Release in the Environment

Genetically Modified Organisms

What are Genetically Modified Organisms?

Genetically Modified Organisms (GMOs) are organisms (bacteria, viruses, fungi, plants and animals) in which the genetic material has been altered in a way that does not occur naturally. All organisms contain genes, which are lengths of deoxyribonucleic acid (DNA) that are present in the nucleus of every cell. These genes determine specific characteristics, such as insect resistance. Thus, through genetic engineering, selected individual genes are transferred from one organism into another, to confer the desired traits. This transfer is also possible between non-related species.

How are GMOs released into the environment?

There are two broad categories of release of GMOs into the environment:

- releases for experimental purposes, known as field trials (Part B releases)
- releases by placing on the market for commercial purposes (Part C releases)

Why and how are these releases regulated?

Although considerable work has been carried out in the field of GMOs and a large amount of data has been gathered, there are still concerns as regards the safety of human health and the environment.

Consequently, in the EU and Malta there are strict regulations controlling the release of GMOs into the environment. The Deliberate Release of GMOs into the Environment Regulations, 2002 (Legal Notice 170/2002) give effect to Directive 2001/18/EC on the Deliberate Release of GMOs into the Environment. The Malta Environment and Planning Authority (MEPA) is the designated Competent Authority in Malta for the implementation of these regulations.

The regulations apply to all GMOs, although plants have been the subject of most interest in recent years. The legislation adopts a step-by-step approval process on a case-by-case assessment of the risks to human health and the environment before any GMO, such as maize,

tomatoes, or micro-organisms, can be released into the environment.

The entire regulatory process is underpinned by a detailed environmental risk assessment, prepared by the applicant, who examines and evaluates any possible harmful consequences of releasing a particular GMO. The competent authority reviews this assessment with the help of its advisory committee, the Biosafety Co-ordinating Committee.


By courtesy of Central Science Laboratory, UK

Products derived from GMOs, such as paste or ketchup from a GMO tomato, are not covered by these regulations.

Who are the key stakeholders ?

The key stakeholders who may be affected by these regulations include:

- importers of seeds, grains and crops
- importers of other organisms, such as animals and micro-organisms
- farmers

How is consent for a field trial obtained?

Consents to release GMOs into the environment for experimental purposes (Part B releases), are only valid for releases in Malta, and are subject to the following procedure:

Submission

The applicant should contact MEPA prior to submitting a notification, in order to advise that a notification is to be submitted and clarify any uncertainties before submission.

Applicants must then submit a detailed notification to MEPA. Amongst the information required in the notification, it should include: information on the nature of the GMO; how it has been

modified; the precise nature of the research programme proposed; where it will be released and how will the release be monitored.

Once MEPA confirms that the notification is complete, the notification is considered as valid, and the review process commences.

Review

MEPA has 90 days to review the notification. The information in the notification, which is duly marked for inclusion in the public register, would be made available to the public.

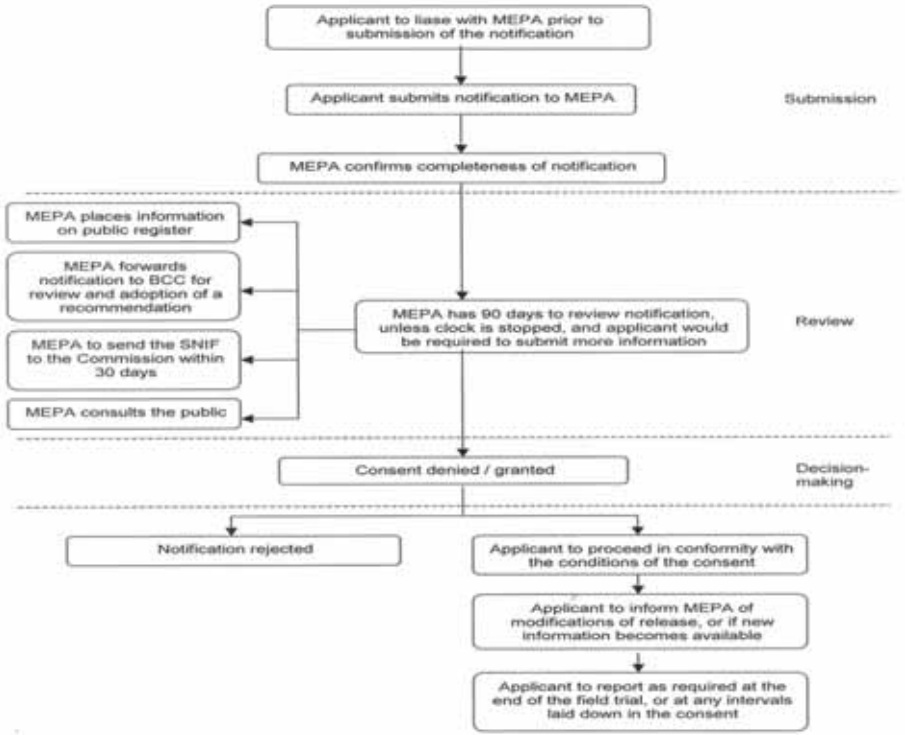
MEPA forwards the notification to its advisory committee, the Biosafety Co-ordinating Committee (BCC), which is composed of various government entities. The latter will examine the application and a recommendation is given.

The Summary Notification Information Format (SNIF) submitted with the notification would be also sent to the European Commission within 30 days after the review process has initiated.

Decision-making

Following consideration of the recommendation by the BCC, MEPA will grant / reject consent. If a consent is granted it is likely to include a number of conditions, by which the applicant has to abide.

Procedural steps and timescales for the experimental release of GMOs



How is consent for a GMO to be placed on the market obtained ?

Consents for GMOs to be grown, processed or imported for commercial purposes (Part C releases) are valid across the EU, and are subject to the following procedure:

Submission

The applicant submits a notification to a national competent authority of a Member State of his own choice.

The notifications must contain a full environmental risk assessment, including amongst others, a post-marketing monitoring plan and a proposal for labelling and packaging.

Review

The Member State where the notification was submitted takes the lead and conducts a thorough review of the notification.
If a negative opinion is given, the applicant may wish to withdraw the notification, before it is circulated and hence becomes public.

If a favourable opinion is given by the lead Member State, the full notification, the Member State's assessment report and the SNIF are forwarded to the European Commission.

Consultation

The Commission circulates the notification to the other 24 Member States for further evaluation and comments by their

competent authorities, as the final decision is then subject to a collective decision by all EU Member States.

MEPA can therefore be:

- the competent authority which takes the lead, if the applicant submits the notification in Malta, or
- one of the competent authorities of the 24 Member States, which are consulted at this stage

This first consultation period is of 60 days and as part of the review of any such application, MEPA seeks the recommendation of the Biosafety Co-ordinating Committee (BCC).

If there are no objections by the Member States, the competent authority that carried out the original assessment, grants the consent for the placing on the market of the GMO. This consent is valid throughout the EU.

If objections are raised, the applicant is allowed to respond to the Member States' objections and comments. The applicant's responses are circulated by the Commission to the Member States and a further 45 days are allowed for Member States to evaluate the information submitted by the applicant. If objections are maintained by any of the Member States during this second and final period of consultation, a decision has to be taken at Community level.

Decision-making

The Commission first asks the opinion of its Scientific Committees. If the scientific opinion is favourable, the Commission then proposes a draft Decision to the Regulatory Committee composed of representatives of Member States, for opinion.

If the Regulatory Committee gives a favourable opinion, the Commission adopts the Decision and a consent is issued accordingly by the competent authority of the lead Member State. If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not reach a decision within 3 months, the Commission can adopt the Decision.

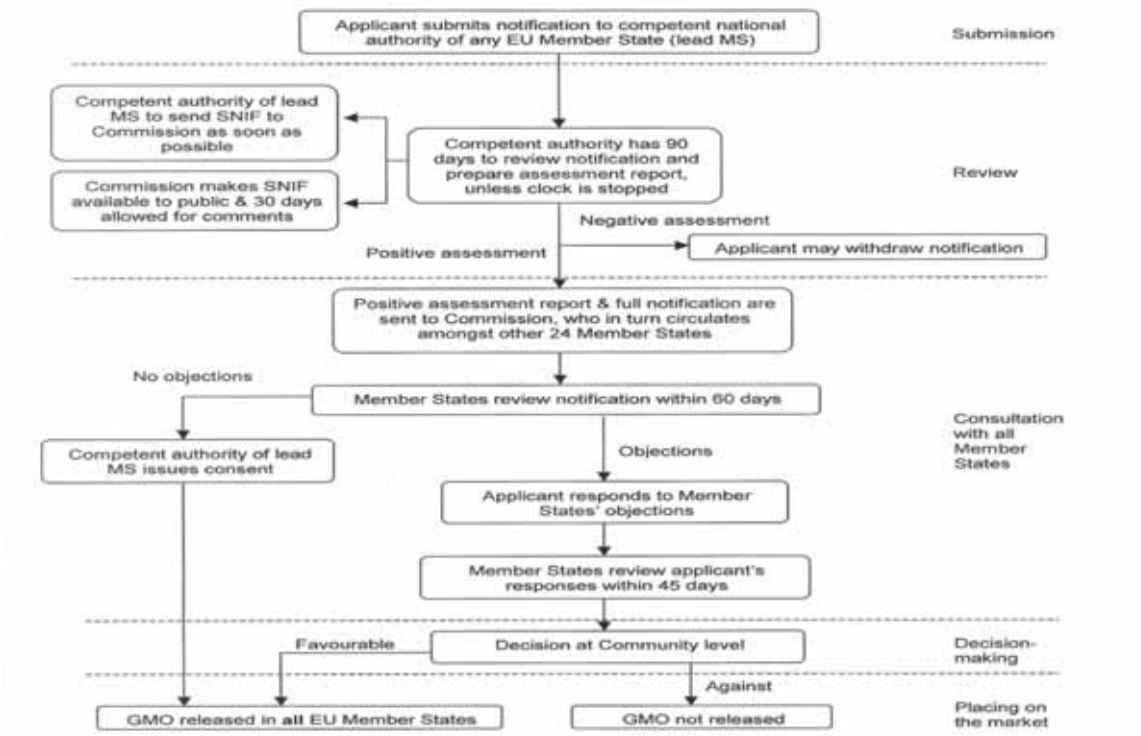
Placing on the market

The consent is valid for the whole of the EU and it is subject to any conditions or restrictions agreed by Member States.

Public Participation & Consultation

During the regulatory process, the public is informed and has access to the publicly available data on the Internet at http://gmoinfo.jrc.it. Such data includes the SNIF and assessment report of the lead Member State. Comments may also be submitted here.

Procedural steps and timescales for placing on the market of GMOs



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:

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