MALAYSIA - COMMENTS ON CONTAINED USE OF LIVING MODIFIED ORGANISMS (LMOS)

CBD NOTIFICATION 2016-009 – SUBMISSION OF INFORMATION REQUESTED IN DECISION ON CONTAINED USE (ARTICLE 6)

A. RELEVANT REGULATORY REQUIREMENTS FOR CONTAINED USE ACTIVITY

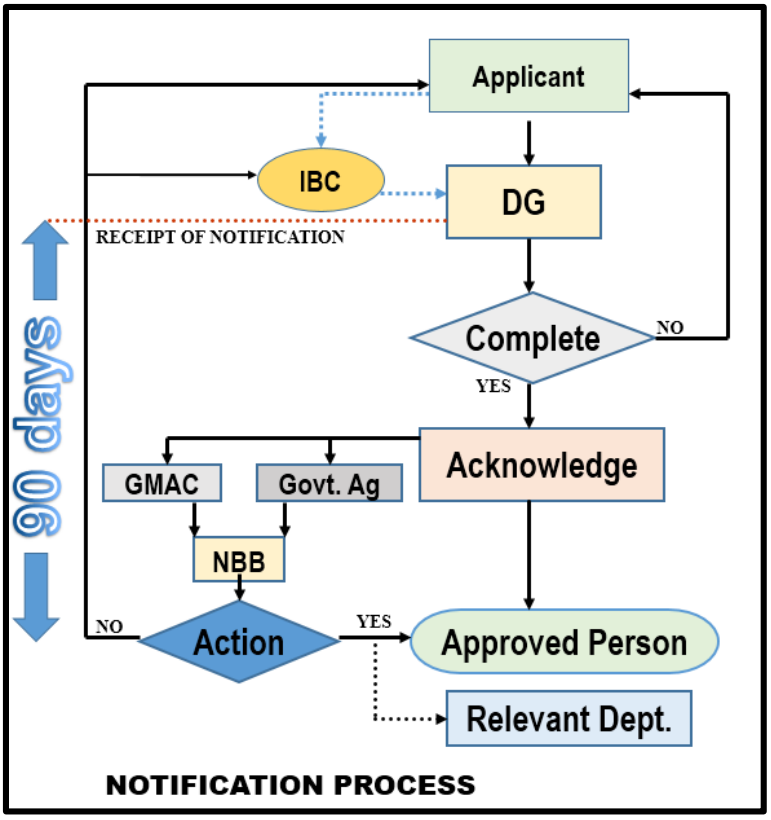
1. All activities involving Living Modified Organism (LMO) in Malaysia is regulated by the Biosafety Act. The objective of the Act is to protect human, plant and animal health, the environment and biological diversity from any possible risks resulting from LMO or its product.
2. All contained use activity involving LMOs are regulated. Under the law, contained use carries the definition of any operation including research and development, production or manufacturing operation involving LMO, or storage of LMO, undertaken within a facility, installation or other physical structure such that it prevents the contact and impact of the LMO on the external environment.
3. All activities involving contained use of LMOs and import of LMOs for the purposes of contained use requires an approval from the National Biosafety Board (NBB)(refer to S.22 of the Act). A penalty is imposed for any non-compliance.
4. A Notification is required to be submitted for the purpose of getting clearance from the NBB. Information about the contained use activity and the proposed risk assessment of the activity and specific management of those risks are submitted using the relevant form, and this includes an emergency response plan.
5. There are some exemptions given to some techniques and activities that have been assessed over time and have proven to have low risk. It involves working with very well understood organisms and processes for creating and studying LMOs. However some conditions apply for the techniques or activities or be exempted. Even though some activities are exempted, it is expected that these activities are to be conducted with Good Laboratory Practices and it has to be ensured that no release can take place. The full details of exempted activities are found in the First Schedule of the Biosafety (Approval and Notification) Regulations 2010.
6. All Institutes involved in research and development involving LMOs are required to set up an Institutional Biosafety Committee (IBC). This is a formal expert committee set up by these institutes and the members are appointed by management of the institute. This committee is recognized through registration with the NBB [Regulations 5 of the Biosafety (Approval and Notification) Regulations 2010].
7. The role of monitoring all modern biotechnology activities by the NBB is delegated to the IBC. Therefore, the IBC is set up to:
   a) Provide guidance for safe use of modern biotechnology
   b) Monitor activities relating to modern biotechnology
   c) Establish and monitor the implementation of policies and procedures for the purpose of handling LMOs

d) Determine the classes of Biosafety Levels for contained use activity for the purpose of modern biotechnology research and development undertaken within a facility where the IBC is established

8. The IBC determines the Biosafety Level for the activity. Inspection of facilities are conducted to ensure that it fulfills the criteria set in the Guidelines. The specific biosafety levels (BSL) used are specified under the Second Schedule of the Biosafety (Approval and Notification) Regulations 2010. The final decision on the risk management measures that is mandatory to be implemented is determined by the NBB after consultation with Genetic Modification Advisory Committee (GMAC).
9. Guidance to conduct an inspection of facilities is provided on the Department of Biosafety website resources (www.biosafety.nre.gov.my).
10. In addition, the IBC also monitors any exempted LMO activities that take place in their respective institutes.

B. BRIEF EXPLANATION ON THE ADMINISTRATIVE PROCESS

1. An application for notification must be completed and submitted to the Director General (DG) of Biosafety and be accompanied with Emergency Responses Plan and Specific measures for the contained use activity.
2. There is no fee imposed for submission of a Notification.
3. For all research and development activities of contained use, the application of Notification must be assessed and approved by the respective IBCs prior to submission to the DG.
4. 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.
5. DG shall refer the notification to the GMAC and any relevant agencies for its recommendation. GMAC is a committee appointed by the NBB to provide scientific, technical and other relevant advice.
6. Upon completion of the assessment, GMAC will forward its recommendation on the notification to the NBB.
7. Upon having considered the recommendations of the GMAC, the 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 the NBB thinks fit in the interest of biosafety.
8. The NBB will make its decision within ninety days from the date of receipt of the notification and will communicate its decision in writing to the approved person.
9. A flowchart of the process is provided below:



C. GUIDANCE AVAILABLE

1. Biosafety Guidelines : Contained Use Activity of Living Modified Organisms
2. Institutional Biosafety Committee Guidelines

D. CAPACITY BUILDING INITIATIVES

1. Biosafety Training Workshops are conducted by the Department of Biosafety with the expertise of the GMAC members. This is a two day workshop module that provides training on requirements of the Biosafety Act, specific requirements for handling LMOs and conducting risk assessment and risk management of LMOs.
2. The Department of Biosafety has conducted 29 of these trainings to date since 2011.

E. PRACTICAL EXPERIENCE

1. Malaysia has reviewed and approved at least 82 contained use activities handling LMOs to date since 2010.
2. Contained use activities of LMOs that have been approved by the NBB thus far involves microbes (39%), plants (50%), arthropods (2%), and animals (9%).
3. So far, only facilities of BSL1 and BSL2 are being used for these contained use activities. There has been no application yet for any LMO activity requiring a higher BSL.
4. Continuous monitoring of the activity is done by the respective IBCs as well as scheduled/random inspection by a Monitoring Committee under the GMAC to ensure compliance to all terms and conditions imposed for the approved contained use activities.