Contained Use

Genetically Modified Organisms

What are Genetically Modified Organisms and Genetically Modified Micro-organsims ?

Genetically Modified Organisms (GMOs) are organisms in which the genetic material has been altered in a way that does not occur naturally. GMOs can be bacteria, fungi, viruses, plants or animals, with the exception of human beings. All organisms contain genes, which are lengths of deoxyribonucleic acid (DNA) that is present in every cell. Genes carry the information necessary to produce the numerous proteins that determine the organism's particular form and function. Therefore, genes are responsible for specific characteristics of organisms.

In the past, traditional plant breeders have introduced desired characteristics into a plant by crossing different varieties to mix their genes and thereby alter the genetic make-up. This process is called selective breeding. Nowadays, research and development have led to a better understanding of the science of genes. In fact, scientists have managed to take out a single gene from the DNA of one organism and insert it into the DNA of another organism, to confer the desired traits, such as a plant that is resistant to a specific pest. This transfer is also possible between non-related species. The process of genetic modification which results in GMOs is called genetic engineering.

Genetically Modified Micro-organisms (GMMs) are micro-organisms who's DNA has been altered by inserting a gene from a different organism. Examples of GMMs include bacteria, viruses and viroids as well as animal and plant cells in culture.

Contained Use

Contained use covers any activity involving GMOs (or GMMs) carried out under containment and in which measures are taken to limit contact between these organisms, people and the environment. It relates to the actual process of genetic modification, as well as to the use, storage, transport and destruction of GMOs. Typical

contained use facilities can be microbiology laboratories, animal houses, greenhouses or industrial production facilities.

Why do we need controls and legislation?

A considerable number of contained use activities involve organisms which do not cause disease and are very unlikely to survive in the environment outside a containment facility. However, some contained use activities are carried out with more hazardous organisms whose escape from containment could result in adverse effects on human health and / or the environment. It is, therefore, very important to assess the risks of all activities and to make sure that any necessary controls are put in place to protect

people and the environment. Consequently, there is legislation in Malta and the EU to control and lay down measures for contained use activities. The Contained Use of GMMs Regulations, 2002, (Legal Notice 169 of 2002), as amended, give effect to EU Directive 90/219/EEC, as amended by Directive 98/81/EC. Malta Environment and Planning Authority (MEPA) is the

designated competent authority in Malta for the implementation of these regulations.

The legislation requires the applicant to carry out a thorough risk assessment, which is then reviewed by MEPA with the help of its advisory committee, the Biosafety Co-ordinating Committee (BCC). In its annexes the legislation outlines the risk assessment procedure that should be followed to determine which containment level is necessary and into which classification category the GMM and the proposed activity fall.

In some cases, the containment measures indicated in the risk assessment and those recommended for a particular class by the authorities will not match exactly, thus falling in between two classes. In such cases, the activity will be assigned to the class of higher risk.

Obligations under LN169 of 2002

Anyone carrying out contained use activities must comply with LN169/02, particularly:

1. Notify MEPA of their intention to use their premises for contained use activities for the first time
2. Carry out an assessment of the risks to human health and the environment associated with every contained use activity before it begins, review and revise the assessment as necessary, and keep relevant records
3. Establish a genetic modification safety committee to advise on risk assessments
4. Classify all activities as described in Annex IV and notify MEPA

5. Apply the necessary containment and control measures indicated by the risk assessment
6. Draw up emergency plans for activities of higher risk, and notify the authorities regarding any accidents that occur

Classification of GMOs

Local and EU legislation classify GMOs into four classes:

- Class 1 – activities of no or negligible risk
- Class 2 – activities of low risk
- Class 3 – activities of moderate risk
- Class 4 – activities of high risk

Most genetically modified plants are considered to be Class 1 because they are not usually modified to contain DNA sequences from human disease causing organisms. On the contrary Class 4 is reserved for highly dangerous pathogens such as small pox which are highly transmissible and for which there is no prophylaxis.

Public register and Confidentiality Claims

LN169/02 has provisions for public access to notifications of both premises and activities. All information is accessible to the public, except where a specific confidentiality claim is made by the applicant and deemed valid by MEPA. However, no confidentiality claims may be made on information listed in Article 17 (3) of LN169/02.

Application Procedures

When undertaking genetic modification procedures for the first time, each applicant must register the premises with MEPA and specify the activity concerned. For premises in which Class 1 activities are being carried out applicants are required to keep record of each risk assessment and make it available to MEPA on request. Applicants undertaking Class 2, 3 and 4 activities need to notify MEPA regarding each new activity.

Notification processes required for different classes of micro-organisms				
CLASS 1 negligible risk	**CLASS 2 low risk**		**CLASSES 3 - 4 moderate & high risk**	
	PREMISES ALREADY NOTIFIED	PREMISES NOT NOTIFIED	PREMISES ALREADY NOTIFIED	PREMISES NOT NOTIFIED
Class 1 Notify premises **THEN** Proceed without further notification but keep record of each assessment to be available on request	**Class 2** Proceed without further notification **or** OPTIONAL Request decision on a formal authorisation by the competent authority (within 45 days)	**Class 2** Submit notification **THEN** Proceed 45 days after submission or earlier with the agreement of the competent authority	**Classes 3 - 4** Submit notification **THEN** Proceed after written decision at least 45 days after submission	**Classes 3 - 4** Submit notification **THEN** Proceed after written decision at least 90 days after submission

For more information on the BCC, the regulatory process and application forms please visit the MEPA website on:
www.mepa.org.mt

Any requests for information can also be sent to:

Nature Protection Unit
Environment Protection Directorate
Malta Environment & Planning Authority
St. Francis Ravelin,
Floriana

Mail: PO Box Marsa GPO 01 Malta
Email: gmo@mepa.org.mt
Tel: (+356) 2290 6009
Tel: (+356) 2290 3091
Fax: (+356) 2290 2295

This publication was financed by the UNEP-GEF project for the Development of a National Biosafety Framework for Malta

ISBN 99932-82-26-6

Printed on TCF paper