>Dendrobium, Mokara, Oncidium</i>	Transformation protocols	M.Mahmood <i>et al.</i> Summary available at: <a href="http://www.nbbnet.gov.my/research/list07.htm">http://www.nbbnet.gov.my/research/list07.htm</a>
Papaya <i>Carica papaya</i>	Delayed ripening	ISAAA: "Biotechnology Transfer Projects: Asia. SEA Researchers Target PSRV Resistant and Delayed Ripening Papaya." <a href="http://www.isaaa.org/projects/SEAsia/Papaya.htm">http://www.isaaa.org/projects/SEAsia/Papaya.htm</a>
Papaya <i>Carica papaya</i>	PRSV resistance	Reviewed in Umi K. Abu Bakar <i>et al.</i> (2005) Food Nutr Bull 2005 Dec;26(4):432-5 <a href="http://www.unu.edu/Unupress/food/fnb26-4.pdf">http://www.unu.edu/Unupress/food/fnb26-4.pdf</a>
Pegaga <i>Centenela asiatica</i>	Metabolic Engineering	Z. Abdul Aziz, (accessed Feb 2009) <a href="http://www.ums.edu.my/sst/new_sst/penyelidikan.htm">http://www.ums.edu.my/sst/new_sst/penyelidikan.htm</a>
Pineapple <i>Ananas comosus</i>	Resistance to Blackheart disease	ACIAR Project ID:PHT/1999/040 <a href="http://www.aciar.gov.au/project/PHT/1999/040">http://www.aciar.gov.au/project/PHT/1999/040</a>
Rice <i>Oryza sativa</i> L	Fungal resistance	Zamri Zainal, Summary available at: <a href="http://www.mosti.gov.my/mosti/tech_fund/list technoFund.pdf">http://www.mosti.gov.my/mosti/tech_fund/list technoFund.pdf</a>
Rubber <i>Hevea</i> sp.	Biopharming	K.Arokiajaraj (2006) In: International Symposium on Molecular Farming in Plants: Prospect for the Asia Pacific, Abstract available at: <a href="http://msmbb.org.my/apjhome/htm">http://msmbb.org.my/apjhome/htm</a>
Senduduk <i>Melastomataceae</i> sp.	Optimization of agrobacterium-mediated transformation parameters	Yong, W. T. L., Abdullah, J. O., & Mahmood, M. (2006). Scientia Horticulturae, Vol 109(1): 78-85.
Sweet potato <i>Ipomaea batatas</i>	Transformation protocols/ Vaccine	Report in IHMC, UNIMAS bulletin <a href="http://www.unimas.my/research/ihcm/ihcm_JE.htm">http://www.unimas.my/research/ihcm/ihcm_JE.htm</a>
Teak <i>Tectonis grandis</i>	Biolistic Process /UidA gene	N. Adnan <i>et al.</i> (2007) Asia Pacific Journal of Molecular Biology and Biotechnology, Vol. 15 (3) : 115-120 <a href="http://www.msmbb.org.my/apjmbb/html153/153c.pdf">http://www.msmbb.org.my/apjmbb/html153/153c.pdf</a>

# Inception Workshop on Risk Assessment: Collaborative Project between University of Malaya, Malaysia and Queensland University of Technology, Australia

*Prepared by Prof. Dr. Norzulaani Khalid*

*Prof. Dr. Norzulaani Khalid is Head of Centre for Research in Biotechnology for Agriculture (CEBAR) and Coordinator of the Plant Biotechnology Incubation Unit, University of Malaya.*

The workshop was organised by the Center of Research in Biotechnology for Agriculture (CEBAR) University of Malaya on 10 Nov 2008 at the CEBAR Seminar Room, Institute of Post Graduate Studies, University of Malaya.

This workshop was attended by CEBAR laboratory members as an inception workshop for a collaborative programme on risk assessment of transgenic banana. The invited speaker for this workshop was Dr. Douglas Becker, an academic staff of the Queensland University of Technology (QUT), Brisbane, Australia. He is the Institutional Biosafety Committee Chairperson for QUT and is also involved in the risk assessment of the field trials of transgenic bananas with disease resistance and nutritional

improvement genes. For the disease resistant gene, a novel anti-apoptotic gene was used which confers resistance towards *Fusarium* wilt race1, a major problem for the banana industry in Australia. The research was funded by the Australian Research Council. QUT has also successfully secured funding from Bill and Melinda Gates Foundation for nutritional improvement of banana via biotechnology approaches. The participants were fortunate that Dr. Doug Becker gave them an insight on the scientific details of the banana field trials and also in the preparation of the documents of the banana field trials submitted to the Office of the Gene Technology Regulator (OGTR), Australia for biosafety compliance.

Dr. Doug Becker gave a presentation titled 'GM Plant Gene Technology Regulation: an Australian Perspective'. In his lecture, he elaborated on the Australian application process for the submission of GMO approval to OGTR which includes the definition of GMO in the Australian context, penalties for unauthorised dealings with GMO, types of dealings and procedures and time period taken for the application process. He also shared details of the QUT banana field trial which included OGTR questions/concerns following application submission which were proven to be useful for our future local transgenic banana and rice glasshouse and field trials.



QUT Banana Field Trial, Brisbane, Australia.

# 10<sup>th</sup> ISBGMO

## 16-21 November 2008

### Wellington, New Zealand



The land of the tuatara, the kiwi and the hobbit, coupled with breathtaking natural beauty where Mother Nature (still) rules – New Zealand is a magical destination in itself. What better venue then for the 10th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO) organised by the International Society for Biosafety Research (ISBR).

The ISBGMO is held as a biennial event since 1990 to highlight environmental biosafety research. This 10th meeting in Museum of Te Papa, Wellington puts the spotlight on past achievements in biosafety research in genetically-modified organisms (GMOs) and also charts the future directions for the field as a whole. In line with the aim of fostering meaningful dialogue via a multidisciplinary approach, a diverse array of stakeholders such as scientific researchers, policy makers, regulators, non-governmental organisations and industry representatives, attended this meeting.

The symposium programme comprised of plenary sessions, workshops and posters over 5 days. Topics reviewed include the use of current scientific knowledge on the risk analysis on GMOs. New research focusing on the impact of biotic and abiotic stress resistance on the fitness and invasiveness of GMOs were discussed. As GMOs can either be of plant or animal origin, biosafety issues associated with genetically-modified (GM) domestic animals, fishes and insects were highlighted.

From an environmental point of view, impacts of GMOs on soil systems formed part of the programme. Methods to restrict gene flow from GM crops to non-target crops, especially for GMOs with higher potential, generated interesting viewpoints from the audience. The scientific rationale and methods of post-market environmental monitoring of GMOs were



presented and there was a general consensus that a post-market monitoring needed to be improved for optimum effectiveness. Looking at the symposium topics, one could imagine that regulation of GMOs would be a topic that consistently generates the most discussions. Questions and suggestions as to how the regulation of GMOs can be brought more in line with scientific requirements were discussed.

Workshops on field trials case study, risk assessment and risk communication were useful and well organised. A special forum was arranged at which members of the public were invited to put questions to a panel of scientists regarding issues surrounding GMOs. This was a good platform for both laypersons and scientists to exchange their thoughts and opinions.

Overall, the 10th ISBGMO was successful in meeting its stated objectives and its role will only increase in importance in tandem with growing public and political awareness regarding GMOs.

The 11th ISBGMO will be held in Buenos Aires, Argentina. Malaysia will be putting a rival bid to host this meeting in year 2012. If all plans go well, the 12th ISBGMO will be held in Kuala Lumpur. In line with the impending introduction of the Malaysia Biosafety Act, this would be a good opportunity to spur research interest in biosafety and to raise awareness in our part of the world.

**Prepared by  
Ng Cheah Wei**

*Ng Cheah Wei is a Research Officer attached to CEBAR, University of Malaya.*

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# UNIDO-UM e-Biosafety Masters Programme

The **UNIDO-UM e-BIOSAFETY MASTERS PROGRAMME** is an internationally accredited course in the field of biosafety. It is based on a combination of distance-learning and on-campus training sessions. The programme duration is twelve months and upon graduation students will be awarded an academically accredited Master in Biosafety from the University of Malaya. This programme is endorsed by the Ministry of Natural Resources and Environment (NRE) of Malaysia and is supported through technical cooperation under the aegis of the United Nations Industrial Development Organisation (UNIDO).

This programme is an upgrade of the previous postgraduate diploma training course. GMO detection with theoretical and practical aspects, together with hands-on training has been added to the course. The Malaysian Biosafety Act 2007 and other regional Biosafety Regulations will also be introduced as part of the course material.

At the end of the programme, successful graduates will be able to conduct risk assessments and apply risk management options in the field of biosafety. They will have acquired skills to deal with public policy issues at the interface of science, government, industry and civil society. They will also have the analytical knowledge necessary to comply with regulatory legislations in the field of biotechnology.

This programme is targeted at individuals interested in, or are, engaged as biosafety professionals in government agencies or industry. It is also tailored for individuals with an interest in public policy, legal and ethical aspects of biotechnology.



For further information, please contact:

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or

**The Secretariat**

**UNIDO-UM e-BIOSAFETY MASTERS PROGRAMME**

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A limited amount of funding is available for Malaysians. Applicants from the government agencies are strongly encouraged.

**TO APPLY**, kindly contact:

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# International Centre for Genetic Engineering and Biotechnology

The International Centre for Genetic Engineering and Biotechnology (ICGEB) provides a scientific and educational environment of the highest standard and conducts innovative research in life sciences for the benefit of developing countries. It strengthens the research capability of its members through training and funding programmes and advisory services and represents a comprehensive approach to promoting biotechnology internationally.

ICGEB is dedicated to advanced research and training in molecular biology and biotechnology and holds out the prospect of advancing knowledge and applying the latest techniques in the fields of:

- biomedicine
- crop improvement
- environmental protection/remediation
- biopharmaceuticals and biopesticide production

With components in Trieste, Italy, New Delhi, India and Cape Town, South Africa, ICGEB forms an interactive network with Affiliated Centres in its Member States. ICGEB is part of the United Nations System.

In 1997, ICGEB established a dedicated Biosafety Unit aimed at providing its Member States with services related to the safe and sustainable use of biotechnology in agriculture, and in particular to the environmental release of genetically modified organisms (GMOs). The Unit is involved in several activities, including information dissemination and the establishment of biosafety clearing-houses (BCH), scientific training in risk assessment for the environmental release of GMOs (capacity building and technology transfer), and co-operation with other international agencies involved in biosafety.

Malaysia became the 56th Member of ICGEB on 10 January 2008. The Ministry of Science, Technology and Innovation (MOSTI) is the scientific focal point in order to facilitate cooperation among the local scientific community and the secretariat at ICGEB. The Undersecretary of the National Biotechnology Division in MOSTI has been named as the Governor and Liaison Officer. All the activities and programme of ICGEB can be found at [www.icgeb.org](http://www.icgeb.org) >>

The following are some of the courses that the ICGEB is organising in 2009 pertaining to Biosafety. Please contact the Malaysian liaison officer for more information.

Date	Event	Organiser(s)
21-22 April	<b>Conference: Measures of Hope and Promises Delivered: An International Conference on Socioeconomic and Environmental Impact Assessment of Genetically Modified (GM) Crops</b> Bangkok, Thailand	The Southeast Asian Regional Center for Graduate Study and Research in Agriculture (SEARCA) Dr. Arnulfo Garcia agg@agri.searca.org <a href="http://www.searca.org">http://www.searca.org</a>
10- 12 May	<b>Course: The Analysis of Agricultural Products for the Presence of Genetically Modified Organisms</b> Tehran, Iran	Haleh Hashemi Sohi and Amir Mousavi (National Institute of Genetic Engineering and Biotechnology- NIGEB, Tehran, Iran) Dr. Haleh Hashemi Sohi hashemi@nigeb.ac.ir, halehsohi@gmail.com
18-30 Aug	<b>Theoretical and Practical Course: "Developments in Biosciences for Enhanced Food and Environmental Biosafety"</b> Dar es Salaam, Tanzania	Mugassa Stephen Thomas Rubindamayugi (University of Dar es Salaam, Tanzania) Paul S. Gwakisa (Sokoine University, Tanzania) Requests for information and applications directly to: Dr. Mugassa Stephen Thomas Rubindamayugi Department of Molecular Biology and Biotechnology Faculty of Science, University of Dar es Salaam Dar es Salaam, Tanzania Tel.: +255-754-270791 Fax: +255-22-2410078 E-mail: mugassa@amu.udsm.ac.tz, mugassa@udsm.ac.tz
28 Sept – 2 Oct	<b>Workshop: Theoretical Approaches and their Practical Application in the Risk Assessment for the Deliberate Release of Genetically Modified Plants</b> Ca' Tron di Roncade, Italy	ICGEB Padriciano 99, I - 34012 Trieste, Italy Tel.: +39-040-3757333 Fax: +39-040-226555 E-mail: courses@icgeb.org Deadline for receipt of applications at ICGEB Trieste: 27 May 2009
18-21 Oct	<b>Conference: 52nd Annual Biological Safety Conference</b> Miami, FL, USA	Further Information: <a href="http://www.absa.org/confsem.html">http://www.absa.org/confsem.html</a>

**Courses Organised by NRE-UNDP-GEF Biosafety Project together with its Working Group Partners in Malaysia:**

Date / Venue	Event	Organiser(s)
4-8 May	<b>Monitoring &amp; Detection of GMO –Module 1</b>	NRE-UNDP-GEF & JKM
21 May	<b>Workshop on Management of Containment Facilities</b>	NRE-UNDP-GEF & CEBAR, UM
4-6 August	<b>Risk Assessment Workshop on Transgenic Trees</b>	NRE-UNDP-GEF & CEBAR, UM
October (date to be confirmed)	<b>Workshop on Transgenic Microorganisms</b>	NRE-UNDP-GEF & CEBAR, UM
November (date to be confirmed)	<b>Monitoring &amp; Detection of GMO – Module 2</b>	NRE-UNDP-GEF & JKM

# Useful Biosafety Links

## **Biosafety Clearing-House**

<http://bch.cbd.int/>

## **Cartagena Protocol on Biosafety (CPB)**

<http://www.cbd.int/biosafety/>

## **Codex Alimentarius**

<http://www.codexalimentarius.net/web/biotech.jsp>

## **International Centre for Genetic Engineering and Biotechnology (ICGEB)**

<http://www.icgeb.org>

## **Program for Biosafety Systems**

<http://www.ifpri.org/themes/pbs/pbs.htm>

## **United Kingdom: Advisory Committee on Releases to the Environment (ACRE)**

<http://www.defra.gov.uk/environment/acre>

## **UNEP-GEF Biosafety Project**

<http://www.unep.org/biosafety/>

## **AGBIOS**

<http://www.agbios.com/main.php>

## **Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP)**

<http://www.bigmap.iastate.edu/>

## **AgBioWorld**

<http://www.agbioworld.org/about/index.html>

