

SUBSIDIARY LEGISLATION 549.31**BIOSAFETY CO-ORDINATING COMMITTEE
REGULATIONS**

13th February, 2004

LEGAL NOTICE 290 of 2002.

- 1.** The title of these regulations is the Biosafety Co-ordinating Committee Regulations. Citation.
- 2.** The objective of these regulations is to set up a committee with the aim to achieve an integrated approach on biosafety, the contained use of genetically-modified micro-organisms, the deliberate release into the environment of genetically-modified organisms and the placing of the market of genetically-modified organisms, in order to achieve a high level of protection of human health and the environment taken as a whole, without prejudice to other relevant regulations. Objective.
- 3.** In these regulations, unless the context otherwise requires: Interpretation.
- "competent authority" means the Environment and Resources Authority as prescribed by the Nomination of the Competent Authority Order, 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; S.L. 549.19
- "contained use" means any activity in which micro-organisms are genetically modified or in which such genetically modified micro-organisms 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;
- "deliberate release" means any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;
- "genetically modified 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 of the Contained Use of Genetically Modified Micro-Organisms Regulations; S.L. 549.49

S.L. 549.49	<p>(ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification of the Contained use of Genetically modified Micro-Organisms Regulations;</p> <p>"genetically modified organisms" (GMO) means an organism, 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; within the terms of this definition:</p>
S.L. 549.60	<p>(a) genetic modification occurs at least through the use of the techniques listed in Schedule I A of the Deliberate Release into the Environment of Genetically Modified Organisms Regulations;</p>
S.L. 549.60	<p>(b) the techniques in Schedule IA, Part 2, of the Deliberate Release into the Environment of Genetically Modified Organisms Regulations are not considered to result in genetic modification;</p>
S.L. 549.49 S.L. 549.60	<p>"main regulations" mean the Contained use of Genetically Modified Micro-Organisms Regulations, and the Deliberate Release into the Environment of Genetically Modified Organisms Regulations;</p> <p>"Minister" means the Minister responsible for the environment;</p> <p>"notifier" means the person submitting the notification;</p> <p>"notification" means the submission to the competent authority of the requisite information specified in the main regulations;</p> <p>"placing on the market" means making available to third parties, whether in return for payment or free of charge;</p> <p>"time-frames" means the time-frames for different notifications and processes cited in the main regulations;</p> <p>"user" means any natural or legal person responsible for the contained use of genetically modified micro-organisms.</p>
Integrated approach.	<p>4. The competent authority shall ensure that the conditions of, procedure for the grant of the permit and compliance monitoring shall be fully co-ordinated, in order to guarantee an effective integrated approach by all authorities competent for this procedure.</p>
Establishment of the BCC.	<p>5. For this purpose, there shall be a Biosafety Co-ordinating Committee, hereafter referred to as the BCC or the Committee.</p>
Composition and terms of reference of the BCC.	<p>6. (1) The composition and terms of reference of the BCC shall be as shown in Schedules I and II respectively.</p> <p>(2) The competent authority shall appoint a secretary to the Committee.</p> <p>(3) The members of the Committee shall be so appointed for a term of three years:</p> <p>Provided that the Chairman and the other members of the Committee may resign their office at any time by giving notice in writing to the Minister, and the Minister may at any time remove the Chairman and, or any of the members of the Committee on grounds of disability to perform their functions, bankruptcy or</p>

neglect of duty.

(4) Without prejudice to any of these regulations, the Committee may regulate its own procedures and meetings.

7. (1) A Scientific Support and Advisory Sub-Committee may be set up by the Chairman in order to assist the BCC on specific scientific and advisory issues:

Establishment of the Scientific Support and Advisory Sub-Committee.

Provided that, once set up, a permanent representative of this sub-committee will be on the BCC for a period specified in regulation 6(3).

(2) The Chairman may set up any other sub-committees to assist the BCC as it may be required.

8. Any person requiring any permit under the main regulations shall submit the notifications for a permit to the competent authority, which shall forward such notifications to the Biosafety Co-ordinating Committee.

Permit procedures.

9. (1) Should such notifications be required under the main regulations, individual institutions represented in the Committee and mentioned in Schedule I shall assess the notifications in terms of their legal remits and requirements and report back to the BCC within the period set in the main regulations.

Submission of notifications.

(2) The Committee may decide to forward the notifications to the Scientific Support and Advisory Sub-Committee or to any other public entity for consultation before finalising its recommendations.

(3) Based on the assessment and consultations mentioned in subregulations (1) and (2), the Committee will forward its recommendations to the competent authority within the period set in the main regulations.

(4) The competent authority shall assess these recommendations and the notifications and shall forward its decision to the notifier or user on the legal basis set in the main regulations.

10. Any monitoring compliance and enforcement activities of relevance to the main regulations or the BCC shall be undertaken by the individual institutions represented in the Committee and mentioned in Schedule I, and the committee shall act in terms of the legal remits and requirements of the institutions and report back to the BCC.

Monitoring requirements.

11. Schedules I to II are being published in the English language with the English text of these regulations.

Language of Schedules.

SCHEDULE I

Composition of the Biosafety Co-ordinating Committee

The Biosafety Co-ordinating Committee shall consist of:

- (a) the Director of the Environment Protection Directorate or his authorised representative as Chairman of the Committee,
- (b) a public officer responsible for biosafety, designated by the Chairman of the Environment and Resources Authority,
- (c) a public officer responsible for public health, designated by the Minister responsible for public health,
- (d) a public officer responsible for occupational health and safety, designated by the Chairman of the Occupational Health and Safety Authority,
- (e) a public officer responsible for biodiversity protection, designated by the Chairman of the Environment and Resources Authority,
- (f) a public officer responsible for agriculture and fisheries, designated by the Minister responsible for agriculture and fisheries,
- (g) a scientist to act as a representative and Chairman of the Scientific Support and Advisory Sub-Committee,
- (h) any other representative as required by the competent authority.

SCHEDULE II

The terms of reference of the Biosafety Co-ordinating Committee shall include the following:

- (a) to ensure the implementation of the provisions of the main regulations;
- (b) to evaluate the notifications required in connection with the main regulations and these regulations;
- (c) to supply the recommendations resulting from the evaluation referred to in paragraph (b) above to the competent authority within the time-frames set in the main regulations;
- (d) to ensure that appropriate monitoring and enforcement measures are taken in accordance with the provisions of these regulations and the main regulations;
- (e) to collaborate with relevant entities forming the BCC with respect to monitoring, inspections and enforcement;
- (f) to deal with infringements of permit conditions;
- (g) to identify any existing laboratories or installations which fall under the scope of these regulations and the main regulations;
- (h) to establish criteria for emergency plans;
- (i) to set up procedures for consultation of the public;
- (j) to establish a public register of locations utilised for the deliberate release of genetically modified organisms;
- (k) to ensure that confidentiality of information and intellectual property rights with respect to genetically modified micro-organisms and

genetically modified organisms are respected;

- (l) to liaise with the Malta Standardisation Authority in connection with labeling and packaging requirements and ensure that the products placed on the market comply with specified labelling and packaging requirements;
 - (m) to advise the competent authority on educational campaigns and training exercises necessary;
 - (n) to liaise with other entities involved in related issues, including nature protection, phytosanitary requirements, civil protection, land use, waste management, etc.;
 - (o) to establish a reporting system aimed at supplying the general public and the competent authority with relevant information;
 - (p) to keep abreast of developments in the field of biosafety and genetically-modified organisms;
 - (q) to propose any improvements required for the implementation of these regulations and the main regulations;
 - (r) any other function as may be conducive to the better performance of its functions under these regulations and the main regulations.
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