

BICnews

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BIOTECHNOLOGY AND BIOSAFETY

GENETIC Modification (GM) techniques have given rise to a new breed of 'improved' food and crops, and along the way have sparked ferocious debates about the safety and possible risks of such creations to the consumer, and the environment as a whole. This edition of BICnews will address the importance of proper biosafety regulations in containing such scenarios, and will review the existing and proposed biosafety regulations in Malaysia.



THE NEED FOR BIOSAFETY REGULATIONS

In 1994, the first genetically modified food crop, Calgene's Flavr-Savr™ tomato, was produced and consumed in an industrialized country. Since that time, genetically modified (GM) crops have been rapidly adopted worldwide reflecting the satisfaction of growers and consumers alike. While advances in biotechnology have great potential to improve human well-being, the technology must be developed with

adequate safety measures. This gives rise to the issues of biosafety which deals with the safe transfer, handling and use of living modified organisms (LMOs) created through modern biotechnology. Biosafety regulations was adopted early by the USA, with most other developed countries establishing regulations following numerous basic models over the years.

Genetically modified food undergoes extensive screening.



MODERN BIOTECHNOLOGY

Recombinant DNA technology is used to produce Genetically Modified Organisms (GMO). GM plants for example contains a gene or genes which have been artificially inserted instead of the plant acquiring them through pollination. The inserted gene sequence (known as the transgene) may come from another unrelated plant, or from a completely different species. Transgenic Bt corn, for example, which produces its own insecticide, contains a gene from a bacterium.

In reality all crops have been genetically modified from their original wild state by domestication, selection and controlled breeding over long periods of time. Traditional plant breeding has been limited to artificially crossing plants within the same species or with closely related species to bring different genes together. For example, a gene for protein in soybean could not be transferred to a completely different crop such as corn using traditional techniques. GM tech-

nology has enabled plant breeders to incorporate useful genes from within crop species or closely related plants and beyond. Compared to conventional breeding methods, this allows plant breeders to generate superior plant varieties in a faster and more accurate way. With such expectations, recombinant DNA technology has broad application in developing countries and has the potential to impact the economy positively, in particular, the agricultural based ASEAN countries.

THE CARTAGENA PROTOCOL

The Cartagena Protocol on Biosafety is a legally binding protocol to the Convention on Biodiversity (CBD). It was named in honor of Cartagena, Columbia, where negotiations were held in February 1999. A year later, on January 29, 2000, the Protocol was finalized and adopted in Montreal,

Canada by unanimous consent with 135 countries present. The protocol will begin to take effect on 11th Sept, 2003, 90 days after it was ratified by its 50th member country.

WHAT IS THE OBJECTIVE?

Article 1 of the Protocol states that it

aims to "contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biology diversity, **CONTINUED ON PAGE 2 >>>**

CARTAGENA PROTOCOL continued

CONTINUED FROM PAGE 1 >>> taking also into account risks to human health, and specifically focusing on transboundary movements". In short, it seeks to protect the environment from potential risks that may be presented by the products of modern biotechnology.

WHAT DOES THE PROTOCOL DO?

The Protocol covers the "transboundary movement, transit and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health". It deals primarily with GMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing).

More specifically:

- s It assists developing countries in building their capacity for managing modern biotechnology.
- s It creates an advanced informed agreement (AIA) procedure requiring exporters to seek consent from importing countries before the first shipping of LMOs meant to be introduced into the environment (e.g. seeds for planting, fish for release, and microorganisms for bioremediation).
- s It establishes an internet-based "Biosafety Clearing-House" to help countries exchange scientific, technical, environment and legal information about LMOs.
- s It requires bulk shipments of LMO commodities, such as corn or soybeans that are intended to be used as food, feed or for processing, to be accompanied by documentation stating that such shipments "may contain" LMOs and are "not intended for intentional introduction into the environment".
- s The Protocol includes a clause that makes clear the Parties' intent that the agreement does not alter the rights and obligations of governments under the World Trade

Organization (WTO) or other existing international agreements.

WHAT DOES IT NOT DO?

- s The Protocol does not address food safety issues. This is addressed by experts in other international fora.
- s The Protocol does not require segregation of bulk shipments of commodities that may contain living modified organisms.

With the Cartagena Protocol in place, export of GMOs will be monitored.

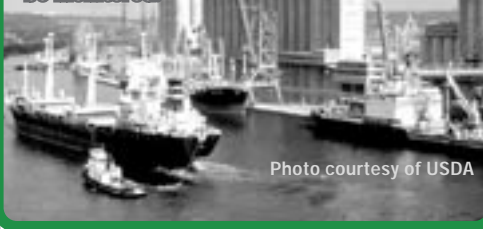


Photo courtesy of USDA

- s It does not require consumer product labeling.
- s It does not subject shipments of bulk commodities to Protocol procedures.
- s It does not cover products derived from LMOs (e.g. paper from GM trees)
- s It does not cover LMOs which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.

KEY FEATURES of the PROTOCOL

Advanced Informed Agreement (AIA)

The Protocol's main mechanism is its Advanced Informed Agreement (AIA) requirement. It is a procedure that must be followed before the first intentional transboundary movement of an LMO into the environment of the importing country. The exporter must provide a notification to the importing country containing detailed information about the LMO, previous risk assessments of the LMO and its regulatory status in the exporting country. The importing country must acknowledge receiving the information within 90 days and whether the notifier should proceed under a domestic regulatory system or under the Protocol procedure. In either case, the importing country must decide whether to allow

the import, with or without conditions or deny it within 270 days.

What is NOT subject to the requirement?

- s Consecutive shipments. The Protocol's AIA only covers first time shipments.
- s LMOs not intended for release into the environment such as commodities, LMOs in transit, and LMOs destined for contained use.

Biosafety Clearing-House (BCH)

The BCH is a website administered by the Secretariat to the Convention (<http://bch.biodiv.org>). It was established to:

- 1) facilitate the exchange of scientific, technical, environmental and legal information on as well as experience with LMOs; and
- 2) assist parties to implement the Protocol. Examples of information in the BCH include: any existing laws, regulations, as well as guidelines for implementation of the Protocol, summaries of risk assessments or environmental reviews of LMOs, and final decisions regarding importation or release of LMOs.

Risk Assessment

The Protocol requires that decisions on proposed imports to be based on risk assessments.

- s Risk assessments must be undertaken in a scientific manner based on established risk assessment techniques, taking into account advice and guidelines developed by relevant international organizations.

- s Lack of scientific knowledge or scientific consensus must not necessarily be interpreted as indicating a particular level or risk, an absence or
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Consumers will benefit from the implementation of the Cartagena Protocol



Photo courtesy of USDA

BIOSAFETY STATUS OF MALAYSIA

Biotechnology is one of the five strategic technologies expected to accelerate Malaysia's transformation into a highly industrialized nation by 2020. The National Agriculture Policy 3 (NAP 3) for 1998-2010, highlighted the importance of human resource development in order to generate highly skilled and innovative manpower in new and emerging sciences such as food, genetic engineering and biotechnology.



Photo courtesy of Monash University Malaysia

The Ministry of Science, Technology and Environment (MOSTE) is the lead agency in Malaysia for biosafety matters. Several divisions have been set up to spearhead the development in this area, notably the Science and Technology Division, the International Division, the Conservation and Environmental Management Divisions and the National Biotechnology Directorate (BIOTEK), a division set up to facilitate the development of the country's biotechnology sector.

Malaysia signed the Cartagena Protocol on Biosafety in May 2000, at the Fifth Meeting of the Conference of Parties to the Convention in Nairobi, Kenya. Consequently, any national biosafety legislation will be required to comply with the Protocol.

Like many other ASEAN members, Malaysia has no specific laws addressing the biosafety issues in any holistic way. However, several laws from different governmental sectors do address specific segments such as the Food Act 1983, the Fisheries Act 1963

(revised 1978), the Plant Quarantine Act 1976, the Poisons Act 1979 and the Pesticide Control Act of 1974. The Genetic Modification Advisory Committee (GMAC) was set up under the National Committee on Biodiversity of MOSTE to be the national advisory body. GMAC is currently chaired by Prof. Dr. Mohamad Noor Embi, Deputy Vice Chancellor of the National University of Malaysia (UKM) and consists of the following members:

1. Prof. Dr. Koh Chong Lek, Institute of Biological Sciences, University Malaya.
2. Dr. Low Fee Chon, BIOTEK.
3. Dr. Vilasini Pillai, Malaysian Agricultural Research & Development Institute (MARDI).
4. Prof. Dr. Mohd. Sanusi Jangi, Open University.
5. Assoc. Prof. Dr. Nazlan Najimudin, University of Science Malaysia.
6. Prof Datin Dr. Khatijah Mohd Yusoff, University Putra Malaysia.
7. Dr. Nor Shahidah Khairullah, Institute of Medial Research (IMR).
8. Dr. Sharifah Sharul Rabiah Syed Alwee, Malaysian Palm Oil Board (MPOB).
9. Mr. Martin Khor, Third World Network.
10. Director, Crop Protection and Plant Quarantine Division, Department of Agriculture, Ministry of Agriculture.
11. Representative, Ministry of Primary Industry.
12. Director, Food Quality Control Division, Department of Public Health, Ministry of Health.
13. Representative, Attorney's General Chamber, MOSTE.
14. Administrative Secretary, MOSTE.

The Biosafety Bill was drafted to regulate and manage the import, deliberate the release of, placing on the market and the contained use of genetically modified organisms and its derivatives. It is important to note that the biosafety bill is drafted in accordance with the Precautionary Principle,

the principle of sustainable development, and ethical and cultural norms. This is deliberately done to protect human, plant and animal health, and the environment and maintain biological diversity. The biosafety guidelines for research and development are also included in the draft Bill.

The National Guidelines for the Release of Genetically Modified Organisms into the Environment, formulated by GMAC, set the regulatory framework for the proposed biosafety bill. The guidelines cover all GMOs at any stage of research and development, use, handling, transboundary movement, release and also placing in the market of GMOs and products containing GMOs and address biosafety issues in biotechnology such as risk assessment, risk management and monitoring. The guidelines was essentially developed using the UNEP Guidelines.

According to the official sources, there are currently no commercial release of GM plants actually growing in Malaysia. To date, 2 applications for the release of a GMO have been received and approved by GMAC Malaysia, namely glyphosate resistant "Round Up Ready" soybean for food and feed as well as genetically modified papaya for increased shelf life.

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Photo courtesy of Monash University Malaysia

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risk, or an acceptable risk.

- s Risks associated with LMOs or products thereof should be considered in the context of risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
- s Risk assessment should be carried out on a case by case basis.

Capacity building

The Protocol promotes international cooperation to help developing countries acquire resources and capacity to use biotechnology safely and regulate it



Photo courtesy of ISAAA



efficiently. It does this by encouraging member governments to assist with scientific and technical training to promote the transfer of technology, knowledge and financial resources.

Governments are also expected to facilitate greater involvement of the private sector.

Public awareness

Member governments must commit themselves to promoting public awareness, insuring public access to information, and public consultation. The Protocol recognizes that national measures are important to make its procedures effective. Nations must also take measures to prevent illegal shipments or accidental releases of LMOs.

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The environmental impact and safety assessment of GM soybean was reviewed and approved in 1997 before it was even allowed to be imported into Malaysia. From the data reviewed, it was agreed that the likelihood of the GM soybean causing environmental harm was very low indeed.

GLOSSARY

BIOSAFETY PROTOCOL ~ Legislation intended to ensure the safe transfer, handling, use and disposal of genetically and biochemically modified plants, animals and microorganisms.

LIVING MODIFIED ORGANISMS (LMO) ~ Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

TRANSBOUNDARY MOVEMENT ~ LMOs movement across country boundaries.

GENETICALLY MODIFIED ORGANISMS (GMO) ~ An organism that contains a gene(s) that

has been artificially inserted.

RECOMBINANT ~ Refers to progeny organisms, cells, or DNA molecules bearing gene combinations that differ from the combinations in the parents.

MODERN BIOTECHNOLOGY (In context of this newsletter) ~ Refers to the application of advanced genetic engineering techniques (including recombinant DNA technology and cell fusion) that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.

For a more complete list of terms, please refer to our website at the glossary section.

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Q & A with Dr. Low Fee Chon, Consultant on Biosafety & Head of the Interim Secretariat for Biosafety

Describe biosafety in simple terms?

Biosafety refers to the procedure to avoid harm to human health and the environment, resulting from the use or release of products of biotechnology into the environment.

What is the status of biosafety regulations in Malaysia?

The Malaysian Biosafety Bill is expected to come into force in late 2003. In the meantime, the voluntary "Malaysian Guidelines for the Release of Genetically Modified Organisms" have been in place since 1997.

How is Malaysia affected by signing the Cartagena Biosafety Protocol?

As signatory to the Cartagena Protocol on Biosafety, Malaysia is obliged to implement the advanced informed agreement (AIA) procedure pertaining to the import and export of living modified organisms between countries. In addition, Malaysia has to ensure that a regulatory framework for biosafety is in place to undertake all the other obligations encompassed in the Protocol.

What about consumer (specifically food) products? Is GM labeling a part of the proposed Bill?

All living modified organisms (LMOs) and products containing LMOs will be have to be labeled under the proposed Bill. Labelling of food and food products containing GM food will be covered under the proposed revised Food Regulation 1985.

Once the bill is passed in Malaysia, which body will monitor the regulations?

The Ministry of Science, Technology and the Environment (MOSTE) will be the implementing agency for the Bill. MOSTE will work with existing enforcement mechanisms in other government agencies for compliance of the Bill.

How are traders (importers and exporters) affected?

The proposed Bill is in harmony with the Cartagena Protocol on Biosafety, which comes into force on 11 Sept. 2003. Under the proposed Bill as well as the Cartagena Protocol, the import and export of all LMOs by parties to the Protocol (i.e. countries which have ratified the Protocol) have to abide by the Advanced Informed Agreement (AIA) procedure, which makes it compulsory for information on LMOs to be sent by the exporting country to the importing country before these arrive at the importing country.

How are the farmers affected?

The farmers will be affected if they release unapproved LMOs into the environment through cultivation. On the other hand, importers or developers of these GM-crops will need to obtain approval from MOSTE before they can sell or distribute the GM-crops. Farmers who buy the seeds of GM crops for planting do not need further approval if the LMO has already been approved for release.

How are the consumers affected?

With implementation of the proposed Bill, the safety of consumers will be further enhanced, because all LMOs have to be approved prior to their release into the market. Additionally,



Dr. Low Fee Chon

the revised Food Regulation 1985 will ensure that food and food ingredients containing GMOs will be labeled so that consumers have a choice regarding the purchase of these items.

If the exporting party fails to declare the goods as LMOs, how would the importing country know? Aren't there many loopholes?

Yes, loopholes do exist, if parties deliberately do not abide by their international responsibilities. If the exporting country fails to declare the goods as LMOs, the importing country will not know, unless it undertakes GMO detection tests. This process can be expensive in financial and human resources. However, if the item is an LMO, some indication may be obtained since the number of LMOs, which are presently commercialized globally, is relatively small and their origins of production are known. Detection of GM-ingredients and products will pose a challenge. This problem will be further exacerbated when the next generation of GMOs is commercialized because these will not have foreign genes, but a difference in the expression of inherent genes.



Editorial Team : Mahaletchumy Arujanan & Kelvin Keh.

Malaysian Biotechnology Information Centre (MABIC)
c/o Biotechnology Resource Centre, Monash University Malaysia.
No.2, Jalan Kolej, Bandar Sunway, 46150 Petaling Jaya.

Tel: 603-5880.4384 Fax: 603-5880.4384 Email: info@bic.org.my Website: www.bic.org.my

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EVENT ANNOUNCEMENT

International Seminar on Biotechnology for Sustainable Agriculture: State of the Art of Research and Product Commercialization

An event organized by INDOBiC, in collaboration with SEAMEO BIOTROP and ISAAA

Date: 7-8 October 2003

Venue: SEAMEO BIOTROP, Bogor, Indonesia

For more information on event details, please contact:

Dr Ir Sudarsono, MSc.

SEAMEO BIOTROP Jl. Raya Tajur, Km 6, Bogor, INDONESIA

Phone: 0251-323848 ext.147

Fax: 0251-326851

E-mail: indobic@biotrop.org

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No. 2, Jalan Kolej, Bandar Sunway

46150 Petaling Jaya, Selangor, Malaysia

Telephone: +603-58804384

Fax: +603-58804384

Email: info@bic.org.my