

5. Emerging Biosafety Capabilities in Malaysia A Country Report

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Crop production is still one of the main components of our country's economy. As we move into the next millennium, plant scientists need to accelerate efforts for improving and creating new technologies to cope with the challenges ahead. Biotechnology may enable to achieve this objective by facilitating the adoption of new technologies, increasing productivity and enhancing returns among other factors.

In Malaysia, agriculture economy is based on high value crops such as rubber, oil palm, cocoa and timber. The government has set up research institutions according to the needs of these commodities to enhance and develop the respective industries. Biotechnology research and development, thus is carried out mainly in these institutions as well as various universities.

The Malaysian Agricultural Research and Development Institute (MARDI) carries out research mainly on food crops, tobacco and ornamental crops. One of the problems addressed by this institute deals with the control of pests and diseases of the major food crops such as rice and fruits. Various approaches have been adopted to tackle this problem among which is the development of resistance through viral coat protein-mediated resistance. The viral coat protein gene can be introduced to the plant by different gene delivery systems.

At this stage, attempts at overcoming viral diseases in both rice and papaya are being made by using both the particle bombardment as well as the *Agrobacterium*-mediated gene delivery system. MARDI is also focusing on the postharvest aspects of our local fruits to make them more amenable to export, by studying the various enzymes involved in the ripening process and employing biotechnological tools to delay ripening and increase the shelf life of fruits such as papaya and pineapple.

The Palm Oil Research Institute of Malaysia (PORIM) is currently concentrating research efforts on oil quality, tissue culture and genetic studies. The genetic engineering of oil palm for the production of oil high in mono-unsaturated and free fatty acid content tops the list of the many projects undertaken by this Institute. Work is directed at developing a reproducible transformation system in oil palm to materialize the research efforts to improve the oil quality.

The Rubber Research Institute of Malaysia (RRIM) has adopted a 2-point approach in plant biotechnology, to ultimately improve *Hevea* with the introduction of useful foreign genes of importance, and the use of tissue-specific promoters to target the genes for expression in the appropriate tissues of the tree. DNA delivery systems have already been developed in *Hevea* and preliminary results using reporter genes have indicated stable transformation.

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Besides biotechnological research carried out by these institutes, the universities namely the Agricultural University of Malaysia, Science University of Malaysia, University Malay and The National University of Malaysia have also invested time and effort in this area to help overcome the various constraints faced by the agriculture industry.

The development of new technologies has generated the emergence of products (including organisms) that will revolutionize agriculture in Malaysia. However, like everything else, if the technology is not applied safely, effectively and with utmost precaution, adverse effects will be detrimental both to human health and the environment. Thus due consideration was given to this very important aspect and several steps were taken, among which the setting up of the National Advisory *ad hoc* Committee on Genetic Manipulation (NACGM), organization of one day consultations on Biosafety and a National Consultative Workshop on Biosafety. The draft document on guidelines for the release of GMOs into the environment has been scrutinized and is awaiting Cabinet approval. Accompanying and complementing this document is also a guideline on laboratory code of conduct and contained use of GMOs.

The objectives of the NACGM are to ensure that any risks associated with the use, handling and transfer be identified and safely managed and to advise the government about matters on genetic manipulation technology and its applications. Among the many functions of the committee are :

- provide advice to research organisations, Federal and State agencies and institutions in the private sector on matters concerning biosafety and factors associated with genetic modification activities.
- serve as a focal point for handling inquiries, proposals and ensuring enforcement concerning use, handling, transfer and release of GMOs.
- establish the guidelines for importation, research involving genetic modification, testing, release and utilization of GMOs.
- monitor and assess the implementation of the guidelines.
- manage databases on work considered by the NACGM.
- notify relevant authorities, whether Federal or State-based of any activities in relation to GMOs.
- promote public awareness programs for safety in biotechnology.
- promote harmonization of regulation, processes and guidelines as deemed relevant.

In pursuing the functions the Committee shall:

- 1) Provide the Ministry: advice on whether or not a particular project or product/processes using genetic modification should proceed and report from time to time on activities of the committee.
- 2) Provide advice to Institutional Biosafety Committee (IBC) on the implementation of the guidelines.
- 3) Provide specialist technical advice and training on biosafety issues to organizations using these techniques and to regulatory agencies.

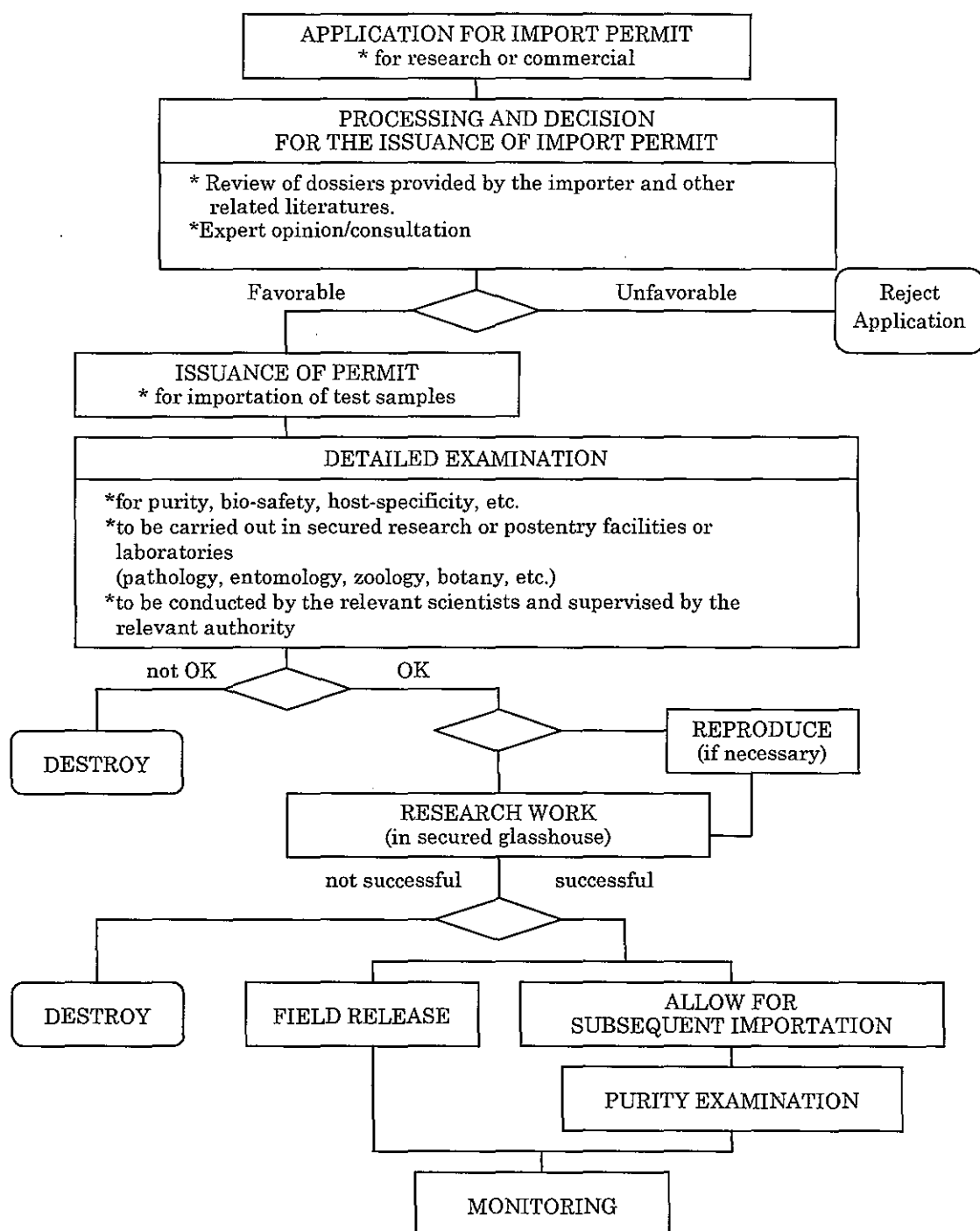
- 4) Institute procedures to protect commercially sensitive information submitted as part of any risk assessment review.
 - 5) Immediately advise the IBC and the most appropriate Federal or State agency, should the Committee become aware of any project or activity in which biosafety is known, or thought likely, to be seriously compromised.
 - 6) Review and assess proposal on genetic modification activities and on the planned release of genetically modified organisms (GMOs) into the environment; and make available detailed statements to appropriate agencies of reasons for the assessment made, including agriculture, health, safety, environmental and any broader social issues taken into account.
 - 7) Disseminate information on release of GMOs to the public.
- The establishment of the Institutional Biosafety Committee (IBC) within an institution is vital in providing a focal point for overall assessment and advice on the genetic modification activities and compliance with the guidelines. The roles and responsibilities of the IBC are as follows :
 - 1) The IBC is responsible for ensuring that all genetic modification activities comply with the guidelines.
 - 2) Institute risk safety analysis in order to identify all potential hazards.
 - 3) Inform NACGM with regard to IBC assessment of the proposal for review and assessment.
 - 4) Provide advice and risk management strategies to the proposer following NACGM assessment of the risk associated.
 - 5) Ensure Institution complies with the correct containment levels, transgenic animal facilities, infectious animal holding facilities, and glasshouses for use in genetic modification activities.
 - 6) Continuous assessment of the facilities, procedures, and of the training and expertise of personnel involved.
 - 7) Provide reports of the institutional activities to NACGM from time to time.
 - 8) Implement emergency plans covering accidental spills, decontamination procedures and plans to recall.

At present, only preliminary glasshouse trials of transgenic materials are being carried out in research institutes and universities under very strict regulations. Once the biosafety guidelines have been approved by the government, the researchers will be able to carry out field trials of both locally produced transgenic materials as well as imported ones, taking Malaysian agriculture to the heights that we once dreamed of.

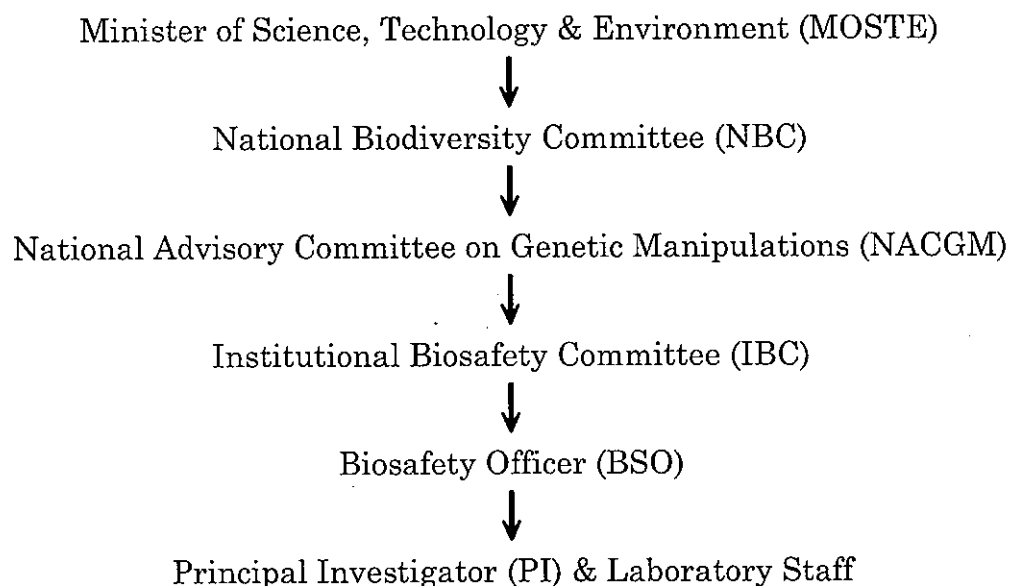
References

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GENERALIZED FLOW CHART FOR THE
IMPORTATION AND RELEASE OF MICROORGANISMS



FRAMEWORK OF ORGANISATION

List of Departments related to the role and responsibilities of NACGM:

Dept. of Environment (DOE)
Dept. of Agriculture (DOA)
Fisheries Department
Veterinary Services Department