Minister for Home affairs and the Environment

L.N. 169 Of 2002

Environment Protection Act, 2001
(ACT NO.XX OF 2001

Contained use of genetically modified micro -organisms Regualtions, 2002

BY virtue of the powers conferred by articles 9 and 11 of the Environment Protection Act, 2001, hereinafter referred to as "the Act", the Minister for Home Affairs and the Environment has made the following regulations:-

Citation and commencement

1. (1) The title of these regulations is Contained use of genetically modified micro-organisms Regualtions, 2002

(2) (a) These regulations shall come into force on such date as the Minister responsible for the environment may by notice in the Gazette appoint and different dates may be so appointed for different provisions and different purposes of these regulations.

(b) A notice under paragraph (a) of this sub-regulation may make such transitional provisions as appear to the Minister to be necessary or expedient in connection with the provisions thereby brought into force.

OBJECTIVES

2. The objective of these regulations is to lay down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

INTERPRETATION

3. In these regulations, unless the context otherwise requires :

"micro-organism" means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

"genetically modifie d micro-organism" (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;

(ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification;

"contained use" means any activity in which micro-organisms are genetically modified or in which such GMMs 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;

"accident" means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

"user" means any natural or legal person responsible for the contained use of GMMs;

"notification" means the presentation of the requisite information to the Authority.

'Minister' means the Minister responsible for the environment

'Authority' means the Malta Environment and Planning Authority as prescribed by the notice entitled Nomination of the Malta Environment and Planning authority as the competent authority, and such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe and different bodies or persons may be designated as the competent authority for different provisions and different purposes of these regulations;

EXEMPTIONS

4. (1) Without prejudice to Article 6(1) these regualtions shall not apply:

- where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A, or
- for contained uses involving only types of GMMs meeting the criteria listed in Annex II, Part B which establish their safety to human health and the environment. These types of GMMs shall be listed in Annex II, Part C.

(2) Article 5(2), 5(5), 5(6), 5(7) and Articles 6 to 11 shall not apply to the transport of GMMs by road, sea or air.

(3) To the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with the deliberate release into the environment of genetically modified organisms regulations, 2002 or pursuant to other relevant legislation, which provides for a specific environmental risk assessment similar to that laid down in the said regulations, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

ASSESSMENT

5. (1) In order to ensure that the contained use of GMMs does not produce adverse effects on human health and the environment the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may incur, using as a minimum the elements of assessment and the procedure set out in Annex III, sections A and B.

(2) The assessment referred to in sub-article (1) shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with sub-articles (6) and (7) :

Class 1 : activities of no or negligible risk, for which level 1 containment is appropriate.

Class 2 : activities of low risk, for which level 2 containment is appropriate.

Class 3 : activities of moderate risk, for which level 3 containment is appropriate.

Class 4 : activities of high risk, for which level 4 containment is appropriate.

(3) Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless sufficient evidence, in agreement with the competent authority, justifies the application of less stringent measures.

(4) The assessment referred to in sub-article (1) shall especially take into account the question of disposal of waste and effluents. Where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment.

(5) A record of the assessment referred to in sub-article (1) shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification pursuant to Articles 6, 8 and 9 or on request.

(6) The user shall apply, except to the extent that paragraph 2 of Annex IV allows other measures to be applied, the general principles and the appropriate containment and other protective measures set out in Annex IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

(7) The assessment referred to in sub-article 5(1) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

(a) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct, or

(b) there is reason to suspect that the assessment is no longer appropriate judged in the light of new scientific or technical knowledge.

PREMISES USED FOR THE FIRST TIME

6. When premises are to be used for the first time for contained uses, the user shall be required to submit to the competent authority, before commencing such use, a notification containing at least the information listed in Annex V, Part A.

CLASS 1 CONTAINED USE

7. Following the notification referred to in Article 6, subsequent class 1 contained use may proceed without further notification, and users of GMMs in class 1 contained uses shall be required to keep the record of each assessment referred to in sub-article 5(5), which shall be made available to competent authority on request.

CLASS 2 CONTAINED USE

8. (1) For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part B shall be submitted to the competent authority.

(2) If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification.

Provided that the applicant can, however, himself request a decision on a formal authorisation from the authority. The decision must be made within a maximum of 45 days from the notification.

(3) If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to in sub-article (1), or earlier with the agreement of the competent authority.

CLASS 3 AND CLASS 4 CONTAINED USE

9. (1) For first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with Article 7, a notification containing the information listed in Annex V, Part C shall be submitted.

(2) A class 3 or higher class of contained use may not proceed without the prior consent of the authority which shall communicate its Decision in writing:

(a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a

higher class than the contained use with which it is intended to proceed;
(b) at the latest 90 days after submission of the notification, in other cases.

NOTIFICATIONS TO THE COMPETETN AUTHORITY

10 (1) The competent authority shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the assessment referred to in Article 5(1) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

(2) If necessary, the Authority may:
(a) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to the contained use(s).

Provided that in this case the Authority may require that the contained use, if proposed, does not begin, or, if in progress, is suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;
(b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

(3) For the purpose of calculating the periods referred to in Articles 8 and 9, any period of time during which the Authority:
- is awaiting any further information which it may have requested from the notifier in accordance with sub-article 2(a), or
- is carrying out a public inquiry or consultation in accordance with Article 12
shall not be taken into account.

NEW INFORMATION ON RISKS OF CONTAINED USE

11. If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences for the risks posed by it, the Authority shall be informed as soon as possible and the notification pursuant to Articles 6, 8 and 9 shall be modified.

Provided that if information subsequently becomes available to the competent authority which could have significant consequences for the risks posed by the contained use, the competent authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

PUBLIC CONSULTATION

12. Where the competent authority considers it appropriate, it may hold public consultations on aspects of the proposed contained use, without prejudice to Article 18.

EMERGENCY PLANS

13. The competent authority shall ensure that before a contained use commences:

(a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment, except where such an emergency plan has been drawn up under other relevant legislation;

(b) information on such emergency plans, including the relevant safety measures to be applied, is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

The authority shall at the same time make available to other States concerned, the same information as that which is disseminated to their nationals.

OCCURRENCES OF ACCIDENTS

14. (1) In the event of an accident, the user shall be required to inform immediately the competent authority and provide the following information:

- the circumstances of the accident,
- the identity and quantities of the GMMs concerned,
- any information necessary to assess the effects of the accident on the health of the general population and the environment,
- the measures taken.

2. Where information is given pursuant to sub-article (1), the competent authority shall be required to:

- ensure that any measures necessary are taken, and immediately alert other States which could be affected by the accident,
- collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

COMMUNICATION WITH OTHER STATES

15. The competent authority shall consult with other Member States, likely to be affected in the event of an accident, on the proposed implementation of emergency plans.

INSPECTIONS AND CONTROL MEASURES

16. The competent authority shall organise inspections and other control measures to ensure user compliance with these regulations.

DISCLOSURE OF CONFIDENTIAL DATA

17.(1) Where disclosure of data affects one or more of the following:

- the confidentiality of the proceedings of public authorities, international relations and national defence,
- public security,
- matters which are, or have been, sub judice, or under enquiry (including disciplinary enquiries), or which are the subject of preliminary investigation proceedings,
- commercial and industrial confidentiality, including intellectual property,
- the confidentiality of personal data and/or files,
- material supplied by a third party without that party being under a legal obligation to do so,
- material, the disclosure of which would make it more likely that the environment to which such material related would be damaged,

the notifier may indicate the information in the notifications submitted pursuant to these regulations that should be treated as confidential.

Provided that a verifiable justification must be given in such cases.

(2) The Authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

(3) In no case may the following information, when submitted according to Articles 6, 8 or 9, be kept confidential:

- the general characteristics of the GMMs, name and address of the notifier, and location of use,
- class of contained use and measures of containment,
- the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(4) The competent authority shall not divulge to third parties any information decided to be confidential according to sub-article 2 and notified or otherwise provided pursuant to these regulations, and shall protect intellectual property rights relating to the data received.

(5) If, for whatever reasons, the notifier withdraws the notification, the Authority must respect the confidentiality of the information supplied.

Offences.

18. Any person shall be guilty of an offence under these regulations if:

(a) he fails to comply with any provision of these regulations or fails to comply with permit conditions or with any order lawfully given in terms of any provision of these regulations; or

(b) he contravenes any restriction, prohibition or requirement imposed by or under these regulations; or

(c) he acts in contravention of any of the provisions of these regulations; or

(d) he conspires or attempts, or aids, or abets, any other person by whatever means, including advertising, counselling or procurement to contravene the provisions of these regulations or to fail to comply with any such provisions, including any order lawfully given in terms of any of the provision of these regulations, or to contravene any restriction, prohibition or requirement imposed by or under the said regulations.

Penalties

19. Any person who commits an offence against these regulations shall, on conviction, be liable:

(a) on a first conviction to a fine (multa) of not less than five hundred Maltese liri but not exceeding one thousand Maltese liri;

(b) on a second or subsequent convictions, to a fine (multa) of not less than one thousand Maltese liri, but not exceeding two thousand Maltese liri or to imprisonment for a term not exceeding two years, or to both such fine and imprisonment:

Provided that the court shall order any person who has been found guilty of committing an offence against these regulations to pay for the expenses incurred by the competent authority as a result of the said offence, the revocation of the permit issued by the competent authority and the confiscation of the corpus delicti.

Applicability of the Criminal Code Cap.9

20. (1) The provisions of articles 23 and 30 of the Criminal Code shall, mutatis mutandis, apply to proceedings in respect of offences against these regulations, so however that the disqualification from holding or obtaining a licence, permit or authority shall in no case be for less than one year.

(2) Notwithstanding the provisions of article 370 of the Criminal Code, proceedings for an offence against these regulations shall be held before the Court of Magistrates (Malta) or the Court of Magistrates (Gozo), as the case may be, and shall be in accordance with the provisions of the Criminal Code regulating the procedure before the said courts as courts of criminal judicature.

(3) Notwithstanding the provisions of the Criminal Code, the Attorney General shall always have a right of appeal to the Court of Criminal Appeal from any judgement given by the Court of Magistrates (Malta) or the Court of Magistrates (Gozo) in respect of proceedings for any offence against these regulations.

21. The Schedules I to IV to these regulations are being published in the English language with the English text of these regulations.

ANNEX I

PART A

Techniques of genetic modification referred to in Article 3 paragraph 2 (i) are, inter alia:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.
2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation.
3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART B

Techniques referred to in Article 4(b)(ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than techniques/methods excluded by Annex II, PART A:

(1) in vitro fertilisation;
(2) natural processes such as: conjugation, transduction, transformation;
(3) polyploidy induction.

ANNEX II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Directive on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.
2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.
3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.
4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into

cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants. Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

ANNEX III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 5(1)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 5(1). It may be supplemented, as regards in particular section B, by guidance notes which may be issued by the Authority .

A. ELEMENTS OF ASSESSMENT

1. The following should be considered as potentially harmful effects:
- disease to humans including allergenic or toxic effects,
- disease to animals or plants,
- deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,
- deleterious effects due to establishment or dissemination in the environment,
- deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in Article 5(1) should be based on the following:

(a) the identification of any potentially harmful effects, in particular those associated with:

(i) the recipient micro-organism;

(ii) the genetic material inserted (originating from the donor organism);

(iii) the vector;

(iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);

(v) the resulting GMM;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised.

B. PROCEDURE

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 5:

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants (1);

(1) This would only apply to animals and plants in the environment likely

to be exposed.

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants, or likely to cause deleterious effects in the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Council Directive 90/679/EEC). International or national classification schemes (e.g. WHO, NIH, etc.) and their revisions due to new scientific knowledge and technical progress may also be considered. These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 90/679/EEC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance to the categorisation of the contained use activities in the four classes of risk referred to in Article 5(2). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with paragraphs 3 to 5, should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level or risk associated with the GMMs together with consideration of:

(i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

(ii) the characteristics of the activity (e.g. its scale; nature);

(iii) any non-standard operations (e.g. the inoculation of animals with GMMs; equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under paragraph 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 5(2).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 5(2).

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES

General principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene, shall apply:

(i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;

(ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;

(iii) to test adequately and maintain control measures and equipment;

(iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(v) to provide appropriate training of personnel;

(vi) to establish biological safety committees or subcommittees, if required;

(vii) to formulate and implement local codes of practice for the safety of personnel, as required;

(viii) where appropriate to display biohazard signs;

(ix) to provide washing and decontamination facilities for personnel;

(x) to keep adequate records;

(xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;

(xii) to prohibit mouth pipetting;

(xiii) to provide written standard operating procedures where appropriate to ensure safety;

(xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;

(xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

In some cases users may, with the agreement of the Authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables "optional" means that the user may apply these measures on

a case-by-case basis, subject to the assessment referred to in Article 5(1).

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms "glasshouse" and "growth-room" refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

>TABLE POSITION>

>TABLE POSITION>

>TABLE POSITION>

ANNEX V

PART A

Information required for the notification referred to in Article 6:

- name of user(s) including those responsible for supervision and safety,
- information on the training and qualifications of the persons responsible for supervision and safety,
- details of any biological committees or subcommittees,
- address and general description of the premises,
- a description of the nature of the work which will be undertaken,
- the class of the contained uses,
- only for class 1 contained uses, a summary of the assessment referred to in Article 5(1) and information on waste management.

PART B

Information required for the notification referred to in Article 8:

- the date of submission of the notification referred to in Article 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification,
- the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
- the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the purpose of the contained use including the expected results,
- approximate culture volumes to be used,
- description of the containment and other protective measures to be applied, including information about waste management including the wastes to be generated, their treatment, final form and destination,
- a summary of the assessment referred to in Article 5(1),
- the information necessary for the Authority to evaluate any emergency response plans if required under Article 13.

PART C

Information required for the notification referred to in Article 9:

(a) - the date of submission of the notification referred to in Article 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification;

(b) - the recipient or parental micro-organism(s) to be used,

- the host-vector system(s) to be used (where applicable),
- the source(s) and intended functions(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the culture volumes to be used;

(c) - description of the containment and other protective measures to be applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination,
- the purpose of the contained use including the expected results,
- description of the parts of the installation;

(d) information about accident prevention and emergency response plans, if any:
- any specific hazards arising from the location of the installation,
- the preventive measures applied such as safety equipment, alarm systems and containment methods,
- procedures and plans for verifying the continuing effectiveness of the containment measures,
- a description of information provided to workers,
- the information necessary for the Authority to evaluate any emergency response plans if required under Article 13;

(e) a copy of the assessment referred to in Article 5(1).