

L.N. 170 of 2002

**ENVIRONMENT PROTECTION ACT, 2001
(ACT NO. XX OF 2001)**

**Deliberate Release into the Environment of Genetically Modified
Organisms Regulations, 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:-

1. (1) The title of these regulations is the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2002. Citation and commencement.

(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.

(3) These regulations provide for the protection of human health and the environment when:

- carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within Malta,

- placing on the market genetically modified organisms as or in products within Malta.

Part A: General Provisions

2. (1) In these regulations, unless the context otherwise requires: Interpretation.

“organism” means any biological entity capable of replication or of transferring genetic material;

“genetically modified organism” (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:

(a) genetic modification occurs at least through the use of the techniques listed in Schedule I A, part 1;

(b) the techniques listed in Schedule I A, part 2, are not considered to result in genetic modification;

“deliberate release” means any intentional introduction into the environment of a GMO or a combination of GMOs 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;

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“competent 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;

“placing on the market” means making available to third parties, whether in return for payment or free of charge;

The following operations shall not be regarded as placing on the market:

- making available genetically modified microorganisms for activities regulated under the Regulations of 2002 dealing with the contained use of genetically modified microorganisms including culture collections;

- making available GMOs other than microorganisms referred to in the first indent, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level

of safety for the general population and the environment, the measures should be based on the same principles of containment as laid down in the Regulations of 2002 dealing with the contained use of genetically modified microorganisms including culture collections;

- making available GMOs to be used exclusively for deliberate releases complying with the requirements laid down in part B of these regulations;

“notification” means the submission of the information required under these regulations to the competent authority;

“notifier” means the person submitting the notification;

“product” means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;

“environment impact assessment” means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Schedule II.

3. (1) These regulations shall not apply to organisms obtained through the techniques of genetic modification listed in Schedule I B. Exemptions.

(2) These regulations shall not apply to the carriage of genetically modified organisms by road, sea or air.

4. (1) GMOs may only be deliberately released or placed on the market in conformity with part B or part C of these regulations respectively. General Obligations.

(2) Any person shall, before submitting a notification under part B or part C, carry out an environment impact assessment. The information which may be necessary to carry out the environment impact assessment is laid down in Schedule III.

Provided that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment shall be taken into particular consideration when carrying out an environment impact assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment.

Provided that this phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.

(3) (i) Potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, shall be accurately assessed on a case-by-case basis.

(ii) This assessment shall be conducted in accordance with Schedule II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.

(4) The competent authority shall be the organ responsible for ensuring compliance with the requirements of these regulations, and it shall examine notifications under part B and part C for compliance with the requirements of these Regulations and whether the assessment provided for in sub-article 2 is appropriate.

(5) The competent authority shall organise inspections and other control measures as appropriate, to ensure compliance with these regulations.

Provided that in the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, the competent authority shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform the public, and other states which might be adversely effected.

(6) The competent authority shall take the necessary measures to ensure traceability, in line with the requirements laid down in Schedule IV, at all stages of the placing on the market of GMOs authorised under part C.

Part B: Deliberate Release of GMOs for any other Purpose than for Placing on the Market

Applicability of Articles 6 to 10.

5. (1) Articles 6 to 10 shall not apply to medicinal substances and compounds for human use consisting of, or containing, a GMO or combination of GMOs provided that their deliberate release for any purpose other than that of being placed on the market is authorised by

(a) for a specific environment impact assessment in accordance with Schedule II and on the basis of the type of information specified in Schedule III without prejudice to additional requirements provided for by the said legislation;

(b) for explicit consent prior to release;

(c) for a monitoring plan in accordance with the relevant parts of Schedule III, with a view to detecting the effects of the GMO or GMOs on human health or the environment;

(d) in an appropriate manner for requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in these regulations and in the measures taken in accordance therewith.

(2) Assessment of the risks to the environment presented by such substances and compounds shall be carried out by the competent authority, in accordance with the procedures laid down in these regulations.

6. (1) Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs in Malta, or any other area outside the territory of Malta, submit a notification to the competent authority.

Standard
Authorisation
Procedure.

Provided that when the deliberate release of a GMO or of a combination of GMOs is done outside the territory of Malta, the Competent Authority must notify the Authorities concerned within whose territory release is to take place.

(2) The notification referred to in sub-article (1) shall include:

(a) a technical dossier supplying the information specified in Schedule III necessary for carrying out the environment impact assessment of the deliberate release of a GMO or combination of GMOs, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the potential receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Schedule III in order to identify effects of the GMO(s) on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier;

(b) the environment impact assessment and the conclusions required in Schedule II, section D, together with any bibliographic reference and indications of the methods used.

(3) The notifier may refer to data or results from notifications previously submitted by other notifiers, provided that the information, data and results are non confidential or these notifiers have given their agreement in writing, or may submit additional information he considers relevant.

(4) The competent authority may accept that releases of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

(5) The competent authority shall acknowledge the date of receipt of the notification and shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with these Regulations and that the release may proceed; or

(b) indicating that the release does not fulfil the conditions of these Regulations and that notification is therefore rejected.

(6) For the purpose of calculating the 90 day period referred to in sub-article 5, no account shall be taken of any periods of time during which the competent authority:

(a) is awaiting further information which it may have requested from the notifier, or

(b) is carrying out a public inquiry or consultation in accordance with Article 9; this public inquiry or consultation shall not prolong the 90 day period referred to in sub-article 5 by more than 30 days.

(7) If the competent authority requests new information it must simultaneously give its reasons for so doing.

(8) The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

(9) No material derived from GMOs which are deliberately released in accordance with part B shall be placed on the market, unless in accordance with Part C.

7. (1) If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems, and the GMOs concerned meet the criteria set out in Schedule V, the competent authority may apply *differentiated procedures* to such types of GMOs.

(2) The notifier may proceed with the release only when he has received the written consent of the competent authority, and in accordance with the minimum amount of Schedule III technical information necessary for evaluating any foreseeable risks from release, in particular :

(a) information relating to GMOs;

(b) information relating to conditions of release and potential receiving environment;

(c) information on interactions between GMOs and environment;

(d) environmental risk assessment.

(3) Without prejudice to sub-articles 1 and 2, the simplified procedures concerning the deliberate release into the environment of genetically modified plants, in the case of more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted/deleted sequences or have the same inserted/deleted sequence but differ in phenotypes shall be those laid down in Schedule IX.

Handling of modifications and new information.

8. (1) In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if new information has become available on such risks, either while the notification is being examined by the competent authority or after the competent authority has given its written consent, the notifier shall immediately:

(a) take the measures necessary to protect human health and the environment;

(b) inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available;

(c) revise the measures specified in the notification.

(2) If information becomes available to the competent authority referred to in sub-article 1 which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in sub-article 1, the competent authority shall evaluate such information and make it available to the public.

Provided also that it may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof.

Consultation of and information to the public.

9. (1) The competent authority shall, without prejudice to the provisions of Articles 7 and 20, consult the public and, where appropriate, groups on the proposed deliberate release.

(2) Provided that in so doing, the competent authority shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

(3) Without prejudice to the provisions of Article 20, the competent authority shall make available to the public information on all part B releases of GMOs in Malta.

Reporting by notifiers on releases.

10. After completion of a release, and thereafter, at any intervals laid down in the consent on the basis of the results of the environment impact assessment, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with, where appropriate, particular reference to any kind of product that the notifier intends to notify at a later stage.

Part C: Placing on the market of GMOs as or in products

11. (1) Articles 12 to 19 shall not apply to any GMO as or in products, as far as they are authorised by any relevant legislation which provides for a specific environment impact assessment, to be carried out in accordance with the principles set out in Schedule II and on the basis of information specified in Schedule III, without prejudice to additional requirements provided for by the relevant legislation, and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in these Regulations, or in any other relevant regulations concerning medicinal products for human and veterinary use. Sectoral legislation

(2) Any GMO as or in products as far as they are authorised by other relevant legislation shall only be placed on the market after having been accepted for placing on the market in accordance with these Regulations.

12. (1) (a) Before a GMO or a combination of GMOs as or in products is placed on the market for the first time, a notification shall be submitted to the competent authority. Notification procedure.

(b) The competent authority shall acknowledge the date of receipt of the notification.

(c) The competent authority shall without delay examine whether the notification is in accordance with sub-article 2 and shall, if necessary, ask the notifier for additional information.

(2) The notification shall contain:

(a) the information required in Schedules III and IV. This information shall take into account the diversity of sites of use of the GMO as or in a product and shall include information on data and results obtained from research and developmental releases concerning the impact of the release on human health and the environment;

(b) the environment impact assessment and the conclusions required in Schedule II, section D;

(c) the conditions for the placing on the market of the product, including specific conditions of use and handling;

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(d) with reference to article 14(4), a proposed period for the consent which should not exceed ten years;

(e) a plan for monitoring in accordance with Schedule VII, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent;

(f) a proposal for labelling which shall comply with the requirements laid down in Schedule IV and, the labelling shall clearly state that a GMO is present and, the words "this product contains genetically modified organisms" shall appear either on a label or in an accompanying document;

(g) a proposal for packaging which shall comprise the requirements laid down in Schedule IV;

(h) a summary of the dossier as may be established by the competent authority from time to time.

Provided that if on the basis of the results of any release notified under part B, or on other substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a GMO as or in a product do not pose a risk to human health and the environment, he may propose to the competent authority not to provide part or all of the information required in Schedule IV, section B.

(3) The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either in Malta or abroad.

(4) The notifier may also refer to data or results from notifications previously submitted by other notifiers or submit additional information he considers relevant, provided that the information, data and results are non-confidential or these notifiers have given their agreement in writing.

(5) In order for a GMO or combination of GMOs to be used for a purpose different from that already specified in a notification, a separate notification shall be submitted.

(6) If new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment, and

inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification.

13. (1) On receipt and after acknowledgement of the notification in accordance with article 12(2), the competent authority shall examine it for compliance with these regulations. Assessment report.

(2) (a) Within 90 days after receipt of the notification the competent authority shall prepare an assessment report and send it to the notifier.

(b) A subsequent withdrawal by the notifier shall be without prejudice to any further submission of the notification to another competent authority.

(3) The assessment report shall indicate whether:

(a) the GMO(s) in question should be placed on the market and under which conditions; or

(b) the GMO(s) in question should not be placed on the market.

The assessment reports shall be established in accordance with the guidelines laid down in Schedule VI.

(4) For the purpose of calculating the 90 day period referred to in sub-article 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account, and the competent authority shall state the reasons in any request for further information.

14. (1) (a) In the cases referred to in article 13(3), the competent authority may ask for further information, make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 60 days from the date of circulation of the assessment report. Standard procedure.

(b) The Competent Authority may grant to the notifier further time to submit further information provided that reasons are stated in any request for such information.

(c) If the competent authority after having prepared the assessment report decides that the product may be placed on the market, it shall give its consent in writing for placing on market of the GMOs in question and this shall be transmitted to the notifier.

(2) In the case referred to in article 13(3)(b), if the competent authority decides that the GMO(s) should not be placed on the market, the notification shall be rejected, and this decision shall state the reasons.

(3) If the competent authority decides that the product may be placed on the market, the competent authority shall give its consent in writing for placing on the market.

(4) (a) The consent shall be given for a maximum period of ten years starting from the date on which the consent is issued.

(b) For the purpose of approval of a GMO or a progeny of that GMO intended only for the marketing of their seeds the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the GMO on an official national catalogue of plant varieties.

(c) In the case of forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the GMO on the official national register of basic material.

Renewal of consent. 15. (1) By way of derogation from Articles 12, 13 and 14, the procedure set out in sub-articles 2 to 5 shall be applied to the renewal of consents granted under part C.

(2) At the latest nine months before the expiry of the consent the notifier under this Article shall submit a notification to the competent authority, which shall contain:

(a) a copy of the consent to the placing on the market of the GMOs;

(b) a report on the results of the monitoring which was carried out according to Article 17;

(c) any other new information which has become available with regard to the risks of the product to human health and/or the environment; and

(d) as appropriate, a proposal for amending or complementing the conditions of the original consent, inter alia the conditions concerning future monitoring and the time limitation of the consent.

Provided that the competent authority shall acknowledge the date of receipt of the notification.

(3) The assessment report shall indicate whether:

(a) the GMO(s) should remain on the market and under which conditions; or

(b) the GMO(s) should not remain on the market.

(4) (a) In the case of sub-article 3(a) the competent authority shall transmit to the notifier the final decision in writing.

(b) The validity of the consent should not, as a general rule, exceed ten years and may be limited or extended as appropriate for specific reasons.

(c) The validity of the consent may be limited as appropriate.

(5) Following a notification for the renewal of a consent in accordance with sub-article 2, the notifier may continue to place the GMOs on the market under the conditions specified in that consent until a final decision has been taken on the notification.

16. (1) Only if a written consent has been given for the placing ^{Consent.} on the market of a GMO as or in a product by a competent authority of a Member state of the European Union may that product be used without further notification to the competent authority in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

(2) (a) The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 14, and 15 and in conformity with any conditions required in that consent.

(b) The competent authority shall take all necessary measures to ensure that written consent decision, where applicable, are made accessible to public and that conditions specified in written consent and the decision, where applicable, are complied with.

(3) The written consent referred to in Articles 14 and 15 shall, in all cases, explicitly specify:

(a) the scope of the consent, including the identity of the GMO(s) to be placed on the market as or in products, and their unique identifier;

(b) the period of validity of the consent;

(c) the conditions for the placing on the market of the product, including any specific condition of use, handling and packaging of the GMO(s) as or in products, and conditions for the protection of particular ecosystems/environments and/or geographical areas;

(d) that, without prejudice to Article 20, the notifier shall make control samples available to the competent authority on request;

(e) the labelling requirements, in compliance with the requirements laid down in Schedule IV. The labelling shall clearly state that a GMO is present.

The words "This product contains genetically modified organisms" shall appear either on a label or in a document accompanying the product or other products containing the GMO(s);

(f) monitoring requirements in accordance with Schedule VII, the time period of the monitoring plan and, where appropriate, any obligations on any person selling the product or any user of it, inter alia, in the case of GMOs grown, concerning a level of information deemed appropriate on their location.

Monitoring and handling of new information.

17. (1) Following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent.

Provided that the reports of this monitoring shall be submitted to the competent authority, and on the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority may adapt the monitoring plan after the first monitoring period.

(2) If new information has become available, from the users or other sources, with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In

addition, the notifier shall revise the information and conditions specified in the notification.

(3) If information becomes available to the competent authority which could have consequences for the risks of the GMO(s) to human health or the environment, or under the circumstances described in sub-article 2, it may avail itself of the provisions in articles 14(1) where appropriate, when the information has become available before the written consent.

Provided that when the information has become available after the consent has been given, the competent authority shall amend the consent and shall transmit the amended consent to the notifier.

(4) The competent authority shall make the results of the monitoring carried out under part C of these regulations publicly available.

18. (1) At all stages of the placing on the market, the labelling and packaging of GMOs placed on the market as or in products shall comply with the relevant requirements specified in the written consent referred to in articles 14(3), and 16(3). Labelling.

Provided that the competent authority may set minimum thresholds for products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded.

19. (1) Without prejudice to this article the competent authority may not prohibit, restrict or impede placing on market of GMOs, as or in products, which comply with these regulations except, where, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, the competent authority has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under these Regulations constitutes a risk to human health or the environment, the competent authority may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product. Safeguard clause.

(2) The competent authority shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

Part D

Confidentiality.

20. (1) The competent authority shall not divulge to third parties any confidential information notified or exchanged under these Regulations and shall protect intellectual property rights relating to the data received.

(2) The notifier may indicate the information in the notification submitted under these Regulations, the disclosure of which might harm his competitive position and which should therefore be treated as confidential, and verifiable justification must be given in such cases.

(3) The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions.

(4) In no case may the following information when submitted according to Articles 6, 7, 8, 12, 15, 17 or 19 be kept confidential:

- general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;

- methods and plans for monitoring of the GMO or GMOs and for emergency response;

- environment impact assessment.

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

Labelling of GMOs referred to in the definition of placing on the market in Article 2(1).

21. The GMOs to be made available for operations referred to in the definition of 'placing on the market' in Article 2(1), shall be subject to adequate labelling requirements in accordance with the relevant sections of Schedule IV in order to provide for clear information, on a label or in an accompanying document, on the presence of GMOs.

To that effect the words "This product contains genetically modified organisms" shall appear either on a label or in an accompanying document.

22. (1) Without prejudice to sub-article 2 and point A No 7 of Schedule IV, the competent authority shall: Establishment of public registers

(a) establish public registers in which the location of the release of the GMOs under part B is recorded.

(b) also establish registers for recording the location of GMOs grown under part C, inter alia so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 16(3)(f) and 17(1).

(2) Without prejudice to such provisions in Articles 16 and 17, the said locations shall:

- be notified to the competent authority, and

- be made known to the public in the manner deemed appropriate by the competent authority.

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

(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.

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

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(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.

25. (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.

Language of
Annexes.

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

SCHEDULE I A

Techniques referred to in the definition of GMO in article 2

PART 1

Techniques of genetic modification referred to in sub-paragraph (a) in the definition of GMO in article 2 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 an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast 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 2

Techniques referred to in sub-paragraph (b) in the definition of GMO which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Schedule I B:

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

SCHEDULE I B

Techniques referred to in article 5

Techniques/methods of genetic modification yielding organisms to be excluded from this Regulation, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

- (1) mutagenesis,
- (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

SCHEDULE II

Principles for the Environment impact assessment

This Schedule describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environment impact assessment (e.i.a) referred to in Articles 4 and 12. Without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, the following terms are described as follows:

- “direct effects” refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

- “indirect effects” refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Observations of indirect effects are likely to be delayed;

- “immediate effects” refers to effects on human health or the environment which are observed during the period of the release of the GMO.

Immediate effects may be direct or indirect;

- “delayed effects” refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environment impact assessment is also that an analysis of the “cumulative long-term effects” relevant to the release and the placing on the market is to be carried out. “Cumulative long-term effects” refers to the accumulated effects of consents on human health and the environment, including inter alia flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an e.i.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The e.i.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the e.i.a.:

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

- the e.i.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

- the e.i.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.e., GMOs already in the environment;

- if new information on the GMO and its effects on human health or the environment becomes available, the e.i.a. may need to be readdressed in order to:

- determine whether the risk has changed;

- determine whether there is a need for amending the risk management accordingly.

C. Methodology

C.1. Characteristics of GMOs and releases

Depending on the case the e.i.a. has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or parental organism(s);

- the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

- the GMO;

- the intended release or use including its scale;

- the potential receiving environment; and

- the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the e.i.a.

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C.2. Steps in the e.i.a.

In drawing conclusions for the e.i.a. referred to in Articles 4, 6, 7 and 12 the following points should be addressed:

1. Identification of characteristics which may cause adverse effects:

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Schedule III A, and B 7 in Schedule III B);

- disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Schedule III A, and B 7 and D 8 in Schedule III B);

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Schedule III A);

- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Schedule III A);

- effects on biogeochemistry(biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Schedule III A, and D 11 in Schedule III B).

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of the GMO(s) in the environment,

- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,

- phenotypic and genetic instability,
 - interactions with other organisms,
 - changes in management, including, where applicable, in agricultural practices.
2. Evaluation of the potential consequences of each adverse effect, if it occurs.

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur.

The magnitude of the consequences is likely to be influenced by the environment into which the GMO(s) is (are) intended to be released and the manner of the release.

3. Evaluation of the likelihood of the occurrence of each identified potential adverse effect

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO(s) is intended to be released, and the manner of the release.

4. Estimation of the risk posed by each identified characteristic of the GMO(s)

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. Application of management strategies for risks from the deliberate release or marketing of GMO(s)

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. Determination of the overall risk of the GMO(s)

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

D. Conclusions on the potential environmental impact from the release or the placing on the market of GMOs

On the basis of an e.i.a. carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections

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D1 or D2 should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs:

D.1. In the case of GMOs other than higher plants

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

D.2. In the case of genetically modified higher plants (GMHP)

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).

5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

SCHEDULE III

Information Required in the Notification

A notification referred to in part B or part C of these regulations is to include, as appropriate, the information set out below in the sub-Schedules.

Not all the points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

Future developments in genetic modification may necessitate adapting this Schedule to technical progress or developing guidance notes on this Schedule.

Further differentiation of information requirements for different types of GMOs, for example single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Community.

The description of the methods used or the reference to standardised or internationally recognised methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

Schedule III A applies to releases of all types of genetically modified organisms other than higher plants. Schedule III B applies to release of genetically modified higher plants.

The term "higher plants" means plants which belong to the taxonomic group Spermatophytæ (Gymnospermae and Angiospermae).

SCHEDULE III A

Information Required in Notifications concerning Releases of Genetically Modified Organisms other than Higher Plants

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s)

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name,
2. taxonomy,
3. other names (usual name, strain name, etc.),
4. phenotypic and genetic markers,
5. degree of relatedness between donor and recipient or between parental organisms,
6. description of identification and detection techniques,
7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,
9. organisms with which transfer of genetic material is known to occur under natural conditions,
10. verification of the genetic stability of the organisms and factors affecting it,
11. pathological, ecological and physiological traits:
 - (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
 - (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
 - (c) information on survival, including seasonability and the ability to form survival structures;
 - (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses).

Ability to colonise other organisms;

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(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) sequence;

(b) frequency of mobilisation;

(c) specificity;

(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. Characteristics of the vector

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

(c) description of the insert and/or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) methods and criteria used for selection;

(f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of the expressed protein(s);

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO;

(i) considerations for human health and animal health, as well as plant health:

(i) toxic or allergenic effects of the GMOs and/or their metabolic products;

(ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iii) capacity for colonisation;

(iv) if the organism is pathogenic to humans who are immunocompetent:

- diseases caused and mechanism of pathogenicity including invasiveness and virulence,

- communicability,

- infective dose,

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- host range, possibility of alteration,
- possibility of survival outside of human host,
- presence of vectors or means of dissemination,
- biological stability,
- antibiotic resistance patterns,
- allergenicity,
- availability of appropriate therapies.

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. description of the proposed deliberate release, including the purpose(s) and foreseen products,
2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,
3. preparation of the site previous to the release,
4. size of the site,
5. method(s) to be used for the release,
6. quantities of GMOs to be released,
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),
8. worker protection measures taken during the release,
9. post-release treatment of the site,
10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product),
2. physical or biological proximity to humans and other significant biota,
3. proximity to significant biotopes, protected areas, or drinking water supplies,
4. climatic characteristics of the region(s) likely to be affected,
5. geographical, geological and pedological characteristics,
6. flora and fauna, including crops, livestock and migratory species,
7. description of target and non-target ecosystems likely to be affected,
8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,
9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. biological features which affect survival, multiplication and dispersal,
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),
3. sensitivity to specific agents.

B. Interactions with the environment

1. predicted habitat of the GMOs,
 2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,
 3. genetic transfer capability
- (a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

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(b) postrelease transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability.

Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s),

10. identification and description of the target organisms if applicable,

11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable,

12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1. methods for tracing the GMOs, and for monitoring their effects,

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,

3. techniques for detecting transfer of the donated genetic material to other organisms,

4. duration and frequency of the monitoring.

B. Control of the release

1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use,

2. methods and procedures to protect the site from intrusion by unauthorised individuals,

3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. type of waste generated,

2. expected amount of waste,

3. description of treatment envisaged.

D. Emergency response plans

1. methods and procedures for controlling the GMOs in case of unexpected spread,

2. methods for decontamination of the areas affected, for example eradication of the GMOs,

3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,

4. methods for the isolation of the area affected by the spread,

5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

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SCHEDULE III B

Information Required in Notifications concerning Releases of Genetically Modified Higher Plants (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),
2. Name, qualifications and experience of the responsible scientist(s),
3. Title of the project,

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:

- (a) family name
- (b) genus
- (c) species
- (d) subspecies
- (e) cultivar/breeding line
- (f) common name.

2. (a) Information concerning reproduction:

- (i) mode(s) of reproduction
- (ii) specific factors affecting reproduction, if any
- (iii) generation time.

(b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

3. Survivability:

- (a) ability to form structures for survival or dormancy

(b) specific factors affecting survivability, if any.

4. Dissemination:

(a) ways and extent (for example an estimation of how viable pollen and/or seeds declines with distance) of dissemination

(b) specific factors affecting dissemination, if any.

5. Geographical distribution of the plant.

6. In the case of plant species not normally grown in any of the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

7. Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.

2. Nature and source of the vector used.

3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted/deleted:

(a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;

(b) in case of deletion, size and function of the deleted region(s);

(c) copy number of the insert;

(d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.

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3. Information on the expression of the insert:

(a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;

(b) parts of the plant where the insert is expressed (for example roots, stem, pollen, etc.).

4. Information on how the genetically modified plant differs from the recipient plant in:

(a) mode(s) and/or rate of reproduction;

(b) dissemination;

(c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.

6. Any change to the ability of the GMHP to transfer genetic material to other organisms.

7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

10. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification.

11. Potential interactions with the abiotic environment.

12. Description of detection and identification techniques for the genetically modified plant.

13. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Location and size of the release site(s).

2. Description of the release site ecosystem, including climate, flora and fauna.
3. Presence of sexually compatible wild relatives or cultivated plant species.
4. Proximity to officially recognised biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Purpose of the release.
2. Foreseen date(s) and duration of the release.
3. Method by which the genetically modified plants will be released.
4. Method for preparing and managing the release site, prior to, during and postrelease, including cultivation practices and harvesting methods.
5. Approximate number of plants (or plants per m²).

G. INFORMATION ON CONTROL, MONITORING, POSTRELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Any precautions taken:
 - (a) distance(s) from sexually compatible plant species, both wild relatives and crops
 - (b) any measures to minimise/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).
2. Description of methods for postrelease treatment of the site.
3. Description of postrelease treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques.
5. Description of any emergency plans.
6. Methods and procedures to protect the site.

SCHEDULE IV

Additional Information

This Schedule describes in general terms the additional information to be provided in the case of notification for placing on the market and information for labelling requirements regarding GMOs as or in product to be placed on the market, and GMO exempted under Article 2 definition of "placing on the market". It may be supplemented by guidance notes, as regards the description of how the product is intended to be used, which may be issued by the Authority. The labelling of exempted organisms as required by Article 21 shall be met by providing appropriate recommendations for, and restrictions on, use:

A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Schedule III:

1. proposed commercial names of the products and names of GMOs contained therein, and any specific identification, name or code used by the notifier to identify the GMO. After the consent any new commercial names should be provided to the Authority,

2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,

3. name and full address of the supplier(s) of control samples,

4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,

5. description of the geographical area(s) and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,

6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,

7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology.

Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,

8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

B. The following information shall be provided in the notification, when relevant, in addition to that of point A, in accordance with Article 12 of these regulations:

1. measures to take in case of unintended release or misuse,
2. specific instructions or recommendations for storage and handling,
3. specific instructions for carrying out monitoring and reporting to the notifier. These instructions should be consistent with Schedule VII part C,
4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,
5. proposed packaging,
6. estimated production in and/or imports to the Community,
7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

SCHEDULE V

Criteria for the Application of Differentiated Procedures (Article 7)

The criteria referred to in Article 9(1) are set out below.

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenicity) of the non-modified (recipient) organism shall be well-known.

2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.

3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.

4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.

5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.

SCHEDULE VI

Guidelines for the Assessment Reports

The assessment report provided for by Articles 12, 15, 16 and 17 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of the GMO(s) in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.
2. Description of the result of the genetic modification in the modified organism.
3. Assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.
4. Identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s), based on the environment impact assessment carried out in accordance with Schedule II.
5. A conclusion on whether the GMO(s) in question should be placed on the market or as (a) product(s) and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission are sought for on specific issues of the e.i.a.. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the GMOs should not be placed on the market, the Competent authority shall give reasons for its conclusion.

SCHEDULE VII

Monitoring Plan

This Schedule describes in general terms the objective to be achieved and the general principles to be followed to design the monitoring plan referred to in Articles 12(2), 16(3) and 17. It may be supplemented by guidance notes to be issued by the competent authority.

A. Objective

The objective of a monitoring plan is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the e.i.a. are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the e.i.a.

B. General principles

Monitoring, as referred to in Articles 12, 16 and 17, takes place after the consent to the placing of a GMO on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post marketing monitoring regime required for the placing on the market of GMOs as or in products.

C. Design of the monitoring plan

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the e.i.a.,
2. 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,
3. incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the e.i.a.:

3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the e.i.a.,

3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.

4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.

5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).

6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

SCHEDULE VIII

1. In the case of more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted/deleted sequences or have the same inserted/deleted sequence but differ in phenotypes, a single notification dossier shall be submitted.

2. A notifier can submit in a single notification information on several releases of genetically modified crop plants, to be released on several different sites, on the following conditions: the taxonomic status and biology of the recipient plant species is well known, information is available on the interactions of the recipient plant species in the ecosystems in which the experimental and/or agricultural releases are scheduled, scientific data is available on the safety to human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species, the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release, the inserted sequences have been well characterized, all the inserted sequences are integrated into the plant nuclear genome, all the releases are for an a priori specified programme of work, all the releases take place within an a priori specified time period.

4. Only one single consent is required for all the releases described in the single notification submitted to the competent authority. The procedure to be used in granting that consent is the following:

(1) any person, wishing to undertake a deliberate release of a GMO or a combination of GMOs in Malta for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority;

(2) the notification shall include:

(a) a technical dossier supplying the information specified in Schedule II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

(3) the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either in Malta or abroad.

The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;

(6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after the competent authority has given its written consent, the notifier shall immediately:

(a) revise the measures specified in the notification,

(b) inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

(7) (i). On receipt and after acknowledgment of the notification the Competent authority shall:

- examine it for compliance with these regulations,

- evaluate the risks posed by the release,

- record its conclusions in writing, and, if necessary,

- carry out tests or inspections as may be necessary for control purposes.

(7)(ii). The competent authority, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

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(a) indicating that it is satisfied that the notification is in compliance with these regulations and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of these regulations and the notification is therefore rejected.

(7)(iii). For the purpose of calculating the 90-day period referred to in the preceding paragraph, any periods of time during which the competent authority:

- is awaiting further information which it may have requested from the notifier, or
- is carrying out a public inquiry or consultation in accordance with paragraph (8) shall not be taken into account.

(7)(iv). The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

(7)(v). If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

(8) Where the competent authority considers it appropriate, it may consult groups or the public on any aspect of the proposed deliberate release.

(9) After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

5. In order to obtain one single consent covering several releases, all the necessary information for each release should be indicated in the single notification, including sufficient information on the different sites of the releases and on the experimental design, as well as indication of any conditions for risk management for each different release. Clear reference to each release to be covered should be made in the notification, and the appropriate information should be included to allow completion of the summary notification information format.

6. A notifier can also submit a single notification covering a whole, a priori specified, programme of development work with a single specific recipient plant species and a specified range of inserts/deletions over several years and on several different sites, and receive a single consent for the whole programme of work.

6(1). In such cases, detailed indications or descriptions of the different sites of the releases, subsequent intra-specific sexual crosses and/or the conditions of release need

not be given in the notification, as would be required under the conditions indicated in paragraph 5. However, the notification must contain sufficient information to enable overall an evaluation of risk, and a detailed risk assessment to be made for at least the first release in the programme of work. The information that need not be given may only relate to the sites of the releases, the description of the sites and their surface area, the number of plants released, and the subsequent sexual crosses of the initially notified plants (including progenies) with themselves and/or with plant lines of the initially notified recipient plant species (including the progenies of these crossings).

7. In the cases referred to in paragraph 6.1 the notifier will submit to the competent authority the additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation. This information should be sent before the specific release to which it refers is carried out, in the form of a simple additional notice for information only.

7(1). The notifier can proceed with the release in question after 15 days from the date of receipt by the competent authority of this additional information, unless he receives written indication from the competent authority.

7(2). If any new information submitted is such that the original consent under simplified procedures is no longer applicable, then it is for the competent authority to indicate to the notifier within 15 days of receipt of the notification that he may only proceed with the intended release if a consent is granted under the standard procedure laid down in these regulations.

8. When the single consent under simplified procedures is granted, conditions can be attached to each of the releases to which it refers. These conditions can subsequently be altered by the competent authority, as indicated in paragraph 4(7)(v).

9. On completion of one or more of the releases approved within the simplified procedure, the notifier shall submit to the competent authority a report with the results of the release(s) at the time specified in the consent. Such reports may be submitted separately, or as a clearly identifiable section in support of a notification for subsequent releases.

10. The competent authority may alter the conditions of the original consent or intervene to alter the conditions of specific subsequent releases on the basis of the results indicated in the reports or on the basis of information obtained during inspections.