NATIONAL BIOSAFETY FRAMEWORK FOR MALTA

December 2006

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List of Acronyms

BCC	Biosafety Co-ordinating Committee
CBD	Convention on Biological Diversity
CPBS	Cartagena Protocol on Biosafety
EFSA	European Food Safety Authority
EMeA	European Medicines Authority
ENGL	European Network of GMO Laboratories
EPA	Environment Protection Act
EU	European Union
FAVD	Fisheries, Aquaculture & Veterinary Division
FSC	Food Safety Commission
GEF	Global Environment Facility
GMMs	Genetically Modified Micro-organisms
GMOs	Genetically Modified Organisms
LMOs	Living Modified Organisms
LN	Legal Notice
MEPA	Malta Environment and Planning Authority
MSA	Malta Standards Authority
NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategy and Action Plans
NSSD	National Strategy for Sustainable Development
OHSA	Occupational Health and Safety Authority
RAPAD	Rural Affairs and Paying Agency Division
SNIF	Summary Notification Information Format
UNEP	United Nations Environment Programme

Foreword

Executive Summary

Genetically Modified Organisms (GMOs) and genetically modified foods and feeds have become subjects of considerable public debate, since there are differing views concerning the safety of GMOs on human health and the environment. This gave rise to the development of various international and EU laws to regulate and control the use, handling and placing on the market of GMOs and GM products.

Malta has transposed EU laws related to GMOs into national legislation and it is in the process of acceding to the Cartagena Protocol on Biosafety. Furthermore, Malta felt the need to approach this subject in a holistic manner and at a strategic level by means of developing a national framework. Subsequently, Malta applied for funds from the United Nations Environment Programme (UNEP) and Global Environment Facility (GEF) to develop a National Biosafety Framework (NBF).

A NBF commonly consists of a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of GMOs. The main purpose of the NBF for Malta is to give an overview of what has been done and what is in place in Malta and to indicate what still needs to be done.

National Biosafety Policy: Malta does not have a national biosafety policy, however, biosafety and GMOs are addressed in various other policies of different sectors.

Regulatory System: The regulatory system to deal with GMOs & GM products has been set up in Malta. Future goals identified for this system include accession to the Cartagena Protocol, the need to address co-existence of conventional and organic farming with GM crops and a memorandum of understanding to define operating procedures in connection with application concerning clinical trials.

Systems for Handling Notifications: A number of systems to handle notifications are already in place in the relevant competent authorities. However, some improvements that are required have been identified following experience gained through the use of such systems. The document also sets out the different competencies of the different entities with respect to the different types of notifications.

Monitoring and Enforcement Systems: A considerable number of entities should be involved in some way or another in the monitoring and enforcement of GMOs. However, currently there is little enforcement in this field. Consequently, one of the most important future need that has been identified is that each entity takes ownership of its share in the enforcement of biosafety and GMOs.

Mechanisms for Public Participation & Information: Although these systems have been established, they are not in practical use since no applications have been submitted in Malta to date.

This document gives an overall picture of biosafety issues in Malta, their current statues and highlights outstanding issues, which need to be addressed in the future.

1. INTRODUCTION

A National Biosafety Framework (NBF) is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of genetically modified organisms (GMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

These organisms are also known as living modified organisms (LMOs). For example, the Cartagena Protocol on Biosafety refers to GMOs as such. However, these two terms can be considered to be synonyms and can therefore be used interchangeably.

1.1 Outline of the NBF

This chapter summarises the contents of subsequent chapters to provide an overview of the whole framework. The purpose of the NBF and background to it are described. Generic information concerning the funded project through which this NBF was set up is also given, as well as definitions of some of the terminology that was used in this framework.

Although NBFs vary from country to country, they often contain a number of common components:

1. a national policy on biosafety
2. a regulatory regime for biosafety
3. a system to handle notifications or requests for authorisations
4. systems for 'follow up' such as enforcement and monitoring
5. mechanisms for public awareness, education and participation

Thus, chapters two to six discuss each of the above-mentioned components.

The seventh chapter concludes the NBF, whilst highlighting some of its important features and provides some broad recommendations.

1.2 Purpose of the NBF

The purpose of the NBF for Malta is twofold:

a) to give an overview of what has been done and what is in place in Malta (i.e. legislation, administrative systems etc.); and

b) to indicate what still needs to be done in order to complete the NBF. For example, this could include missing legislation that still needs to be drafted/adopted and gaps in administrative or enforcement systems.

1.3 General Background

GMOs and genetically modified foods and feeds have become subjects of considerable public debate. The controversies are the result of differing views concerning the products of the new biotechnology, commonly referred to as recombinant DNA technology or genetic engineering. This technology has allowed scientists to move a gene from one organism into a completely different species – for example Bt-maize, in which the Bt gene (which codes for a Bt toxin) is derived from a soil organism and inserted into maize in order to protect maize plants from insect pests - something that was not possible by traditional selective breeding.

Some believe that this technology has opened new horizons and GMOs are an important humanitarian tool, which could bring life-saving benefits to the developing world, as well as economic benefits to farmers and a better quality of life for consumers. However, others question the consequences of GMOs, especially vis-à-vis the safety of these organisms and their products for human consumption and the potential harm to the environment. Other controversies have also arisen with respect to the ethical concerns of GMOs and GM foods and feeds.

Thus, due to the rapid development of modern biotechnology and the opposing views on this issue, a number of important pieces of legislation concerning biosafety have been developed in the past decades.

The Cartagena Protocol on Biosafety is an important treaty in this respect. It focuses specifically on transboundary movement of any GMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health, and setting out for consideration, in particular, appropriate procedures for advance informed agreement. This Protocol also reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development and takes into account the growing public concern over the potential adverse effects of GMOs on biological diversity and human health. It also recognises that modern biotechnology has great potential for human well being if developed and used with adequate safety measures for the environment and human health.

The European Union (EU), to which Malta acceded in May 2004, has also set up a thorough legal framework for regulating the contained use and deliberate release into the environment of GMOs, their import and export, the production of GM food and feed and their traceability and labelling.

Malta adopts a case-by-case approach when assessing applications related to GMOs. Moreover, the precautionary principle is observed to ensure the highest possible level of safety for the environment and human health.

Besides the development of various pieces of legislation, a number of countries have also felt the need to establish a NBF to ensure that adequate measures and systems are in place or set-up to protect human health and the environment from possible effects of modern biotechnology. Malta has applied for funds from the United Nations Environment Programme (UNEP) and Global Environment Facility (GEF) Project on the Development of a National Biosafety Framework in order to be able to develop a NBF.

1.3.1 UNEP-GEF Project on the Development of a NBF for Malta

The UNEP-GEF Project on the Development of a National Biosafety Framework for Malta started in May 2004 and ended in August 2006.

The *National Executing Agency* for the UNEP-GEF project was:

Malta Environment and Planning Authority (MEPA)
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The *National Project Co-ordinator* was:

Ms. Nadia Suda Lanzon
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St. Francis Ravelin
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The *National Coordination Committee* consisted of ten members, who are representatives from the following entities:

Dr. Godwin Cassar	Director General, MEPA / Chairman
Ms. Nadia Lanzon	National Project Co-ordinator, MEPA / Secretary
Mr. Alfred E. Baldacchino	Assistant Director Nature Protection, MEPA
Mr. Darrin Stevens	CBD National Focal Point, MEPA
Mr. Joseph Abela Medici	CPBS National Focal Point, MEPA
Mr. John Attard Kingswell	Department of Public Health
Mr. Cedric Camilleri	Occupational Health and Safety Authority (OHSA)
Dr. David Mifsud	Rural Affairs and Paying Agency Division (RAPAD)
Dr. Marion Zammit Mangion	Scientific consultant
Mr. Tristan Camilleri	Malta Standards Authority (MSA)

1.4 Definitions

Biosafety: means the use of a range of measures, policies and procedures for minimising potential risks that modern biotechnology may pose to the environment and human health;

Consent: means permit;

Enforcement: means following-up non-compliance situations that are identified during an inspection;

Genetically Modified Organisms (GMOs): means organisms, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. These organisms are also known as living modified organisms (LMOs). The Cartagena Protocol on Biosafety refers to them as such. However, these two terms can be considered to be synonyms and can therefore be used interchangeably;

GM product: means a product which is derived from GMOs and which consists of or contains GMOs;

Inspection: means the check for compliance with biosafety conditions for activities with GMOs. This may include the review and investigation of facilities, materials and documents related to GMOs;

Modern biotechnology: means the application of:
a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

Monitoring: means the scientific collection of data to support the scientific basis for biosafety decisions. It also describes the systematic measurement of the effects of GMOs over time;

Notification: means an application that must be submitted to the competent authority for a permit. In the field of GMOs, this notification is usually a dossier of information submitted by the applicant. Malta refers to these applications as notifications in order to be consistent with EU terminology and legislation;

Organism: means any biological entity capable of replication or of transferring genetic material.

2. NATIONAL BIOSAFETY POLICY

2.1 Current situation

Malta does not have a stand-alone national policy document on biosafety as yet. Since Malta joined the EU in May 2004, its biosafety policy is similar to that advocated by EU legislation. In fact, EU law has been transposed into national legislation, which entered into force in 2004. As a member of the EU, Malta follows the principles of EU legislation and therefore assesses the use of GMOs and GM products on a case-by-case basis. Malta is also in the process of acceding to the Cartagena Protocol on Biosafety.

Biosafety policy in Malta is part of wider policies, especially in the field of environmental protection. The Environment Protection Act (Act XX of 2001, as amended by Act II of 2006) is the principal legislation to protect the environment and to assist in the taking of preventive and remedial measures to protect the environment and manage natural resources in a sustainable manner. In relation to the protection of biodiversity, it specifically allows to:

> *"control, manage and regulate the transport, introduction of, use (including contained use), release or placing on the market or in the environment of genetically modified organisms"*.

Biodiversity conservation policy is one area of environmental protection in which biosafety is commonly addressed. On 12 December 2001, Malta ratified the Convention on Biological Diversity (CBD), which aims to reach the following objectives:

- the conservation of biological diversity
- the sustainable use of its components
- the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Thus, biodiversity conservation policy in Malta is based on the principles of the CBD, as well as on the principles of EU law, which conform to the above.

Moreover, Malta is currently in the process of developing its National Biodiversity Strategy and Action Plans (NBSAP) as one of the obligations as required under Article 6 of the CBD. The main objective of the NBSAP is to ensure the conservation and sustainable use of biological diversity. This principle will also be integrated, as far as possible, into relevant sectoral or cross-sectoral plans, programmes and policies. It has already been identified that GMOs and biosafety will be tackled whilst developing the NBSAP and appropriate actions are also envisaged to be included.

Malta has also compiled a draft National Strategy for Sustainable Development (NSSD) for a ten-year period from 2006 to 2016. This strategy recognises the need for strategic direction in the field of GMOs and supports the development of policy on the use of GMOs. It also recommends that the Cartagena Protocol on Biosafety should be ratified as soon as possible.

Biosafety is currently not specifically addressed in Malta's science and technology policy. However, in the new Research and Innovation Plan for 2007 – 2010, the idea is to move towards the setting up of platforms of strategic importance in the energy / environment and health / biotechnology sectors where the biosafety policy concerns may be addressed.

Malta's main priority and target in relation to biosafety is to become in line with the EU acquis and all international treaties, which concern GMOs, GM food and GM feed.

As can be concluded from the above, although Malta does not have a stand-alone policy on biosafety, it is still partially or fully addressed in other policy areas. The technical and financial support received through the UNEP-GEF project 'Development of a National Biosafety Framework for Malta' has been extremely valuable to initiate discussions between various Maltese stakeholders on how biosafety can be addressed in all sectors. It has also been very useful to speed up the process of understanding the current situation, identifying gaps and future needs and consequently setting up a national framework in relation to biosafety.

2.2 Future goals and needs

There is a necessity to further define national competencies in the areas of GMOs and GM products, so as to avoid lack of commitment due to undefined or overlapping issues. Adequate support in terms of resources is also needed to ensure the efficient and effective implementation of this national biosafety framework and relevant legislation.

In addition, organic farming is increasingly being promoted in Malta and so this results in a need to define a competent authority for co-existence of conventional farming, organic farming and GM crops in order to establish a national policy on these issues.

Accession to the Cartagena Protocol is also of utmost importance in order to complete Malta's policy with respect to GMOs and biosafety.

3. REGULATORY SYSTEM

3.1 Current regulatory system

In Malta, the current regulatory system concerning GMOs and biosafety mirrors closely EU legislation, since Malta joined the EU in May 2004. On the other hand, as regards international legislation Malta is still not a Party to the Cartagena Protocol on Biosafety. However, some steps are already being taken in order to implement its obligations.

Acts are the main pieces of legislation in Malta and this type of legislation is referred to as primary legislation. Under each Act, subsidiary or secondary legislation is issued as necessary. Secondary legislation is often in the form of regulations, which are referred to as legal notices.

The legislation whose scope directly deals with GMOs is described below. However, other legislation which refers to GMOs, but its focus is not on this subject area is included in Annex I. A list of **all** legislation comprising both that described below and that described in Annex I is given in Annex II for ease of reference.

In order to understand better how the competencies on various aspects related to GMOs are distributed, a brief overview of the institutional system of Malta is described below.

The institutional system of Malta

In Malta central government is composed of fourteen ministries which are largely engaged in preparing business for the government, in the form of draft legislation and policies. Each of the fourteen ministries is made up of a number of departments.

Ministries can also have other entities, such as authorities, which fall within their remit. These authorities are autonomous in the sense that they act on their own responsibility, but in accordance with guidelines issued by the government. The role of these entities is to implement at a practical level the decisions of the government.

3.1.1 Legislation in the Environment Protection Sector

A. The Contained Use of Genetically Modified Micro-organisms Regulations, 2002 – Legal Notice (LN) 169 of 2002 as amended

Status: These regulations issued under the EPA have been published in 2002 and entered into force on 1 March 2004.

LN 169 of 2002 was amended by LN 194 of 2002 and subsequently amended again by LN 168 of 2004 on 16 April 2004.

Objective: The objective of these regulations is to lay down measures for the

contained use of GMOs with a view to protecting human health and the environment.

Scope: The Contained Use of GMMs Regulations transpose EU Directive 90/219/EEC as amended by Directive 98/81/EC. Therefore, the scope of the Maltese regulations is very similar to that of the Directive in that they regulate any activity in which organisms are genetically modified or in which such GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.

Procedures and content: The legislation defines the procedures to be followed when applying for a permit for the contained use of GMOs. The legislation also requires the applicant to carry out a thorough risk assessment, which is then reviewed by MEPA. LN 169 of 2002 outlines, in Schedules III and IV, the risk assessment procedure that should be followed to determine which containment level is necessary and into which classification category the GMO and the proposed activity fall.

Responsible institution: MEPA is the responsible institution for the implementation of these regulations.

Enforcement of the provisions of these regulations is carried out as per Table 2 of this document.

Access to legislation: Access to Maltese regulations is available using the following links:

LN 169 of 2002 (English version)
http://www.mepa.org.mt/environment/legislation/LN_169_2002_E.pdf

LN 169 of 2002 (Maltese version)
http://www.mepa.org.mt/environment/legislation/LN_169_2002_M.pdf

LN 194 of 2002 (English version)
http://www.mepa.org.mt/environment/legislation/LN_194_2002_E.pdf

LN 194 of 2002 (Maltese version)
http://www.mepa.org.mt/environment/legislation/LN_194_2002_M.pdf

LN 168 of 2004 (English version)
http://www.mepa.org.mt/environment/legislation/LN_168_2004_E.pdf

LN 168 of 2004 (English version)
http://www.mepa.org.mt/environment/legislation/LN_168_2004_M.pdf

B. Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2002 – LN 170 of 2002

Status: These regulations issued under the EPA have been published in 2002 and entered into force on 1 March 2004.

Objective: The overall objective of these regulations is to protect human health and the environment when:

- carrying out the deliberate release into the environment of GMOs for any other purposes than placing on the market within Malta, and
- placing on the market GMOs.

Scope: The Deliberate Release into the Environment of GMOs Regulations transpose EU Directive 2001/18/EC. Therefore, the scope of the Maltese regulations is very similar to that of the Directive in that it regulates the experimental release of GMOs into the environment and also the placing on the EU market of GMOs.

Procedures and content: As in Directive 2001/18/EC, the Maltese regulations are divided into Parts and Part B describes the authorisation procedures and provisions for handling of new information, reporting by the applicant and consultation with the public in connection with applications for the experimental release of GMOs. Similarly, Part C describes the same issues but in relation to the placing on the market of GMOs.

The legislation also 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. MEPA reviews this assessment, with the help of its advisory committee, the Biosafety Co-ordinating Committee.

Responsible institution: MEPA is the responsible institution for the implementation of these regulations.

Enforcement of the provisions of these regulations is carried out as per Table 2 of this document.

Access to legislation: Access to Maltese regulations is available using the following links:

LN 170 of 2002 (English version)
http://www.mepa.org.mt/environment/legislation/LN_170_2002_E.pdf

LN 170 of 2002 (Maltese version)
http://www.mepa.org.mt/environment/legislation/LN_170_2002_M.pdf

C. Biosafety Co-ordinating Committee Regulations, 2002 – LN 290 of 2002

Status: These regulations issued under the EPA have been published in 2002 and entered into force on 13 February 2004.

Objective: The overall objective of these regulations is to set up a committee with the aim to achieve an integrated approach on biosafety, the contained use of GMMs, the deliberate release into the environment of GMOs, and the placing on the market of GMOs, in order to achieve a high level of protection for the human health and the environment taken as a whole.

Responsible institution: MEPA is the responsible institution for the implementation of these regulations.

Access to legislation: Access to Maltese regulations is available using the following links:

LN 290 of 2002 (English version)
http://www.mepa.org.mt/environment/legislation/LN_290_2002_E.pdf

LN 290 of 2002 (Maltese version)
http://www.mepa.org.mt/environment/legislation/LN_290_2002_M.pdf

D. Regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms

There are some pieces of EU legislation in the field of GMOs and biosafety, which are in the form of EU Regulations, and since they are directly applicable to all Member States they do not need to be transposed into national legislation. However, they still have to be implemented by the Member States.

The Cartagena Protocol on Biosafety is incorporated into EU legislation through a range of legislative measures governing the use of GMOs within the European Union. The cornerstone of this legal framework is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. It is supplemented by the Regulation on the transboundary movements of GMOs.

Status: This Regulation entered into force in all Member States on 5 May 2004.

Objective: The objectives of this Regulation are to establish a common system of notification and information for transboundary movements of GMOs and to ensure coherent implementation of

the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. It specifically focuses on export from the EU to third countries.

Scope: Regulation (EC) No 1946/2003 applies to the transboundary movements of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation.

Procedures and content: The main features of the Regulation are:

- the obligation to notify exports of GMOs intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- the obligation to provide information to the public and to our international partners on EU practices, legislation and decisions on GMOs, as well as on accidental releases of GMOs;
- a set of rules for the export of GMOs intended to be used as food, feed or for processing;
- provisions for identifying GMOs for export.

Responsible institution: MEPA is the responsible institution for the implementation of this Regulation.

Enforcement of the provisions of this Regulation is carried out as per Table 2 of this document.

Access to legislation: Access to Regulation (EC) 1946/2003 is available using the following link:
http://ec.europa.eu/comm/environment/biotechnology/pdf/regu1946_2003.pdf

3.1.2 Legislation in the Food and Feed Safety Sector

A. Regulation (EC) No. 1829/2003 on genetically modified food and feed

Similar to Regulation (EC) No. 1946/2003 mentioned above, this EU Regulation does not require transposition, as it is directly applicable to Malta and the other Member States.

Status: This Regulation entered into force in all Member States on 18 April 2004.

Objective: The overall objective of this Regulation is to provide the basis for

ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market; lay down Community procedures for the authorisation and supervision of genetically modified food and feed; and lay down provisions for the labelling of genetically modified food and feed.

Scope: Regulation (EC) No 1829/2003 applies to applications for the placing on the market in the territory of the EU of the following products:

- GMOs for food and feed use
- food and feed containing GMOs, consisting of such organisms or produced from GMOs (in the Regulation these are called: "genetically modified food" and "genetically modified feed")

Procedures and content: The Regulation puts in place a centralised EU procedure for all applications for placing on the market, whether they concern the GMO itself or the food and feed products derived there from.

This means that business operators may file a single application for the GMO and all its uses: a single risk assessment is performed and a single authorisation is granted for a GMO and all its uses (cultivation, importation, processing into food/feed or industrial products). If one of these uses concerns food, all the uses (cultivation, processing into industrial products, etc.) may be treated under Regulation 1829/2003.

Responsible institutions: The Malta Standards Authority is responsible for receiving notifications under this Regulation and for reviewing the risk assessment when the need arises.

The Food Safety Commission[1] (FSC) within the Ministry of Health, Elderly and Community Care has a co-ordinating role and provides advice on applications relating to this Regulation. The composition of the FSC is given in Annex III. The terms of reference of this Commission are given in the Food Safety Act, Act XIV of 2002, through which it was established. MEPA also submits comments on these applications when formally consulted by EFSA.

Enforcement of the provisions of this Regulation is carried out as per Table 2 of this document.

Access to legislation: Access to Regulation (EC) 1829/2003 is available using the following link:
http://ec.europa.eu/comm/environment/biotechnology/pdf/regu1829_2003.pdf

[1] A Commission established by Article 5 of the Food Safety Act, 2002 and chaired by the Ministry of Health, Elderly and Community Care. The principal function of the FSC is to take all reasonable steps to ensure that food produced, distributed, or marketed in Malta meets the highest standards of food safety and hygiene reasonably available and to ensure that food complies with legal requirements, or where appropriate with recognised codes of good practice.

B. Regulation (EC) No. 1830/2003 on the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

Regulation (EC) No. 1830/2003 is also directly applicable to Malta and the other Member States.

Status: This Regulation entered into force in all Member States on 18 April 2004.

Objective: The overall objective of this Regulation is to provide a framework for the traceability of products consisting of or containing GMOs, and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

Scope: This Regulation applies, at all stages of the placing on the market, to:

- products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;
- food produced from GMOs, placed on the market in accordance with Community legislation;
- feed produced from GMOs, placed on the market in accordance with Community legislation.

This Regulation does not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93.

Procedures and content: The traceability rules oblige the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the EU, to be able to identify their supplier and the companies to which the products have been supplied. The traceability requirement varies depending on whether the product consists of or contains GMOs or has been produced from GMOs.

Besides traceability requirements, Regulation 1830/2003 also sets out labelling requirements for GM products. It also defines the specific conditions under which a technically unavoidable presence of GMOs not yet formally authorised could be permitted, while it lists situations in which labelling is exempted.

Responsible institution: MEPA is the responsible institution for ensuring traceability and labelling of GMOs.

MSA is the responsible institution for ensuring traceability and labelling of food and feed products produced from GMOs.

Enforcement of the provisions of this Regulation is carried out as per Table 2 of this document.

Access to legislation: Access to Regulation (EC) 1830/2003 is available using the following link: http://ec.europa.eu/comm/environment/biotechnology/pdf/regu1830_2003.pdf

3.1.3 Legislation in the Medicines Sector

A. Regulation (EC) No. 726/2004 on the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Status: This Regulation entered into force in all Member States on 31 March 2004.

Objective: The overall objective of this Regulation is to lay down Community procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use, and to establish a European Medicines Agency.

Scope: This Regulation applies to the placing on the market of medicinal products.

Procedures and content: Regulation (EC) 726/2004 requires that an applicant for a marketing authorisation of a biotechnological medicinal product shall submit to the European Medicines Agency (EMeA) a dossier which includes all the necessary administrative, quality, non-clinical and clinical data for the medicinal product. These data are assessed by means of a centralised procedure, in which EMeA co-ordinates the entire process.

The active principles of several biotechnological medicinal products are proteins manufactured using recombinant micro- or macro-organisms or cell cultures. However, in most cases the recombinant systems are not themselves components of the finished medicinal product, and as a consequence these medicinal products neither consist of nor contain a GMO. Exceptionally, human biotechnological medicinal products may consist of or, more likely, contain, a GMO. These products constitute a special regulatory case by virtue of their registration being governed by reciprocal provisions in Directive 2001/18/EC (Article 12.2) and Regulation (EC) 726/2004 (Articles 6.2 and 6.3).

Responsible institution: The Malta Medicines Authority is the responsible institution for the implementation of this Regulation.

The European Commission consults MEPA when a medicinal product consists of or contains a GMO.

Access to legislation: Access to Regulation (EC) 1830/2003 is available using the following link: http://ec.europa.eu/enterprise/pharmaceuticals/review/doc/final_publ/reg_2004_726_20040430_en.pdf

3.2 Future goals and needs

One of the most important future goals that Malta needs to address is accession to the Cartagena Protocol on Biosafety, in order to be in line with the EU acquis. The EU has ratified the Cartagena Protocol in June 2002 and Decision 2002/628/EC refers to its conclusion on behalf of the European Community.

An agricultural issue, which needs to be addressed, is the co-existence of conventional, organic and GM crops. National rules need to be drafted, as current legislation related to GMOs and biosafety does not address this as yet.

In addition, following two years since the entry into force of the Contained Use of GMMs Regulations, 2002 as amended, the Deliberate Release into the Environment Regulations, 2002 and the Biosafety Co-ordinating Committee Regulations, 2002, some experience has been gained and there is scope for improving these regulations.

National legislation to specify who the competent authority in Malta is, what its role is and what enforcement measures are to be taken vis-à-vis EU regulations, which do not require transposition since they are directly applicable in Member States, should be laid down. Such legislation should also describe what consultations are to take place during the various authorisation processes.

The legislative framework regulating clinical trials on medicinal products for human use is laid down in Directive 2001/20/EC. This directive has also been transposed in Maltese national legislation. However, there is no clear guidance as to what procedures should be adopted in order to ensure that the provisions of Directive 2001/18/EC and Directive 90/219/EEC are taken into account. Therefore, a memorandum of understanding between the competent authorities of these three directives can be useful to stipulate adequate operating procedures, when such an application is submitted.

Financial support from government for the implementation of the regulatory regime is also needed.

4. SYSTEM FOR HANDLING NOTIFICATIONS

In order to obtain permission for activities involving the handling of GMOs, applicants need to submit a notification to the relevant national authorities to obtain an authorisation. Thus, a system to handle notifications or requests for authorisations for activities with GMOs has to be established. Such a system typically includes administrative functions, risk assessment, decision-making and public participation.

4.1 Current competencies and procedures

In Malta, different authorities have different responsibilities in the field of GMOs, depending on the subject area and the intended use of the particular GMO. Current competencies and procedures with respect to administrative functions, risk assessment and decision-making are described below for the different activities involving GMOs, and summarised for ease of reference in Annex IV.

4.1.1 Contained use of GMOs

Competent authority

According to the Contained Use of GMMs Regulations, 2002, (LN 169 of 2002 as amended), MEPA is the competent authority in Malta for receiving notifications and granting permits in connection with the contained use of GMOs. The notifications are reviewed with the help of its advisory committee, the Biosafety Co-ordinating Committee (BCC), whose composition is given in Annex V. The terms of reference of the BCC are given in Schedule II of Legal Notice 290 of 2002.

Classification of contained use

National 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

Procedures

Anyone carrying out contained use activities must particularly comply with the following:

Submission: The applicant should notify MEPA of their intention to use their premises for contained use activities for the first time. Application forms are available for applicants who want to submit such a notification.

Applicants have to carry out an assessment of the risks to human health and the environment of every contained use

activity before it begins, reviewing and revising the assessment as necessary, and keeping records. They have to establish a genetic modification safety committee to advise on risk assessments and classify all activities as described in Annex IV of the regulations and submit notifications accordingly.

Applicants should make certain that they apply the necessary containment and control measures indicated by the risk assessment and draw up emergency plans for riskier activities, and notify any accidents that occur.

Review: When undertaking genetic modification procedures in containment for the first time, the premises must be registered with MEPA, specifying their first activity by submitting a notification for first time use. For activities of Class 2 or higher classes MEPA has to be notified of each new activity by submitting a notification for each individual contained use activity. Application forms are available for applicants who want to submit such a notification. For premises in which Class 1 activities are undertaken a notification for each new activity does not need to be submitted. However, records of the risk assessment for each activity have to be kept, as these have to be made available to MEPA upon request.

Decision-making: Table 1 presents the different types of notification and the associated time frames for the different classes of risk.

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	Class 3 & 4 Submit notification THEN Proceed after written decision at least 45 days after submission	Class 3 & 4 Submit notification THEN Proceed after written decision at least 90 days after submission

Table 1: Summary of the different notification processes required for different classes of micro-organisms

4.1.2 Experimental release of GMOs into the environment

Competent Authority

According to the Deliberate Release of GMOs into the Environment Regulations, 2002, (LN 170 of 2002), MEPA is the competent authority in Malta for receiving notifications and granting permits in connection with the experimental release of GMOs into the environment, that is, for field trials. Such notifications are also reviewed with the help of MEPA's advisory committee, the BCC.

Procedures

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: Applicants must submit a detailed notification to MEPA. Application forms are available for applicants who want to submit such a notification. 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 the release will 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 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.

The procedural steps & timescales for the experimental release of GMOs are illustrated in the form of a flowchart in Figure 1 below.

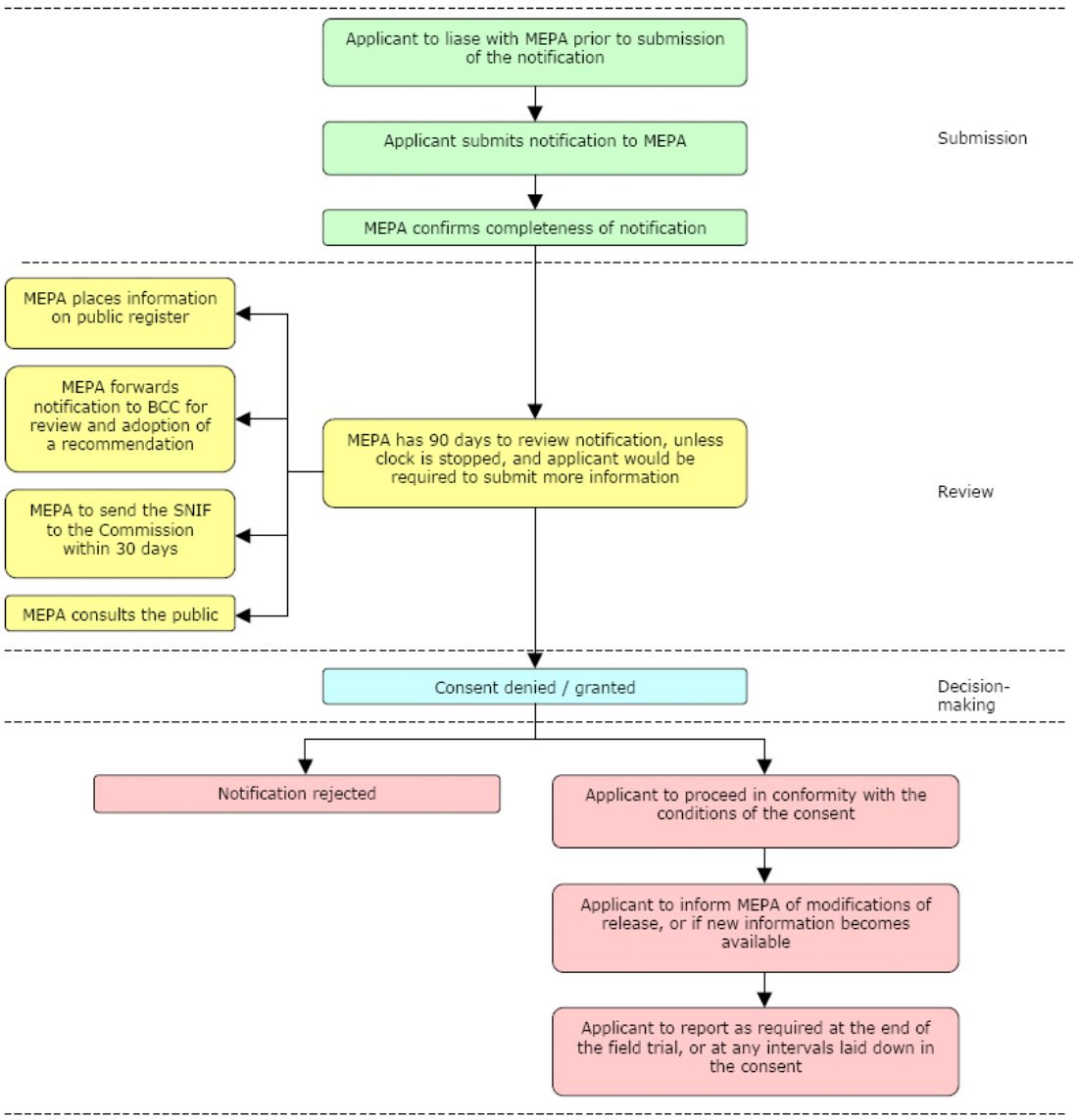

Figure 1: Procedural steps for the experimental release of GMOs

4.1.3 Placing on the market of GMOs (except for food and feed use)

Competent Authority

According to the Deliberate Release of GMOs into the Environment Regulations, 2002, (LN 170 of 2002), MEPA is the competent authority in Malta for receiving notifications in connection with the placing on the market of GMOs, if being placed on the market for the first time through Malta. Such notifications are also reviewed with the help of MEPA's advisory committee, the BCC.

Procedures

Consents for GMOs to be grown, processed or imported for commercial purposes (Part C releases according to Directive 2001/18/EC) 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. Application forms are available for applicants who want to submit such a notification through Malta.

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 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 act 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.

The procedural steps & timescales for the placing on the market of GMOs are illustrated by means of a flowchart in Figure 2 below.

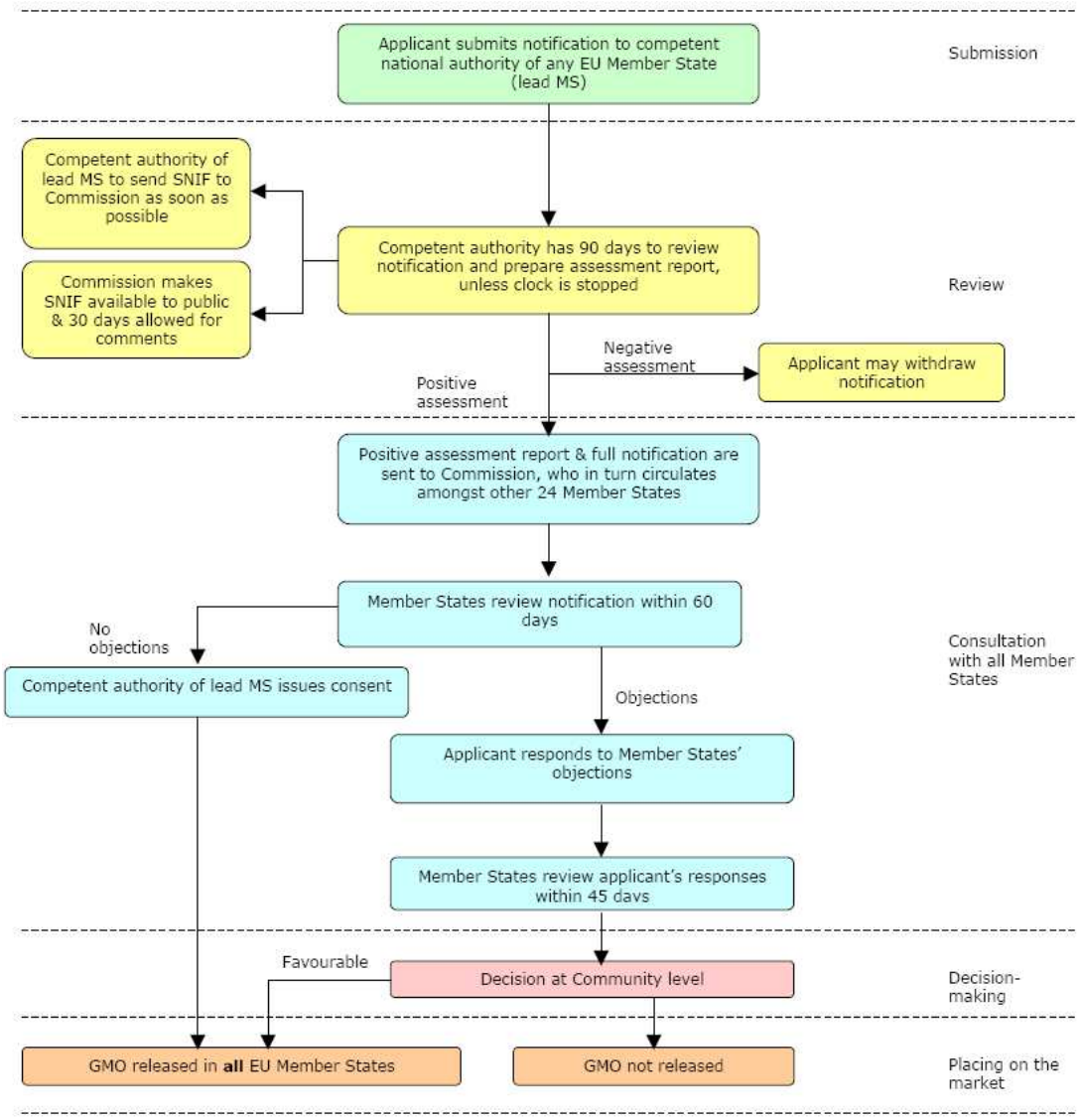

Figure 2: Procedural steps for the placing on the market of GMOs

4.1.4 Placing on the market of GM food & feed

Competent Authority

To obtain authorisation for the placing on the market of:

- a GMO for food use, food containing or consisting of GMOs,
- food produced from or containing ingredients produced form GMOs;
- GMOs for feed use, feed containing or consisting of GMOs, and feed produced from GMOs,

in accordance with Regulation 1829/2003 on GM food and feed, a notification has to be submitted to the competent authority, which is the MSA.

Procedures

Under Regulation 1829/2003 an applicant is able to obtain authorisation of a specific GMO and/or products produced from a GMO for all possible uses in food and/or feed. This Regulation is based on the "one door – one key" principle. Thus, it is possible, to file a single application for obtaining both:

- the authorisation for the use of a GMO in food and/or feed under the criteria laid down in this Regulation
- and within the same application the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18/EC

Similar to the consents for the placing on the market of GMOs, consents for the marketing of GM food and feed are valid across all EU Member States. These authorisations, valid throughout the Community, will be granted subject to a single risk assessment process (covering both the environmental risk and risks to human and animal health), which will be assessed by the European Food Safety Authority (EFSA). Thus, the procedure does not require assessment of the risk assessment by the competent authorities of the Member States, but it will be carried out by EFSA, that is through a centralised procedure. However, the competent authorities of the Member States may provide comments.

The authorisation procedure according to Regulation 1829/2003 on GM food and feed is as follows:

Submission: The applicant submits a notification to a competent authority of a Member State of his own choice. In Malta, such an application would have to be submitted to MSA.

The application shall be accompanied by the information specified in paragraph 3 of Article 5 for GM food and paragraph 3 of Article 17 for GM feed. In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by the information specified in paragraph 5 of Article 5, and in the case of GMOs or feed containing and consisting of GMOs – in paragraph 5 of Article 17.

The competent authority of the Member State acknowledges receipt of the application in writing to the applicant within 14 days of its receipt. The competent authority forwards the application and any supplementary information supplied by the applicant to EFSA.

Without delay, EFSA informs the other Member States and the Commission about the receipt of the application and makes it available to them. The summary of the notification will also be made available to the public.

Review: EFSA evaluates the risk assessment within a time limit of six months as from the receipt of a valid application.

Consultation:

During this period EFSA may ask the competent authority responsible for GM food and feed to undertake the evaluation of the risk assessment. In the case of submission of an application where the GMOs are to be used as seeds or other plant-propagating material EFSA shall ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to undertake evaluation of this assessment.

The competent authorities are given three months after the date of receiving the request within which comments can be submitted.

EFSA also forwards to the Community Reference Laboratory the applicant's submissions on methods of detection, sampling and identification of the transformation event, control samples, and from where the reference material can be accessed. The Community Reference Laboratory tests and validates the method of detection and identification proposed by the applicant.

After all the necessary consultations are completed, EFSA forwards its opinion, including a report describing its assessment, to the Commission, the Member States and the applicant. EFSA's opinion is subsequently made public. The public have 30 days during which comments can be submitted.

Decision-making:

Within three months after receiving the opinion of EFSA, the Commission shall present a draft Decision on the notification in question to its Regulatory Committee.

If the Regulatory Committee gives a favourable opinion, the Commission adopts the Decision and the applicant is informed accordingly. If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority.

After the final decision on the application is adopted, the Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

Placing on the market:

The authorisation granted in accordance with the procedure referred to in this Regulation is valid throughout the EU Member States for 10 years. The authorised food/feed will subsequently be entered in the Community Register of GM food/feed.

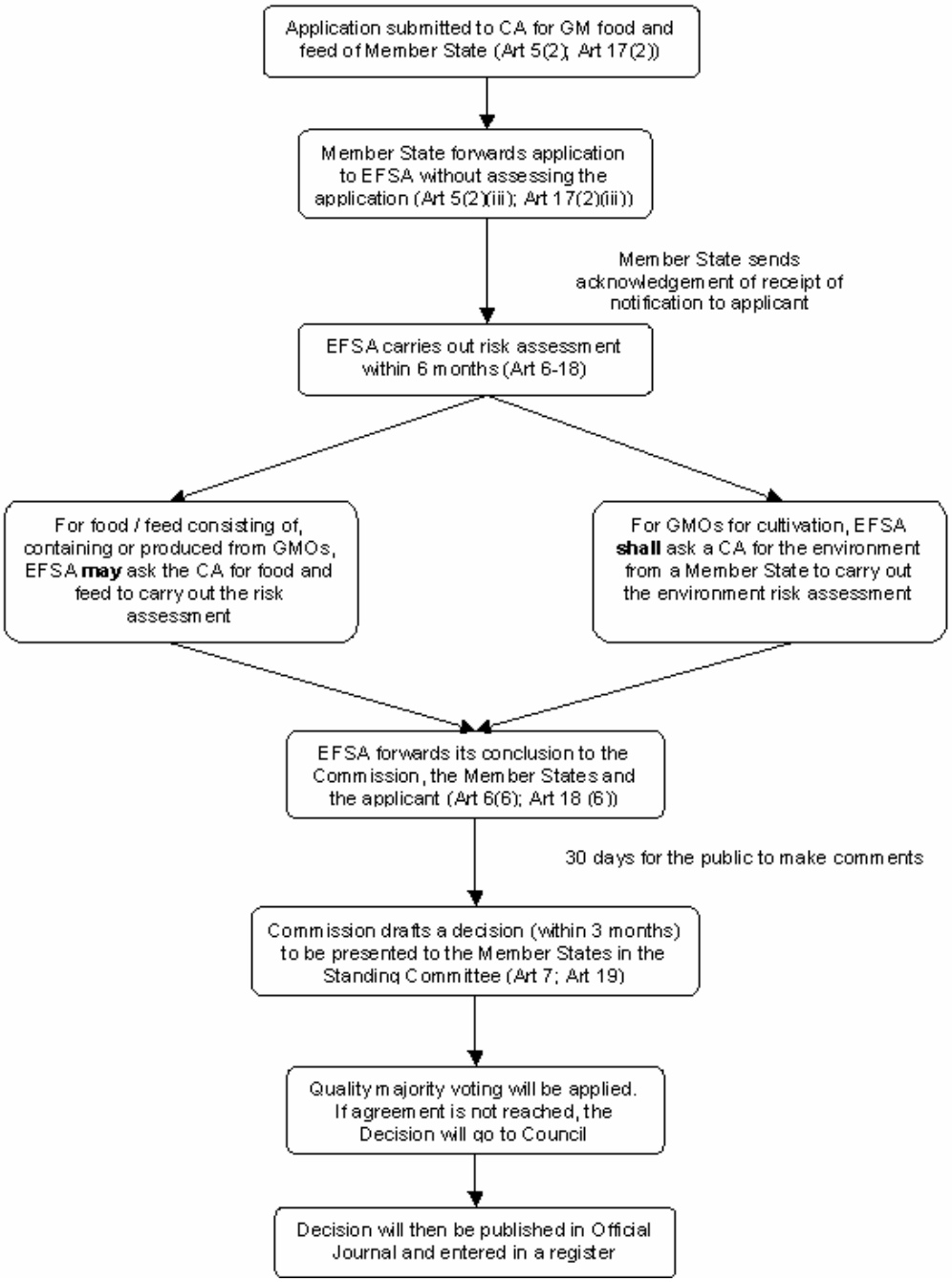

Figure 3: Procedural steps for the placing on the market of GM food & feed

4.1.5 Placing on the market of GM medicines

Competent Authority

In order to obtain an authorisation for placing on the market of a medicinal product intended for human and veterinary use, the applicant has to submit an application, in accordance with Regulation (EC) 726/2004, to EMeA.

Procedures

Authorisations for medicinal products are valid across the whole of the EU market and are subject to the following procedure:

Submission: The applicant submits a dossier for a marketing authorisation of a biotechnological medicinal product, in accordance with Regulation (EC) 726/2004, to EMeA. Such a dossier includes all administrative, quality, non-clinical and clinical data for the medicinal product.

Review: The dossier is then assessed by means of a centralised procedure, in which EMeA co-ordinates the entire process. This is done with the advice of a competent Committee for Medicinal Products, which is required to draw up an opinion concerning the evaluation of the medicinal products. The opinion is given within 210 days after receipt of a valid application.

The Committee takes due account of any requests by Member States for an opinion during the review process. The Committee also formulates an opinion whenever there is disagreement in the evaluation of medicinal products through the mutual recognition procedure. The opinion of the Committee is made publicly accessible.

The applicant is also given the opportunity to ask EMeA to re-examine its opinion, for which there are specific timeframes.

Consultation: The active principles of several biotechnological medicinal products are proteins manufactured using recombinant micro- or macro-organisms or cell cultures. However, in most cases the recombinant systems are not themselves components of the finished medicinal product, and as a consequence these medicinal products neither consist of nor contain a GMO.

Exceptionally, human biotechnological medicinal products may consist of, or more likely, contain a GMO. These products constitute a special regulatory case by virtue of their registration being governed by reciprocal provisions in Directive 2001/18/EC (Article 12.2) and Regulation (EC) 726/2004 (Articles 6.2 and 6.3).

In such instances, the competent authorities responsible for Directive 2001/18/EC (i.e. MEPA) are consulted through the European Commission to give an opinion on such products.

Placing on the The authorisation granted in accordance with the

market: procedure referred to in Regulation (EC) 726/2004 is valid throughout the EU Member States, normally for a period of 5 years.

4.2 Future goals and needs

In Malta, the system to handle notifications related to GMOs has been more or less already established and is functioning accordingly. Short and long terms actions that are required to improve and build on the current system include the following:

- Draft memoranda of understanding between relevant competent authorities, whose work related to GMOs either overlaps or else needs to complement one another in some way. For instance, a memorandum of understanding will be set up between MEPA and the Malta Medicines Authority in order to delineate the roles vis-à-vis clinical trials involving GMOs and contained use obligations. Other similar memoranda might be necessary to better define the areas of competency of various entities in order to devise a way in which these responsibilities are shared in an effective and efficient manner. Legal notices to include the division of work and consultations necessary between the different authorities could be considered instead of memoranda of understanding, as these have a stronger legal value.

- Following the above, liaison between the Maltese competent authority responsible for seeds (RAPAD) and MEPA will be necessary in the future, particularly in view of the amended Directive on seeds, which will also refer to GM seeds, that is being prepared by the European Commission and also in view of the registering of GM seeds within the National Catalogue.

- Revisions to the composition and terms of reference of the BCC might be necessary following experience gained in recent years of operation. In addition, since the BCC is an advisory committee to MEPA on the applications that it receives, similar advisory committees to other entities who receive applications could be set up. Another option could be to establish a central / national Biosafety Commission and have to two or three working groups within this Commission dealing with different subject areas, for example, environment, health and medical issues.

- It is also advisable to alter the BCC to make it a more scientific body by changing its composition.

- The administrative system in connection with the submission of applications under Regulation 1829/2003 needs to be developed further, in that application forms and associated guidance notes for applicants will have to be created.

- The capacity of entities involved with handling of notifications needs to be strengthened in terms of human and financial resources.

5. MONITORING AND ENFORCEMENT SYSTEMS

5.1 Monitoring System

Monitoring is a term used for different activities, varying from general surveillance to a detailed, case-specific monitoring plan, including methodologies of sampling, testing and analysis.

Case specific monitoring according to Annex VII of Directive 2001/18/EC can be defined as the systematic measurement of variables and processes over time and assumes that as a result of the risk assessment there are specific reasons for collection of such data. Whether or not these 'specific' monitoring plans are required depends on the results of the risk assessment. This is usually decided on a case-by-case basis. Case specific monitoring of a potential effect should be required and performed only if it is concluded that there is a reasonable chance that the monitoring can contribute to confirmation or dismissal of assumptions made during the risk assessment.

There are two different types of monitoring associated with the testing and release of GMOs, GM food and GM feed:

- compulsory monitoring which is required by the regulators and is intended to confirm any assumptions made in the risk assessment; and
- voluntary monitoring which is undertaken by the applicant in order to provide further information for their own purposes.

5.1.1 Current Monitoring System

The current monitoring system largely depends on the provisions of national legislation that relate to GMOs. Monitoring applies mostly to the experimental release of GMOs and the placing on the market of GMOs, GM food and GM feed. Thus, monitoring mechanisms for each of these are described below.

<u>Experimental release of GMOs</u>

The applicant is required to provide a description of the monitoring plans and the techniques that will be used during and post-release periods in the notification that must be submitted to the competent authority, which in this case is MEPA. Additional parameters and/or requirements for the monitoring of the consent can be imposed by MEPA.

The onus of carrying out the monitoring is on the applicant, who is subsequently required to report on the monitoring carried out to MEPA, which is the responsible institution for reviewing such reports. The types and frequency of reports required will be on a case-by-case basis and these will be specified on the consent granted to the applicant.

<u>Placing on the market of GMOs</u>

As described in the previous section, LN 170 of 2002 on the Deliberate Release into the Environment of GMOs is very similar to EU Directive 2001/18/EC. Thus,

the monitoring mechanism adopted on the placing on the market of a GMO is very similar to that of the Directive.

When submitting a notification for the placing on the market of a GMO, the applicant is required to submit a monitoring plan. As specified in Schedule VII of LN 170 of 2002, the monitoring plan should be detailed, on a case-by-case basis, and take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released. It should also incorporate general surveillance for unanticipated adverse effects and, if necessary, case-specific monitoring focusing on adverse effects identified in the environmental risk assessment.

Following the placing on the market of a GMO as or in a product, the applicant is required to ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. The reports of this monitoring have to be submitted to competent authority of the Member State in which the notification was originally submitted.

Thus, if Malta were the Member State in which the notification for the placing on the market of a GMO is submitted, then reports on monitoring would be submitted to MEPA according to the consent. MEPA would in turn send these reports to the Commission for dissemination to all competent authorities of the other 24 Member States. On the basis of these reports and in accordance with the consent and within the framework for the monitoring plan specified in the consent, MEPA may adapt the monitoring plan after the first monitoring period. MEPA can also make the results of the monitoring carried out under Part C of these regulations (LN 170 of 2002) publicly available.

MEPA is the responsible institution for reviewing the reports on the monitoring carried out, which are submitted by the applicants.

Placing on the market of GM food and feed

As has been described in previous sections, the placing on the market of GM food and feed falls within the scope of Regulation (EC) No. 1829/2003, which is directly applicable to Malta and the other Member States.

As regards monitoring in connection with the placing on the market of GM food and feed, this Regulation defines the necessity to introduce, where appropriate and on the basis of conclusions of the risk assessment, post-market monitoring requirements for the use of GM foods for human consumption and for the use of GM feed for animal consumption. A proposal for post-market monitoring, where appropriate, should be included in the notification. In the case of GMOs or food/feed containing or consisting of GMOs, the notification should also contain a monitoring plan for environmental effects according to requirements of Directive 2001/18/EC, including a proposal for the duration of the monitoring plan.

The post-market monitoring and/or monitoring are imposed on the applicant, who should ensure that it is carried out and should submit reports to the Commission. The monitoring reports will be made accessible to the public after deletion of confidential information. For the renewal of a consent, a report on the results of

monitoring, if so specified in the consent, and a proposal for amending or complementing the future monitoring, has to be submitted.

The Commission is responsible for reviewing the reports on the monitoring carried out, which are submitted by the applicants. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30 of Regulation 1829/2003.

5.1.2 Future goals and needs

Malta has not received applications for the experimental release of GMOs so far and so no monitoring was carried out in this respect.

Consideration can also be given to the possibility of including a GMO monitoring sub-programme in the National Biodiversity Monitoring Programme.

5.2 Enforcement System

5.2.1 Current Enforcement System

In Malta, the power to carry out inspections and take enforcement measures as is required, is given through legal instruments, which in some cases make specific mention of GMOs, but this is not so in all cases.

Current enforcement practices for each of the institutions that are in some way or another involved in GMOs are described below.

5.2.1.1 Department of Public Health

The Department of Public Health is one of the government departments within the Ministry of Health, the Elderly and Community Care. The general responsibilities of this Department vis-à-vis enforcement of regulations include food products and beverages, food supplements, pharmaceuticals, live animals, and tobacco and its products. Legislation and consequently enforcement of products of animal origin is the responsibility of another department.

Thus, with regards to biosafety, the remit of the Department of Public Health is restricted to GM food for human consumption. The Department of Public Health is mainly concerned with adequate labelling of GM food products. In order to verify whether a product actually contains a GMO, laboratory analysis must be carried out. At present there is no laboratory in Malta which is accredited to carry out GM tests. Thus, MEPA was recently coordinating a call for expression of interest (quotations) through which a laboratory for GM testing would be found. This was done in conjunction with the FSC so that a common laboratory to test for GMOs, GM foods and feeds would be used by the various Maltese competent authorities.

A sampling programme related to GM foods has also recently been compiled by the Department of Public Health.

5.2.1.2 Malta Environment and Planning Authority

With regards to enforcement, MEPA, which is an autonomous authority falling under the responsibility of the Ministry for Rural Affairs and the Environment, is generally responsible for the enforcement of legislation related to environmental and land-use planning issues.

Although MEPA currently does environmental policy and tackles environmental permitting issues related to GMOs, it does not yet do any enforcement on this subject area due to the lack of human resources. In the meantime, a laboratory for testing of GM samples is being identified together with the FSC through the call for expression of interest (quotations), which was mentioned in the previous section.

5.2.1.3 Plant Health Department

The Plant Health Department falls within the Ministry for Rural Affairs and the Environment and is responsible for the establishment of "*the necessary mechanisms and conditions to control and maintain the territory of Malta free from all major pests and diseases harmful to plant production, ensure food safety through absence of pesticide residues in food and encourage the production of quality and healthy plants*".

Inspections carried out by the Plant Health Department are instigated by the Plant Quarantine Act (Act III of 2004) and enforcement practices are based on international (Food and Agriculture Organisation, FAO) and EU procedures. These are generally carried out on consignments of plants, fruits, seeds, and other plant material such as wood.

Currently, the Plant Health Department does not carry out any GMO related inspections.

5.2.1.4 Fisheries, Aquaculture & Veterinary Division

The FAVD within the Ministry for Rural Affairs and the Environment is responsible for:

- Drafting and implementing legislation in the area of veterinary public health, animal health and welfare, veterinary medicinal and animal feeding stuffs;
- Prevention and control of animal diseases;
- Issuing approvals, certificates, licenses and registrations prescribed in law relating to veterinary public health, animal health and welfare; and
- Research and development to promote the efficiency and the quality of livestock production.

At present, FAVD do not have a sampling programme related to GM products.

5.2.1.5 Occupational Health and Safety Authority

By virtue of Article 8 (2) of Act XXVII of 2000 the Occupational Health and Safety Authority (OHSA) carries out inspections related to worker health and safety at work places. OHSA currently comprises the following sections:

- General and Accident Investigation
- Construction
- Radiation
- Biological and Chemical
- Mechanical and Electrical Plant Installations

Currently, OHSA does not carry out any inspections related to biosafety. However, this Authority will be in a position to carry out inspections related to contained use of GMOs, together with MEPA subject to availability of resources. There have already been some preliminary discussions on setting up a memorandum of understanding between OHSA and MEPA in order to define roles and responsibilities, if joint inspections will eventually be carried out.

5.2.1.6 Malta Standards Authority

One of the responsibilities of the Malta Standards Authority (MSA) is to undertake risk assessment (on human health) of foods and feeds. Therefore, MSA's role vis-à-vis biosafety is linked to the introduction of food / feed containing GMOs into the EU. The role of MSA is to assess scientific reports prepared by the European Food Safety Authority and evaluate them from a point of view of risk to human health.

The Authority has no enforcement branch and therefore does not inspect any of the consignments that are imported / exported to and from Malta. However, it plays a role in labelling issues and advises the FSC on labelling standards.

5.2.1.7 Medicines Authority

The Medicines Authority contributes to the protection of public health in Malta through the regulation of the safety, quality and efficacy of medicines for sale or supply on the Maltese market. The Authority is committed to providing high quality licensing, monitoring and inspection service to its customers.

In the field of GMOs, the Medicines Authority is expected to play a role with respect to the enforcement of authorisations concerning GM medicines intended for human use.

5.2.2 Future goals and needs

One of the most important future needs is that each entity takes ownership of its share in the enforcement of biosafety and sets up a system through which effective and efficient enforcement can be carried out, as there is currently little enforcement in the field of GMOs. It is important to note that such enforcement can be easily integrated in standard existing inspection procedures, for example,

in those for food and feed control and for seed certification. Responsibilities to be assumed by each entity are as follows:

GM use	ENTITY					
	MEPA	**FAVD**	**OHSA**	**Dept. Public Health**	**Plant Health**	**Medicine's Authority**
Contained use	✓		✓			
Experimental release of GMOs	✓					
Placing on the market of GM food products				✓		
Placing on the market of GM feed products		✓				
Placing on the market of GM plants					✓	
Placing on the market of GM seeds					✓	
Placing on the market of GM animals		✓				
Placing on the market of GM medicines for animal use		✓				
Placing on the market of GM medicines for human use						✓

Table 2: Competent authorities for the enforcement of all different types of GM products

In order to be able to achieve this, however, more human resources have to be dedicated to the responsible institutions, as there is currently lack of enforcement staff in all of the institutions. Adequate training also needs to be given to enforcement officials so that their work is carried out properly.

In addition, a laboratory for testing of GMOs and GM products needs to be identified so that samples can be sent for analysis. This laboratory could subsequently also participate in EU activities, such as the European Network on GMO Laboratories (ENGL).

Guidance documents, manuals and checklists for enforcement officials should also be developed in order to ensure consistency.

A formal network of communication between all the relevant entities could also be established to exchange information on imports and exports of GMOs, GM food and feed. In this respect, co-ordination efforts with the Customs Department should also be improved in order to deal with transboundary movements of GMOs and GM food and feed.

A series of meetings could also be held to discuss the various possibilities that exist for further cooperation between the various entities.

Due consideration should also be given to include the responsibilities of each entity with respect to enforcement of GMOs in a legal document, such as a legal notice.

6. MECHANISMS FOR PUBLIC PARTICIPATION AND INFORMATION

6.1 Current system for public participation and information

The following are the principal laws that are relevant to public information and participation concerning GMO related issues in Malta.

A. Access to Information

Malta signed the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) in December 1998 and ratified it in April 2002.

The European Community also ratified the Aarhus Convention. In order to ensure that Community law is consistent with the Convention a Directive on this subject was issued – Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC.

Malta has transposed the EU Directive into national law through the 'Freedom of Access to Information on the Environment Regulations, 2005' (Legal Notice 116 of 2005), which came into force on 17th May, 2005. These regulations allow the general public to request environmental information from the competent authority - the MEPA – and those bodies or persons as the Minister responsible for the environment may so appoint.

The system to access environmental information has already been set up and is functioning. Such a system involves a request for information on the environment made by an applicant. The request can be written, electronic or hardcopy and it must usually be answered within 30 days of receipt of the request if the information is readily available. However, this time period can be extended by a further 30 days if the information requested is complex and voluminous.

B. Experimental Release of GMOs into the Environment

As required by legislation, Legal Notice 170 of 2002, MEPA will consult the public when applications for proposed experimental releases are submitted. Such consultations will be published on MEPA's website and members of the public will be able to inspect copies of the application (excluding confidential information) at the MEPA's offices during core office hours. The Summary Notification, which can be downloaded from http://gmoinfo.jrc.it/, will also available for review. Written submissions by e-mail or by post will be accepted within the stipulated deadline.

If after consent is given new information becomes available, which could have significant consequences with regard to risks for human health and the environment, then MEPA will evaluate this information and make it available to the public on its website.

A register, which records the locations of releases of GMOs for experimental purposes, will also be available to the public.

This system described above is in place although it has not been functioning in practical use as yet, because Malta has not received any applications of this type.

C. Contained Use of GMOs

Legal Notice 169 of 2002 on the contained use of GMOs also provides for public consultation on applications submitted for proposed contained uses falling within Class 3 and Class 4 categories. This public consultation procedure follows the same procedure as that described in the previous section in that it will be published on MEPA's website and members of the public would be able to inspect copies of the application (excluding confidential information) at MEPA's offices during core office hours. Written submissions by e-mail or by post would be accepted within the stipulated deadline.

In addition, for each application the applicant should submit an emergency plan which would also be made available to the public on MEPA's website.

This system described above is in place although it has not been functioning in practical use as yet, because Malta has not received any applications of this type.

D. Placing on the market of GMOs

The public is consulted in two instances on applications for the placing on the market of GMOs as in Directive 2001/18/EC (transposed by LN 170 of 2002):

- 30 days of consultation on the Summary Notification (SNIF) at the European Commission website (http://gmoinfo.jrc.it), as soon as a new application is submitted by the applicant to a lead Member State. Written submissions should be made directly through this EC website by not later than the date indicated next to the particular SNIF download link, and

- 30 days of consultation on the application itself and the assessment report of the lead Member State. The application may be inspected at MEPA offices, whilst the assessment report would be available at the European Commission website (http://gmoinfo.jrc.it).

Additionally, MEPA shall also make the results of the monitoring carried out by the applicant as required by legislation publicly available on its website.

Once again, this system is in place.

E. Placing on the market of GM food and feed products

Since the procedure for submitting applications for the placing on the market of GM food and feed as per Regulation (EC) No. 1829/2003 has been centralised through EFSA, public consultation is mainly carried out through EFSA itself.

EFSA makes the summary of the application available to the public once the applicant submits this. It also makes its opinion publicly available for comments which can be submitted within 30 days of publication of its opinion. The monitoring reports submitted by the applicants are also made accessible to the public after deletion of parts classified as confidential information.

The Commission has also established a Community register of genetically modified food and feed, which is available to the public (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

6.2 Public awareness and education

In order to enhance public awareness and education on GMO-related issues the following activities were undertaken until date of publication of the NBF:

Seminars

Three seminars have been held in 2006, as follows:

National Seminar on GMOs & Malta	Target audience included government entities, NGOs, importers, exporters and other interested parties from the general public. Advertisements of this seminar were published in local newspapers.
Workshop on the Cartagena Protocol on Biosafety & Malta	Target audience included mainly government entities, which will in some way be involved in the implementation of the Cartagena Protocol.
Training Seminar on Risk Assessment & Risk Management of GMOs	Target audience include mainly government entities, experts and consultative committees, which are involved in assessing applications related to GMOs, GM food or feed.

Publications

The following publications have been produced through funds received from UNEP-GEF:

- 'Contained Use: Genetically Modified Organisms' – this informative brochure has been published in English in January 2006.
- 'Release in the Environment: Genetically Modified Organisms' – this informative brochure has been published in English in January 2006.
- 'Genetically Modified Organisms' – this back-to-front A4 flyer was published in English in January 2006. A large amount of copies were also distributed

with a local newspaper, which has a readership of about 40,000 people, on Sunday 5th February 2006.

- 'GMO awareness project proposal for schools'. The purpose of this project is to inform school children about the pros and cons of GMOs. Lessons are be delivered through a printed information leaflet designed to prepare the teacher on the subject; a DVD to present to the class; printed leaflets to hand out in class with the summary of the lesson, a classroom competition and a website matching the package in design and theme comprising of pictures and information from the DVD, up to date news, points of interest, quiz, links of interest, contact information, etc.

Media

Interviews on GMO issues aimed to inform the public were held twice (7th January 2005 & 12th August 2005) on a local radio station.

Website

MEPA has created a website, in English, which contains information for the general public on GMO-related issues for which MEPA is responsible. http://www.mepa.org.mt/environment/index.htm?GMOs/mainpage.htm&1

6.3 Future goals and needs

It is envisaged that public awareness activities will be undertaken every now and again in order to ensure continuity in public education on this subject area. Possibilities of financing such activities will have to be researched.

Another important goal is to set-up a Biosafety Clearing House, which is an obligation according to the Cartagena Protocol, and which aims to be an information exchange platform on various issues concerning biosafety and the transboundary movement of GMOs. The current MEPA website can be enhanced further to act a national Biosafety Clearing House.

7. CONCLUSION

This document gives an overall picture of biosafety issues in Malta and the current status of what has been achieved to date and highlights future goals and needs including the following:

a) accession to the Cartagena Protocol on Biosafety;
b) redefinition of national competencies in the areas of GMOs and GM products in order to minimise gaps and overlaps;
c) explore the possibility of describing the division of work and consultations necessary between the different entities in a legal document, such as a legal notice;
d) address the co-existence issue of conventional and organic farming with GM crops;
e) further support in terms of resources for the efficient and effective implementation of this National Biosafety Framework and relevant legislation, especially with respect to enforcement.

Although the National Biosafety Framework for Malta is still relatively new, it has developed quite well during recent years and upon Malta's entry into the EU. In addition, through the UNEP-GEF project for 'Developing a National Biosafety Framework for Malta', resources were brought together to enable the compilation of a National Biosafety Framework, which is the first document of this kind.

One of the most important outcomes of the exercise through which this document was compiled was that various discussions were held between government entities involved in this subject area and this resulted in improved communication and improved sharing of responsibilities.

Further work is to be carried out in order to achieve the future goals that have been identified in this document.

ANNEX I

Other legislation related to GMOs

1. Legislation in the Environment Sector

A. Environment Protection Act – Act XX of 2001, as amended by Act II of 2006

The Environment Protection Act (EPA) is a primary piece of legislation under which numerous legal notices in the field of environmental protection are published. Thus, legal notices on GMOs and biosafety whose principal focus is to safeguard the environment are issued under the EPA.

Status: This Act has been adopted and came into force on 18 September 2001. Minor amendments were subsequently made by means of Act II of 2006.

Objective: The overall objective of the EPA is to protect the environment for the benefit of the present and future generations, by assisting in the taking of preventative and remedial measures and by managing natural resources in a sustainable manner.

Scope: The scope of the EPA is very broad in the sense that it sets a general framework for environmental protection. Amongst other things the EPA describes the duties and powers of the Minister responsible for the environment, including the power to make regulations in practically all fields related to environmental protection. It also establishes a National Commission for Sustainable Development and an Environment Fund.

Article 9(2)(l) specifically allows for the control, management and regulation of the transport, introduction of, use or placing on the market of GMOs; while Article 10(d) provides for the need of obtaining permits in relation to the GMOs.

Responsible institution: The overall responsibility for the implementation of the EPA lies within the Minister responsible for the environment.

Access to legislation: The EPA can be accessed from the website of the Laws of Malta: http://www2.justice.gov.mt/lom/home.asp?lng=ENG

The direct hyperlink is: http://docs.justice.gov.mt/lom/legislation/english/leg/vol_13/chapt435.pdf

2. Legislation in the Food & Feed Sector

A. The Food Safety Act – Act XIV of 2002

The Food Safety Act is a primary piece of legislation under which numerous legal notices in the field of food safety are published.

Status: This Act has been adopted and entered into force on 13 September 2002.

Objective: The overall objective of the Food Safety Act is to make provision for any matter related to food safety, establishes a Food Safety Commission, introduces new provisions for enforcement in relation to food, and repeals the Food, Drugs and Drinking Water Act.

Scope: The scope of the Food Safety Act is very broad in the sense that it sets a general framework for food safety. Amongst other things it applies to all food products, whether produced in Malta, imported into Malta or exported there from, and whether intended for sale on the local market or intended for export.

Responsible institution: The overall responsibility for the implementation of the Food Safety Act lies within the Minister responsible for public health.

Access to legislation: The Food Safety Act can be accessed from the website of the Laws of Malta:
http://www2.justice.gov.mt/lom/home.asp?lng=ENG

The direct hyperlink is:
http://docs.justice.gov.mt/lom/legislation/english/leg/vol_14/chapt449.pdf

3. Legislation in the Medicines Sector

A. Veterinary Services Act – Act XVIII of 2002

The Veterinary Services Act is a primary piece of legislation under which numerous legal notices in the field of Veterinary Services are published.

Status: The Act has been adopted and entered into force on the 1 of February 2002.

Objective: The overall objective of the Veterinary Services Act is to establish and consolidate the requirements in the veterinary field, veterinary medicinal products, feeding stuffs and zoo-technical requirements and for the regulation of the veterinary profession.

Scope: The scope of the Veterinary Services Act is very broad and sets a general framework for all veterinary services**.** This comprises:

i. the requirements in the

veterinary field
- in connection with animal health and public health with regard to live animals
- in connection with animal and public health with regard to products of animal origin, including by-products and plant products

i. the requirements in veterinary medicinal products;
i. the requirements relating to feeding stuffs;
i. the zoo-technical requirements in animal breeding.

Procedures and content: The overall responsibility for the implementation of the Veterinary Services Act lies with the Minister responsible for veterinary services**.**

The Minister may, after consulting the Head of the National Veterinary Laboratory, prescribe rules regarding the authorisation for, and the supervision of, veterinary medicinal products listed in the sixth schedule, of which Part C deals with GMOs.

Responsible institution: The Fisheries, Aquaculture & Veterinary Division (FAVD) within the Ministry of Rural Affairs and the Environment is the competent authority responsible for the implementation of this Act.

Access to legislation: Access to the Veterinary Services Act is available using the following link:
http://docs.justice.gov.mt/lom/legislation/english/leg/vol_13/chapt437.pdf

4. Legislation in the Seeds Sector

A. Plant Quarantine Act – ACT XVIII of 2001

Status: This act was published on 1st September 2001.

Objective: The aim of this act is to prevent the introduction into Malta of plant pests and diseases, to control and check the spread thereof and to provide for other matters incidental and ancillary thereto.

Scope: This act applies to plant material, plant pests, beneficial organisms, soil or packaging material that is imported in Malta.

Responsible institution: The Plant Health Section formerly known as the Plant Health Department is the responsible institution for the implementation of this act.

Access to legislation: The direct link to these regulations is:
http://www.mrae.gov.mt/htdocs/docs/laws_chp433.pdf

B. Seeds of Agricultural Plants and Vegetables Regulations, 2006 – LN 81 of 2006

Status: These regulations were published on 30 March 2006 under the Plant Quarantine Act.

Objective: The aim of these regulations is to control the production, with intent to market within the Community, of seeds of agricultural plants and vegetables of the genera, species and their hybrids listed in the legal notice.

Scope: These regulations shall apply to any seeds produced, placed on the market in Malta or to be exported to the European Community, or being transhipped through Malta prior to its transport to another Member State, to ensure that they meet specified standards of quality.

Procedures and content: The regulations mainly provide procedures for the notification and certification of seeds, whilst also listing criteria for entering seeds in the National Catalogue. These regulations also describe how seeds can be inspected, examined and sampled. Issues related to packaging and marketing of seeds are also provided for in these regulations.

Responsible institution: The Plant Health Section formerly known as the Plant Health Department is the responsible institution for the implementation of these regulations.

Access to legislation: The direct link to these regulations is: http://www.doi.gov.mt/EN/legalnotices/2006/03/LN81.pdf

C. Forest Reproductive Material Regulations, 2004 – LN 273 of 2004

Status: These regulations were published on 15 May 2004 under the Plant Quarantine Act.

Objective: The aim of these regulations is to control the production, with a view to marketing of forest reproductive material of the genera, species and their artificial hybrids listed in the legal notice within the Community.

Scope: These regulations shall apply to any forest reproductive material produced, placed on the market in Malta or to be exported to the European Community, or being transhipped through Malta prior to its transport to another Member State, to assure it meets specified standards of quality.

Procedures and content: The regulations mainly provide procedures for the notification and certification of forest reproductive material, whilst also listing criteria for entering approved material in a National Register.

Responsible institution: The Plant Health Section formerly known as the Plant Health Department is the responsible institution for the implementation of these regulations.

Access to legislation: The direct link to these regulations is: http://www.doi.gov.mt/EN/legalnotices/2004/05/LN273.pdf

D. Propagation Material of Vines Regulations, 2004 – LN 470 of 2004

Status: These regulations were published on 15 December 2004 under the Plant Quarantine Act.

Objective: The aim of these regulations is to control the production of plant material utilized for the vegetative propagation of vines produced and marketed within the Community.

Scope: These regulations shall apply to any vine propagation material produced, placed on the market in Malta or to be exported to the European Community, or being transhipped through Malta prior to its transport to another Member State, to assure that it meets specified standards of quality.

Procedures and content: The regulations mainly provide procedures for the notification and certification of vine propagation material, whilst also listing criteria for including vine varieties in a catalogue. Issues related to packaging and marketing of propagation material of vines are also described for in these regulations.

Responsible institution: The Plant Health Section formerly known as the Plant Health Department is the responsible institution for the implementation of these regulations.

Access to legislation: The direct link to these regulations is: http://www.doi.gov.mt/EN/legalnotices/2004/11/LN470.pdf

5. Legislation in the Occupational Health and Safety Sector

A. Occupational Health and Safety Authority Act – Act XXVIII of 2000

The Occupational Health and Safety Authority Act is a primary piece of legislation under which numerous legal notices relating to workers' safety are published. Therefore, there are a number of legal notices which take into consideration exposure to GMOs.

Status: This Act has been adopted and entered into force in its entirety on the 29 of January 2002.

Objective: The overall objective of the Occupational Health and Safety Authority Act is to provide for the establishment of an Authority to be known as the OHSA, an Occupational Health and Safety

Appeals Board, and for the exercise by or on behalf of that Authority of regulatory functions regarding resources relating to Occupational Health and Safety and to make provision with respect to matters connected therewith or ancillary thereto.

Scope: This Act applies to all work places, to all sectors of activity, both public and private, and to all work activities, but does not apply in the case of those activities carried out by members of the armed forces, the police force or of the civil protection services. This is so provided that in the case of members of the aforementioned public services, the health and safety of workers must be ensured as far as reasonably possible in the light of the overall scope of those services.

Responsible institution: The overall responsibility for the implementation of this Act is the OHSA.

Access to legislation: The direct hyperlink is:
http://www.ohsa.org.mt/showpage.asp?pageid=96

B. Protection of Young Persons at Work Places Regulations, 2000 – LN 91 of 2000 as amended

Status: These regulations were published under the Occupational Health and Safety Authority Act and have entered into force on 1 January 2002. LN 283 of 2004 amended these regulations.

Objective: The aim of these regulations is to protect young people at the work place from agents and process to which they can be exposed.

Scope: This legislation specifically prohibits young people from being exposed to biological agents including GMOs that can cause severe human diseases.

Procedures and content: Before engaging or offering work to any young person, an employer must carry out an assessment of the occupational health and safety hazards which may be involved at the place of work. Such an assessment shall be repeated whenever there is any major change in working conditions. Where such an assessment reveals the risk of exposure to GMOs which can cause severe human disease, young persons cannot be exposed.

Responsible institution: OHSA is the responsible institution for the implementation of these regulations.

Access to legislation: The direct link to these regulations is:
http://www.ohsa.org.mt/docs/laws/ohs_ln_91_00.pdf
that have been amended by :
http://www.ohsa.org.mt/docs/laws/ohs_ln_283_04.pdf

C. Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, 2003 – LN 228 of 2003

Status: These regulations were published under the Occupational Health and Safety Authority Act.

Objective: The aim of these regulations is to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work.

Scope: These regulations shall apply to activities in which workers are potentially exposed to biological agents as a result of their work.

Procedures and content: The regulations mainly provide for the determination and assessment of risk that the workers are exposed to when working with biological agents; for avoiding the use of a harmful biological agent if the nature of the activity so permits; for preventing exposure to workers if the results of the risk assessment reveal risk to workers' health or safety; for providing the information to, consultation, balanced participation and training of workers and their representatives; and for prior notification of the Authority when using certain biological agents.

Responsible institution: OHSA is the responsible institution for the implementation of these regulations.

Access to legislation: The direct link to these regulations is: http://www.ohsa.org.mt/docs/laws/ohs_ln_228_03.pdf

D. Protection of Maternity at Work Places Regulations, 2000 – LN 92 of 2000

Status: These regulations were published under the Occupational Health and Safety Authority Act. These regulations came into force on the 1 January 2001.

Objective: The aim of these regulations is to protect the pregnancy of and pregnant workers, mothers and breast-feeding workers against risks to their health and safety at work.

Scope: These regulations shall apply to activities in which pregnant workers, breast feeding workers and mothers are, or are potentially exposed to hazards at place of work.

Procedures and content: Before engaging or offering work to pregnant workers, breast feeding workers and mothers, an employer must carry out an assessment of the occupational health and safety hazards which may be involved at the place of work, and such assessment shall be repeated whenever there is any major change in working conditions. In carrying out such an assessment, an employer must take into consideration, among other things, the nature, degree and duration of exposure to physical, chemical and biological

agents.

Responsible institution: OHSA is the responsible institution for the implementation of these regulations.

Access to legislation: The direct link to these regulations is: http://www.ohsa.org.mt/docs/laws/ohs_ln_92_00.pdf

ANNEX II

List of legislation

Legislation in the Environment Protection Sector:

- Environment Protection Act – Act XX of 2001
    - Contained Use of GMMs Regulations 2002 – LN 169 of 2002 as amended
    - Deliberate Release into the Environment of GMOs Regulation 2002 – LN 170 of 2002
    - Biosafety Co-ordinating Committee Regulations 2002 – LN 290 of 2002

- Regulation (EC) No. 1946/2003 on transboundary movements of GMOs

Legislation in the Food and Feed Safety Sector:

- Regulation (EC) No. 1829/2003 on GM food and feed

- Regulation (EC) No. 1830/2003 on the traceability and labelling of GMOs and the traceability and labelling of food and feed products produced from GMOs and amending Directive 2001/18/EC

- Food Safety Act – Act XIV of 2002

Legislation in the Medicines Sector:

- Regulation (EC) No. 726/2004 on the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

- Veterinary Services Act – Act XVIII of 2002

Legislation in the Seeds Sector:

- Plant Quarantine Act – Act XVIII of 2001
    - Seeds of Agricultural Plants and Vegetables Regulations – LN 81 of 2006
    - Forest Reproductive Material Regulations – LN 273 of 2004
    - Propagation Material of Vines Regulations – LN 470 of 2004

Legislation in the Occupational Health and Safety Sector:

- Occupational Health and Safety Authority Act – Act XXVIII of 2000
    - Protection of Young Persons at Work Places Regulations 2000 – LN 91 of 2000 as amended

- Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations – LN 228 of 2003
- Protection of Maternity at Work Places Regulations, 2000 – LN 92 of 2000

ANNEX III

Composition of the FSC

At the date of publication of the NBF, the composition of the FSC was:

Chairperson	Dr. Ray. Busuttil Director General (Health)	Department of Health
Permanent Members		
Senior Officer responsible for public health	Dr. Malcolm. Micallef Director Public Health	Department of Public Health
Senior Officer responsible for veterinary services	Mr. Simon Sammut Director General Fisheries, Aquaculture & Veterinary Division Substitute: Dr. A. Casha	Department of Food and Veterinary services
Senior Officer responsible for foodstuffs within the Malta Standards Authority	Mr. Anthony Camilleri Acting Director Foodstuffs, Chemicals and Cosmetics Substitute: Ms. Ingrid Borg	Foodstuffs, Chemicals and Cosmetics Directorate Malta Standards Authority
Senior Officer responsible for consumer affairs	Mr. Marcel Pizzuto Director General Substitute: Mr. Godwin Mangion	Office of Fair Trading Consumer and Competition Division
Senior Officer responsible for health promotion	Dr. Mario Spiteri Director Health Promotion Substitute: Ms. Lucienne Pace	Department of Health Promotion
Senior Officer responsible for environment protection	Mr. Martin Seychell Director Environment Substitute: Mr. Joseph Abela Medici	Environment Protection Directorate Malta Environment and Planning Authority
Senior Officer responsible for Plant Health	Dr. David Mifsud Principal Scientific Officer	Department of Plant Health
Members		
A/ Secretary	Mr. J. Attard Kingswell Manager Health Inspector	Health Inspectorate Services Department of Public Health
	Maria Portelli	Ministry of Tourism

ANNEX IV

Competencies for handling notifications

The following is a summary of who are the competent authorities responsible for handling notifications and decision-making in connection with applications related to GMOs, and GM food and feed:

Type of notification	ENTITY		
	MEPA	MSA	Medicines Authority
Contained use	✓		
Experimental release of GMOs into the environment	✓		
Placing on the market as per Regulation 1829/2003[2]		✓	
Placing on the market as per Directive 2001/18/EC	✓		
Authorisation of medicinal products for human and veterinary use			✓

[2] Since Regulation 1829/2003 covers all possible uses of GMOs, that is, GMOs as food or feed and also GM products of food and feed, the great majority of notifications are being submitted under this regulation. Consequently, very few notifications are being submitted under Directive 2001/18/EC.

ANNEX V

Composition of the BCC

At the date of publication of the NBF, the composition of the BCC was:

Chairman/Director General	Dr. Godwin Cassar	Malta Environment and Planning Authority
Permanent Members		
Secretary / Public officer responsible for biosafety	Ms. Nadia Lanzon	Malta Environment and Planning Authority
Public officer responsible for biodiversity	Mr. Alfred E. Baldacchino	Malta Environment and Planning Authority
Public officer responsible for public health	Mr. John Attard Kingswell	Department of Public Health
Public officer responsible for occupational health and safety	Mr. Cedric Camilleri	Occupational Health and Safety Authority (OHSA)
Public officer responsible for rural affairs	Dr. David Mifsud	Rural Affairs and Paying Agency Division
Scientist representing the scientific community	Dr. Marion Zammit Mangion	Scientific Consultant
Other representative required by the Competent Authority	Mr. Tristan Camilleri	Malta Standards Authority (MSA)
Other representative required by the Competent Authority	Mr. Darrin Stevens	Malta Environment and Planning Authority
BCC Secretariat	Mr. Joseph Abela Medici	Malta Environment and Planning Authority