SUBSIDIARY LEGISLATION 549.60

DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS REGULATIONS

16th November, 2010

LEGAL NOTICE 485 of 2010, as amended by Legal Notice 182 of 2019.

Citation.

1. (1) The title of these regulations is the Deliberate Release into the Environment of Genetically Modified Organisms Regulations.

Objectives.

(2) In accordance with the precautionary principle, the objective of these regulations is to provide for the protection of human health and the environment when:

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

(*b*) placing on the market genetically modified organisms as or in products within Malta.

(3) These regulations provide the provisions required for the implementation in Malta of the European Council Directive 2001/18/EC of the 12th of March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and shall be read and construed as one with such legal instrument.

PART A: GENERAL PROVISIONS

Interpretation.
Amended by: L.N. 182 of 2019.

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

"the Commission" means the European Commission;

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"the 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:

Provided that the competent authorities for issues relating to genetically modified organisms for food and feed and their placing on the market shall be the same as the entities responsible for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed in Malta, as provided in the Enforcement of Various European Union Regulations on Food Safety Regulations.

S.L. 449.56.

"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;

"the Directive" means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;

"environment risk 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;

"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 or natural recombination, and 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;

"Member State" means Member State of the European Community;

"notification" means the submission, in writing and digital format, of the information required under these regulations to the competent authority;

"notifier" means any legal or physical person submitting a notification or, where the context so requires, any legal or physical person responsible for a deliberate release or for a placing on the market, or for meeting any other requirement of these regulations in relation to a deliberate release or a placing on the market;

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

"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:

(*a*) making available genetically modified micro-organisms for activities regulated under the Contained Use of Genetically Modified Micro-organisms Regulations, including culture collections; S.L. 549.49

(*b*) making available GMOs other than micro-organisms referred to in paragraph (*a*), 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 Contained Use of Genetically Modified Micro-organisms Regulations; S.L. 549.49

(*c*) making available GMOs to be used exclusively for

deliberate releases complying with the requirements laid down in Part B of these regulations;

"product" means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market.

Exemptions.

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

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

General obligations.

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.

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

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 risk 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. This phasing out shall have taken place by the 31st December 2004 in the case of GMOs placed on the market according to Part C and by 31st December 2008 in the case of GMOs authorised under Part B.

(3) 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. 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 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-regulation (2) is appropriate.

(5) The competent authority shall organise inspections and other control measures as appropriate, to ensure compliance with these regulations. In the event of a release of any GMO 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, the Commission and other Member States.

PART B:

DELIBERATE RELEASE OF GMOs FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Applicability of regulations 6 to 10.

5. (1) Regulations 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 through the Medicines (Marketing Authorisation) Regulations, and Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, which provide:

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(*a*) for a specific environment risk 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, in accordance with the provisions of Article 5 of the Directive.

Standard authorisation procedure.
Amended by: L.N. 182 of 2019.

6. (1) Without prejudice to regulation 5, any person shall, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority.

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

(*a*) a technical dossier supplying the information specified in Schedule III necessary for carrying out the environment risk 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 any GMO,

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

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

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

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

(vii) a summary of the dossier in the format established in accordance with the procedure laid down in Article 30(2) of the Directive;

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

(*c*) the notification shall be accompanied by the relevant documents and any other requisite information as specified and required by the competent authority. The notifier shall clearly indicate whether the notification would prejudice any enforcement case, court case or other causes currently *sub-judice*.

(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) On receipt of the notification under sub-regulation (1) the competent authority shall:

(*a*) acknowledge to the notifier the date of such receipt in writing;

(*b*) forward to the Commission, within 30 days of receipt of the notification, a copy of the summary of the notification received in accordance with sub-regulation (2)(*a*)(vii);

(*c*) examine it for compliance with these regulations;

(*d*) consider any observations received from a competent authority of another Member State in accordance with Article 11(2) of the Directive;

(*e*) if requested by a competent authority of another Member State for the purposes of the Directive, forward a copy of the full notification to the said authority;

(*f*) evaluate the risks posed by the proposed deliberate release for human health and the environment; and

(*g*) record its conclusions in writing.

(6) The competent authority shall respond in writing to the

notifier within ninety days of receipt of the notification by indicating that consent to the deliberate release is either -

(*a*) granted, with or without, conditions, or

(*b*) refused and the reasons for the refusal.

(7) For the purpose of calculating the ninety day period referred to in sub-regulation (6), 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 regulation 9; this public inquiry or consultation shall not prolong the ninety day period referred to in sub-regulation (6) by more than thirty days.

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

(9) 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.

(10) 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.

Differentiated procedures. *Amended by: L.N. 182 of 2019.*

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, in accordance with the procedure set through Article 7 of the Directive, 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*) environment risk assessment.

(3) Without prejudice to sub-regulations (1) and (2), the simplified procedures laid down in Schedule IX shall be applicable to the deliberate release into the environment of genetically modified plants fitting the definition of genetically modified plants included in item 1 of 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-regulation (1) which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in sub-regulation (1), the competent authority:

(*a*) shall evaluate such information and make it available to the public;

(*b*) may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof;

(*c*) may require the notifier to defray or contribute towards any or all of the costs incurred by it in order to protect human health and the environment.

(3) With respect to both sub-regulations (1) and (2) above, the notifier shall amend the notification on which consent was granted and submit the amended notification to the competent authority.

(4) Where the competent authority receives an amended notification in accordance with sub-regulations (1) and (2), it shall deal with the amended notification as if it were a new notification under regulation 6 in relation to the proposed modified deliberate release.

(5) The notifier shall not proceed with the proposed modified deliberate release unless he has received written consent from the competent authority.

Consultation and informing the public.

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

(2) Subject to sub-regulation (3), the notifier of a proposed deliberate release for the purposes other than placing on the market shall, not more than fourteen days after the date of receipt by the competent authority of the notification, cause to be published in a prominent local newspaper a notice with heading "PROPOSED DELIBERATE RELEASE OF A GENETICALLY MODIFIED ORGANISM" and containing the following information -

(*a*) the name and address of the notifier,

(*b*) the description of the genetically modified organism proposed to be released,

(*c*) the fact that a notification has been submitted to the competent authority, and the location and purpose of the proposed deliberate release,

(*d*) the period of time in which the proposed deliberate release is to be carried out,

(*e*) the fact that further information on the proposed deliberate release may be obtained from the competent authority,

(*f*) the full title of the competent authority and the full postal address of its headquarters,

(*g*) the fact that, in accordance with sub-regulation (5), any person or body may, within the period of twenty-eight days beginning on the day of publication of the notice, make representations in writing to the competent authority regarding the notification,

and shall send a copy of the notice to the competent authority within the said fourteen days.

(3) The information on the location of the proposed deliberate release published pursuant to sub-regulation (2) shall be the same as the information on its location which is placed on the register maintained by the competent authority in accordance with regulation 22, and, for that purpose, the notifier shall ascertain from the competent authority the information on the location which is to be or has been placed on the said register.

(4) The notifier shall, not more than fourteen days after the date of receipt by the competent authority of the notification, send a copy of the notice published pursuant to sub-regulation (2) to -

(*a*) the owner of the site of the proposed deliberate release, if the said owner is a person other than the notifier, and

(*b*) the competent authority.

(5) Any person or body may, within the period of twenty-eight days beginning on the day of publication of a notice pursuant to sub-regulation (2), make representations to the competent authority in relation to the notification. The representations shall be -

(*a*) made in writing,

(*b*) addressed to the competent authority at its headquarters,

(*c*) forwarded so as to reach the competent authority within the period of twenty-eight days beginning on the day of publication of the notice pursuant to sub-regulation (2).

(6) Representations which do not comply with sub-regulation (5) shall be invalid. Where the competent authority receives representations in accordance with sub-regulation (5), it shall -

(*a*) acknowledge receipt of the representations, and

(*b*) consider the representations in determining the notification.

Reporting by notifiers on releases.

10. (1) The notifier shall -

(*a*) on completion of the deliberate release, and

(*b*) at any subsequent intervals specified in the consent,

submit a report to the competent authority on the results of the deliberate release.

(2) The report referred to in sub-regulation (1) shall be provided in such a format or formats as may be determined in accordance with the procedure laid down in Article 30(2) of the Directive, or in the absence of such a determination appropriate to the relevant consent, in such format as may be specified in the consent, and shall include:

(*a*) a post-release evaluation of the risks to human health or the environment, and

(*b*) where appropriate, a statement on the results of the deliberate release in relation to any product, or type of product, in respect of which consent to placing on the market may be sought.

(3) A copy of any report received by the competent authority pursuant to sub-regulation (1) shall, after its receipt, be sent by the competent authority to the Commission in accordance with Article 11(3) of the Directive.

PART C:

PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS

Sectoral legislation.

11. (1) Regulations 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 risk 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.

Duty to comply with Part C.

(2) Without prejudice to Schedule I B and subject to the exclusions in sub-regulation (1), a person shall not place on the market any product containing or consisting of a genetically modified organism unless:

(*a*) consent in writing has been received from the competent authority under Part C, or

(*b*) consent in writing has been received from the competent authority of another Member State in accordance with Part C of the Directive,

and the conditions attached to the consent have been complied with.

Notification procedure. *Amended by: L.N. 182 of 2019.*

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.

(*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-regulation (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 conclusions concerning the impact of the release on human health and the environment;

(*b*) the environment risk assessment and the conclusions required in Schedule II;

(*c*) the conclusions arrived at by the notifier in accordance with Schedule II, together with any bibliographic references and details of the methods used;

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

(*e*) with reference to regulation 14(5), a proposed period for the consent which should not exceed ten years;

(*f*) 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;

(*g*) 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;

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

(*i*) a summary of the notification as may be established by the competent authority from time to time in the format established in accordance with the procedure laid down in Article 30(2) of the Directive; this shall also apply in a case to which Article 16 of the Directive applies;

(*j*) the notifier shall clearly indicate whether the notification would prejudice any enforcement case, court case or other causes currently *sub-judice:*

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 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) The notifier proposing to place a product containing or consisting of a genetically modified organism on the market for the first time shall publish a notice according to regulation 9 with the wording "PROPOSED PLACING ON THE MARKET OF A PRODUCT CONTAINING/CONSISTING OF A GENETICALLY MODIFIED ORGANISM". In addition to the relevant requirements laid down in regulation 9(2) the notice shall also include -

(*a*) the full postal address of the Commission,

(*b*) with respect to a notification submitted in accordance with sub-regulation (1), regulation 9(2)(*g*) shall not apply and shall be replaced by paragraph (*c*),

(*c*) the fact that any person or body may make representations in writing to the said Commission regarding the notification within the period of thirty days beginning on the day that the Commission makes the summary of the notification received by it in accordance with regulation 13(1)(*b*) available to the public.

(6) 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.

(7) 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 and submit an amended notification to the competent authority, and the first notification under sub-regulation (1) shall not be further considered by the competent authority.

Assessment report.
Amended by:
L.N. 182 of 2019.

13. (1) On receipt of a notification under regulation 12(2) the competent authority shall:

(*a*) acknowledge to the notifier the date of such receipt in writing,

(*b*) immediately forward a copy of the summary notification received in accordance with regulation 12(2)(*i*) to the competent authorities of the other Member States for the purposes of the Directive and to the Commission,

(*c*) examine it for compliance with these regulations and in particular regulation 12,

(*d*) ask the notifier in writing for any further information which the competent authority considers necessary, stating its reasons for so doing. Any periods of time during which the competent authority is awaiting further information shall not be taken into account when calculating the ninety-day period referred to in sub-regulation (2),

(*e*) send a copy of the notification to the Commission once it is satisfied that the requirements of regulation 12 have been complied with, and no later than the time at which it sends to the Commission a copy of the assessment report mentioned in accordance with sub-regulation (3) or (4).

(2) Within ninety days of the receipt of a notification under regulation 12, the competent authority shall:

(*a*) prepare, in accordance with Schedule VI, an assessment report which shall also indicate whether:

(i) the genetically modified organism concerned should be placed on the market and under which conditions (referred to as a "favourable assessment"); or

(ii) the genetically modified organism concerned should not be placed on the market (referred to as an "unfavourable assessment"), and

(*b*) send a copy of the assessment report to the notifier.

(3) In the case of a favourable assessment, the competent authority shall send a copy of the assessment report to the notifier and to the Commission, any further information obtained from the notifier in accordance with sub-regulation (l)(*d*), and any other information on which the competent authority has based its report.

(4) In the case of an unfavourable assessment, the competent authority shall, no sooner than fifteen days after it sends a copy of the assessment report to the notifier and no later than one hundred and five days after it received the notification, send to the Commission a copy of the said report, any further information obtained from the notifier in accordance with sub-regulation (l)(*d*), and any other information on which the competent authority has based its report.

(5) Without prejudice to Regulation (EC) No 1829/2003 on genetically modified food and feed:

(*a*) during the authorisation procedure the competent authority or other Member States may demand that the geographical scope of the written consent be adjusted to the effect that all or part of the territory of Malta or the concerned Member State, as the case may be, is to be excluded from cultivation. Such a demand shall be made in accordance with Article 26b (1) of the Directive;

(*b*) within thirty (30) days from the presentation of the demand to the notifier by the Commission, the notifier may adjust or confirm the geographical scope of the initial notification;

(*c*) in the absence of the confirmation of the initial geographical scope by the notifier, the adjustment of the geographical scope shall be implemented in the written consent issued under these regulations;

(*d*) where applicable, the written consent issued under these regulations by the competent authority shall then be issued on the basis of the adjusted geographical scope of the notification.

Standard procedure. *Amended by: L.N. 182 of 2019.*

14. (1) In the case of a favourable assessment, the competent authority shall:

(*a*) provide any further information to the Commission, where such information is requested by the said Commission or by a competent authority of a Member State for the purposes of the Directive,

(*b*) consider any comments, or reasoned objections concerning the placing of the product on the market made by the Commission or by a competent authority of another Member State for the purposes of the Directive where such comments or objections are made within a period of sixty (60) days beginning on the day on which the documents referred to in regulation 13(3) were forwarded to each such competent authority by the Commission, and

(*c*) participate in any discussions in relation to the assessment report initiated by the Commission on grounds of reasoned objections made in accordance with paragraph (*b*) with a view to reaching an agreement within a period of one hundred and five days, beginning on the day on which the documents referred to in regulation 13(3) were forwarded to each such competent authority by the Commission:

Provided that any periods of time during which further information from the notifier is awaited shall not be taken into account for the purpose of calculating the final forty-five day period for arriving at an agreement.

(2) The competent authority shall grant consent to the notifier,

in writing, to place the product on the market where it has concluded a favourable assessment of the proposal, and

(*a*) no reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (1)(*b*), or

(*b*) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (1)(*b*) but the matters concerned have been resolved in accordance with the provisions of Article 15(1) of the Directive, or

(*c*) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (1)(*b*) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(3) If the competent authority decides that the product may be placed on the market, it shall give consent in writing, transmit it to the notifier and inform other Member States and the Commission thereof within a period of thirty (30) days:

Provided that where a demand, or demands, in accordance with regulation 13(5) are communicated to the Commission after the date of the circulation of the assessment report required under regulation 13(2) the timelines to issue the written consent shall be extended by a single period of fifteen (15) days, regardless of the number of the demands presented. Such further provision shall be without prejudice to Regulation (EC) No 1829/2003 on genetically modified food and feed.

(4) The competent authority shall, where it has concluded an unfavourable assessment, or where the Commission has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, inform the notifier in writing, that consent is refused and stating the reasons for the refusal.

(5) Subject to the provisions of sub-regulation (6), the competent authority shall not grant a consent under Part C for a period which exceeds 10 years beginning on the date on which the consent is issued.

(6) In cases relating to a genetically modified organism or a progeny of that organism intended only for the marketing of its seeds under legislation of the European Union for the time being in force, or to genetically modified forest reproductive material, the period of first consent shall be limited in accordance with the provisions of Article 15(4) of the Directive.

Renewal of consent.
Amended by: L.N. 182 of 2019.

15. (1) By way of derogation from regulations 12, 13 and 14, the procedure set out in sub-regulations (2) to (6) shall be applied to the renewal of consents granted under Part C.

(2) A person seeking to renew a consent granted by the

competent authority under regulation 14 or a consent previously renewed under this regulation shall:

(*a*) submit a notification to the competent authority no later than nine months before the expiry of the consent that it is proposed to have renewed,

(*b*) a person who has submitted a notification under this regulation may continue to market the product concerned in accordance with the terms and conditions of the relevant consent until a final decision has been made on the notification.

(3) A notification in accordance with sub-regulation (2)(*a*) shall include:

(*a*) a copy of the consent granted by the competent authority to the product being placed on the market and of any renewed consent,

(*b*) a report on the monitoring carried out in accordance with regulation 17,

(*c*) any new information that has become available with regard to the risks of the product to human health or to the environment, and

(*d*) any proposals the notifier considers appropriate for the amendment of, or measures additional to, the conditions contained in the original consent granted by the competent authority, including conditions relating to future monitoring and time limitation of the consent.

(4) On receipt of a notification under sub-regulation (2), the competent authority shall:

(*a*) acknowledge to the notifier the date of such receipt in writing,

(*b*) examine it for compliance with sub-regulation (3),

(*c*) ask the notifier in writing for any further information which the competent authority considers necessary, stating its reasons for so doing,

(*d*) prepare, in accordance with Schedule VI, an assessment report which shall indicate:

(i) whether the genetically modified organism concerned should remain on the market and under which conditions (referred to as a "favourable assessment");

(ii) or the genetically modified organism concerned should not remain on the market (referred to as a "unfavourable assessment"),

(*e*) send a copy of the notification and of the assessment report to the Commission, and

(*f*) send a copy of the assessment report to the notifier.

(5) The provisions under regulation 13(5) concerning a demand or demands for the adjustment to the geographical scope of a

written consent shall also apply for the renewal of consents.

(6) In the case of a favourable assessment, the competent authority shall:

(*a*) provide any further information to the Commission where such information is requested by the said Commission or by a competent authority of a Member State for the purposes of the Directive,

(*b*) consider any comments, concerns or reasoned objections to the product remaining on the market made by the Commission or by a competent authority of another Member State for the purposes of the Directive where such comments or objections are made within a period of sixty days beginning on the day on which the documents referred to in sub-regulation (4)(*d*) were forwarded to each such competent authority by the Commission, and

(*c*) participate in any discussions in relation to the assessment report initiated by the Commission on the grounds of reasoned objections made in accordance with paragraph (*b*) with a view to reaching an agreement within a period of seventy-five days, beginning on the day on which the documents referred to in sub-regulation (4)(*d*) were forwarded to each such competent authority by the Commission.

(7) The competent authority shall renew consent to market a product where it has concluded a favourable assessment of the proposal, and -

(*a*) no reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (6)(*b*), or

(*b*) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (6)(*b*) but the matters concerned have been resolved in accordance with the provisions of Article 17(7) and (8) of the Directive, or

(*c*) a reasoned objection to the favourable assessment has been made raised by the Commission or by a competent authority of a Member State in accordance with sub-regulation (6)(*b*) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(8) When the competent authority renews a consent in accordance to sub-regulation (7), it shall transmit to the notifier the final decision in writing and shall inform the other Member States and the Commission thereof within thirty (30) days beginning on the day that the consent was renewed:

Provided that where a demand, or demands, in accordance with sub-regulation (5) are communicated to the Commission after the date of the circulation of the assessment report, the timelines to issue the written renewal consent shall be extended by a single period of fifteen (15) days, regardless of the number of the demands presented. This provision shall be without prejudice to Regulation (EC) No 1829/ 2003 on genetically modified food and feed.

(9) The competent authority shall, where it has concluded an unfavourable assessment, or where the Commission has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, inform the notifier that renewal of the consent is refused and stating the reasons for the refusal.

(10) A renewal or a refusal of consent under this regulation shall be conveyed by the competent authority to the notifier in writing. In the case of a renewal of consent, its validity shall not exceed ten years and may be limited or extended as appropriate for specific reasons.

Consent. *Amended by: L.N. 182 of 2019.*

16. (1) Only if a written consent has been given for the placing on the market of a GMO as or in a product by a competent authority of a Member State may that product be used without further notification to the competent authority in so far as the specific conditions of use and the environment 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 regulations 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 any written consent is made accessible to the public and that conditions specified in the written consent are complied with.

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

(*a*) the scope of the consent, including the identity of any GMO 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 any GMO as or in products, and conditions for the protection of particular ecosystems, environments or geographical areas;

(*d*) that, without prejudice to regulation 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 any GMO;

(*f*) monitoring requirements in accordance with Schedule VII, including obligations to report to the Commission, 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 any GMO grown, concerning a level of information deemed appropriate on their location.

(4) (*a*) Another Member State may request the competent authority to reintegrate all or part of its territory into the geographical scope of a consent from which it was excluded pursuant to sub-regulations 13(5) and 15(5). The competent authority shall then amend the geographical scope of the consent accordingly.

(*b*) The competent authority may, if necessary, reintegrate all or part of the Maltese Islands into the geographical scope of the consent from which it had been excluded pursuant to sub-regulations 13(5) and 15(5).

(*c*) Once the adjustment pursuant to paragraph (a) or (b) is completed the competent authority shall duly inform the Commission, the Member States and the consent holder.

Measures restricting or prohibiting the cultivation in all or part of the Maltese territory. *Added by: L.N. 182 of 2019.*

16A. Without prejudice to Regulation (EC) No 1829/2003 on genetically modified food and feed:

(1) Where no demand for the adjustment of the geographical scope of a written consent was made pursuant to the Directive or these regulations, as the case may be, or where the notifier has confirmed the geographical scope of its initial notification, the competent authority may adopt measures restricting or prohibiting the cultivation in all or part of the Maltese territory of a GMO, or group of GMOs defined by crop or trait, once the placing on the market is authorised in accordance with the Directive or through these regulations.

(2) (*a*) Measures adopted pursuant to sub-regulation (1) shall be in conformity with Union law, reasoned, proportional, non-discriminatory and based on compelling grounds, such as those related to:

(i) environmental policy objectives;

(ii) town and country planning;

(iii) land use;

(iv) socioeconomic impacts;

(v) avoidance of GMO presence in other products without prejudice to regulation 16B;

(vi) agricultural policy objectives; and

(vii) public policy.

(*b*) The compelling grounds may be invoked individually or in combination, with the exception of sub-paragraph (vii) of sub-regulation (2)(a), which cannot be invoked individually. Grounds would depend on the particular circumstances of Malta, the region or area in which the measures would apply and shall, in no case, conflict with the environmental risk assessment carried out pursuant to the Directive or these regulations.

(3) A draft of the measures the competent authority intends to adopt and the corresponding grounds invoked shall be duly communicated to the Commission. Such communication may take place before the GMO authorisation procedure under Part C of the Directive or these regulations has been completed.

(4) The competent authority shall issue a notice in the Gazette which shall prohibit the planting of the GMO or GMOs for which measures have been drafted, pursuant to sub-regulation (3). Such notice shall cover a period of seventy-five (75) days, starting from the day that the draft measures are communicated to the Commission.

(5) On the expiry of the seventy-five (75) day period referred to in sub-regulation (4) the competent authority may, for the whole duration of the consent for the placing on the market and as from the date of entry into force of the concerned authorisation, adopt measures restricting or prohibiting the cultivation of the GMO or the group of GMOs referred to in sub-regulation (4). Such measures shall either be those originally proposed by the competent authority, or as amended following the comments received from the Commission.

(6) (*a*) Once the competent authority adopts measures in accordance with this regulation it shall immediately communicate such measures to the Commission, the other Member States and the consent holder without delay.

(*b*) The competent authority shall also publish any measures adopted pursuant to sub-regulation (5) in the Gazette.

(7) The competent authority may revoke the measures taken pursuant to this regulation at any time. Such revocation shall be immediately communicated to the Commission and other Member States.

Measures to avoid cross-border contamination.

16B. The competent authority in collaboration with other relevant authorities, may take appropriate measures in border areas which aim at avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, as appropriate. Such measures shall be communicated to the Commission.

Monitoring and handling of new information. *Amended by: L.N. 182 of 2019.*

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. 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 or subsequent monitoring period.

(2) If new information has become available, from the users or other sources, with regard to the risks of any GMO to human health or the environment after the written consent has been given, the notifier shall:

(*a*) revise the notification, as required; and

(*b*) immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

(3) If information becomes available to the competent authority which could have consequences for the risks of any GMO to human health or the environment, or under the circumstances described in sub-regulation (2), it may avail itself of the provisions in regulation 14 and 15where appropriate, when the information has become available before the written consent.

(4) If, after granting consent under regulation 14 or renewing a consent under regulation 15, the competent authority is informed or becomes aware, of information which could have consequences for the risks of any GMO to human health or the environment, or under the circumstances described in sub-regulation (2), it shall:

(*a*) immediately forward the information to the Commission and to the competent authorities of the Member States for the purposes of the Directive,

(*b*) prepare an assessment report in accordance with Schedule VI which shall indicate:

(i) whether the genetically modified organism concerned should remain on the market and under which conditions (referred to as "favourable assessment");

(ii) or the genetically modified organism concerned should not remain on the market (referred to as "unfavourable assessment"),

(*c*) within sixty days of the receipt of the information, forward a copy of the assessment report to the Commission, and

(*d*) send a copy of the assessment report to the notifier. If the competent authority deems through the assessment

report, that the new information provides considerable changes to the notification, the competent authority may ask the notifier to cease marketing under this regulation and submit an amended notification:

Provided that in case of impacts to human health and the environment, the notifier may be asked to defray or contribute towards any or all of the costs incurred by it in order to protect human health and the environment.

(5) In the case of a favourable assessment, the competent authority shall:

(*a*) provide any further information to the Commission where such information is requested by the said Commission or by a competent authority of a Member State for the purposes of the Directive;

(*b*) consider any comments, concerns or reasoned objections to the assessment report referred to in sub-regulation (4)(*b*) made by the Commission or by a competent authority of another Member State for the purposes of the Directive where such comments or objections are made within a period of sixty days beginning on the day on which a copy of the said assessment report was forwarded to each such competent authority by the Commission, and

(*c*) participate in any discussions in relation to the assessment report initiated by the Commission on the grounds of reasoned objections made in accordance with paragraph (*b*) with a view to reaching an agreement within a period of seventy-five days, beginning on the day on which the documents referred to in sub-regulation (4)(*b*) were forwarded to each such competent authority by the Commission.

(6) The competent authority shall consent to the continued marketing of a product where it has concluded a favourable assessment of the information, and -

(*a*) no reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (5)(*b*), or

(*b*) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (5)(*b*) but the matters concerned have been resolved in accordance with the provisions of Article 20(3) of the Directive, or

(*c*) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation (5)(*b*) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(7) The competent authority shall, within a period of thirty days beginning on the day that consent to the continued marketing is granted, inform the competent authority of each Member State and the Commission that it has done so.

(8) The competent authority shall, where it has concluded an unfavourable assessment, or where the Commission has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, direct the notifier to cease marketing the product and stating the reasons for the direction.

(9) The notifier shall comply with any direction given by the competent authority under sub-regulation (8).

(10) A consent to continue, or a direction to cease, marketing under this regulation shall be conveyed by the competent authority to the notifier in writing.

(11) The competent authority shall make the results of the monitoring carried out under Part C publicly available.

Labelling.
Amended by: L.N. 182 of 2019.

18. (1) At all stages of the placing on the market, the labelling and packaging of any GMO placed on the market as or in products shall comply with the relevant requirements specified in the written consent referred to in regulations 14(2), 15(7) and 16(3).

(2) For products where adventitious or technically unavoidable traces of any authorised GMO cannot be excluded, the competent authority may establish a minimum threshold below which these products shall not have to be labelled in accordance with sub-regulation (1).

(3) For products intended for direct processing, sub-regulation (1) shall not apply to traces of any authorised GMO in proportions no higher than 0.9% or lower thresholds, provided that these traces are adventitious or technically unavoidable.

Saving.
Amended by: L.N. 182 of 2019.

19. (1) 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 or sale of that GMO as or in a product.

(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 giving information to the public.

(3) For the purposes of sub-regulation (1), the procedures mentioned in regulation 17 shall be adopted.

PART D:

CONFIDENTIALITY AND PUBLIC REGISTER

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 regulations 6, 7, 8, 12, 15, 17 or 19 be kept confidential:

(*a*) general description of any GMO, name and address of the notifier, purpose of the release, location of release and intended uses;

(*b*) methods and plans for monitoring of any GMO and for emergency response;

(*c*) environment risk 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 regulation 2. *Amended by: L.N. 182 of 2019.*

21. Any GMO to be made available for operations referred to in the definition of "placing on the market" in regulation 2, 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.

Establishment of public registers.

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

(*a*) establish public registers in which the location of the release of any GMO 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 regulation 16(3)(*f*) and 17(1).

(2) Without prejudice to such provisions in regulation 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.

PART E:

OFFENCES

Offences. *Amended by: L.N. 182 of 2019.*

23. (1) Any person who -

(*a*) fails to observe any provision of these regulations or any other lawful order given by virtue of any provision of these regulations; or

(*b*) infringes any restriction, prohibition or requirement imposed by or under these regulations; or

(*c*) fails to observe any condition of a permit or consent granted under the provisions of these regulations; or

(*d*) acts in contravention of any of the provisions of these regulations; or

(*e*) makes a statement or presents information or documentation, which such person knows to be false for the purpose of obtaining the approval or continuation of a consent under these regulations; or

(*d*) 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 provisions of these regulations, or to contravene any restriction, prohibition or requirement imposed by or under the said regulations,

shall be guilty of an offence under these regulations.

Penalties.

(2) Any person who commits an offence against the provisions concerning the deliberate release of GMOs, for any other purpose than for placing on the market shall, on conviction, be liable:

(*a*) on a first conviction to a fine (*multa*) of not less than fifty thousand euro (€50,000) but not exceeding seventy-five thousand euro (€75,000);

(*b*) on a second or subsequent conviction, to a fine (*multa*) of not less than sixty-five thousand euro (€65,000), but not exceeding one hundred thousand euro (€100,000) or to imprisonment for a term not exceeding two (2) years, or to both such fine and imprisonment.

(3) Any person who commits an offence against the provisions concerning the placing on the market of GMOs shall, on conviction, be liable:

(*a*) on a first conviction to a fine (*multa*) of not less than sixty thousand euro (€60,000) but not exceeding ninety thousand euro (€90,000);

(*b*) on a second or subsequent convictions, to a fine (*multa*) of not less than seventy-five thousand euro (€75,000), but not exceeding one hundred and twenty

thousand euro (€120,000) or to imprisonment for a term not exceeding two (2) years, or to both such fine and imprisonment.

(4) The court shall order any person who has been found guilty of committing an offence against these regulations to pay the expenses incurred by the competent authority as a result of the said offence, the revocation of the notification issued by the competent authority and the confiscation of the *corpus delicti*.

(5) The Court shall order the offender to remove the causes of the offence and to undo anything which was done without a permit within a time sufficient for the purpose to be fixed by the Court; and, if the offender fails to comply with any such order within the time so fixed, he shall be liable to a fine (*multa*) of not less than sixty euro (€60) and not more than five hundred euro (€500), as the Court may fix, for every day that the default continues after the expiration of the said time.

(6) Any person who has been found guilty of committing an offence against these regulations shall also pay for the expenses incurred for the keeping, transport and remedying the damage caused by the said infringement, and for any other expense incurred or mitigation measures required to remedy such doings, damage and infringement.

Applicability of the Criminal Code. Cap. 9.

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

Cap. 9.

(8) 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.

Cap. 9.

(9) 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.

PART E:

FEES

Fee for notification of a proposed deliberate release.

24. (1) A fee shall be paid to the competent authority in respect of a notification under regulation 6 of a proposed deliberate release for purposes other than placing on the market.

(2) The fee payable under sub-regulation (1) shall be thirty-seven thousand euro (€37,000).

Fee for notification of a proposed placing of a product on the market and renewal of consent.

(3) A fee shall be paid to the competent authority in respect of a notification under regulation 12 of a proposed placing on the market of a product and a notification under regulation 15 of a proposal for renewal of a consent.

(4) The fee payable under sub-regulation (3) shall in each case be forty-thousand euro (€47,000).

Fee for amended notification in relation to a deliberate release.

(5) A fee shall be paid to the competent authority in respect of an amended notification under regulation 8(3) in relation to a deliberate release for purposes other than placing on the market.

(6) The fee payable under sub-regulation (5) shall be five thousand euro (€5,000).

Fee for amended notification of a proposed placing of a product on the market.

(7) A fee shall be paid to the competent authority in respect of an amended notification under regulation 12(6) and 17(4)(*d*) in connection with the proposed placing of a product on the market.

(8) The fee payable under sub-regulation (7) shall in each case be fourteen thousand euro (€14,000).

Periodic charges for monitoring.

25. The competent authority may require a notifier to make periodic payments, not exceeding the costs incurred by the competent authority, for the purpose of defraying or contributing towards the costs incurred by the competent authority in monitoring, carrying out inspections, or otherwise ensuring compliance with the requirements of these regulations and any other expenses related to the consent, conditions or other requirements pursuant to these regulations.

Investigations by the competent authority and recovery of costs.

26. The competent authority may carry out, or arrange to have carried out, such investigations as it considers necessary, as part of its examination or monitoring of a notification of a deliberate release, placing on the market or other matter related to these regulations, to enable it properly to assess the notification and may require the notifier to defray or contribute towards the cost of any such investigations.

Free circulation of authorized GMOs. *Added by: L.N. 182 of 2019.*

26A. The provisions of regulations 13(5), 15(5) and 16A shall not affect the free circulation of authorized GMOs as, or in, products

PART F:

OTHER PROVISIONS

Publication of Schedules in the English language.

27. The Schedules I to IX 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 regulation 2

PART 1

Techniques of genetic modification referred to in paragraph (*a*) in the definition of GMO in regulation 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 microinjection, macro-injection and microencapsulation;

(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 regulation 3

Techniques or 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 or 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.

Amended by:
L.N. 182 of 2019.

SCHEDULE II

Principles for the Environment risk 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 risk assessment referred to in regulations 4 and 12. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Annex.

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 risk 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 environment risk assessment 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 environment risk assessment 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 environment risk assessment:

- 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 environment risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- the environment risk assessment 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, *inter alia*, GMOs already in the environment;
- if new information on the GMO and its effects on human health or the environment becomes available, the environment risk assessment may need to be re-addressed in order to:
    - determine whether the risk has changed;
    - determine whether there is a need for amending the risk management accordingly.

C. Methodology

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

C.1. General and specific considerations for the e.r.a.

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Schedule II shall also take into account the GMOs deliberately released or placed on the market in the past.

3. *Quality of the data*

In order to carry out an e.r.a. for a notification under Part C, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under Part C shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

  (i) the requirements of Directive 2004/10/EC; or

  (ii) the "OECD Principles on Good Laboratory Practice" (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

  (i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or

  (ii) be conducted by organisations accredited under the relevant ISO standard; or

  (iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in items (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.

4. *Stacked transformation events in Part C notifications*

The following shall apply to the e.r.a. of a GMO containing stacked transformation

events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

(i) the stability of the transformation events;

(ii) the expression of the transformation events;

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

(c) where the progeny of the GMO can contain various sub-combinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned sub-combinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.

C.2. Characteristics of the GMO and of the releases

The e.r.a. shall take into account the relevant technical and scientific details regarding characteristics of:

(a) the recipient or parental organism(s);

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

(c) the GMO;

(d) the intended release or use including its scale;

(e) the potential receiving environment(s) into which the GMO will be released and into which the transgene may spread; and

(f) the interaction(s) between these characteristics.

Relevant information from previous releases of the same or similar GMOs and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, shall be considered in the e.r.a., subject to regulation 6(3) or regulation 12(4).

C.3. Steps in the e.r.a.

The e.r.a. referred to in regulations 4, 6, 7 and 12 shall be conducted for each relevant area of risk referred to in Section D1 or in Section D2 of Part D in accordance with the following six steps:

1. *Problem formulation including hazard identification*

The problem formulation shall:

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the GMO with those of the chosen non-genetically modified comparator under corresponding conditions of release or use;

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under item (a) above.

Potential adverse effects shall not be discounted on the basis that they are unlikely to occur.

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

(i) effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity;

(ii) altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;

(iii) 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;

(iv) effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material;

(v) disease affecting humans, including allergenic or toxic reactions;

(vi) disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate.

Where potential long-term adverse effects of a GMO are identified, they shall be assessed in the form of desk based studies using, where possible, one or more of the following:

(aa) evidence from previous experiences;

(bb) available data sets or literature;

(cc) mathematical modelling;

(c) identify relevant assessment endpoints.

Those potential adverse effects that could impact the identified assessment endpoints shall be considered in the next steps of the risk assessment;

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur.

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

(i) the spread of the GMO(s) in the environment;

(ii) the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not;

(iii) phenotypic and genetic instability;

(iv) interactions with other organisms;

(v) changes in management, including, where applicable, in agricultural practices;

(e) formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

2. *Hazard characterisation*

The magnitude of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur. The e.r.a shall consider that the

magnitude is likely to be influenced by the receiving environment(s) into which the GMO is intended to be released and by the scale and conditions of the release.

Where possible, the evaluation shall be expressed in quantitative terms.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") shall be used and an explanation of the scale of effect represented by each category shall be provided.

3. *Exposure characterisation*

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the notification shall be taken into consideration.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") of the exposure shall be used and an explanation of the scale of effect represented by each category shall be provided.

4. *Risk characterisation*

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi-quantitative estimation of the risk.

Where a quantitative or semi-quantitative estimation is not possible, a qualitative estimation of the risk shall be provided. In that case, a categorical description ("high", "moderate", "low" or "negligible") of the risk shall be used and an explanation of the scale of effect represented by each category shall be provided.

Where relevant, the uncertainty for each identified risk shall be described and, where possible, expressed in quantitative terms.

5. Risk management strategies

Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed.

The risk management strategies shall be described in terms of reducing the hazard or the exposure, or both, and shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

The consequent reduction in overall risk shall be quantified where possible.

6. *Overall risk evaluation and conclusions*

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management

measures proposed.

D. Conclusions on the specific areas of risk of the e.r.a.

Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, on the basis of an e.r.a. carried out in accordance with the principles outlined in Part B and following the methodology described in Part C, and on the basis of the information required pursuant to Schedule III.

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 any proposed release.

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

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 or delayed environmental risk of the direct and indirect interactions between the GMO and target organisms (if applicable).

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

6. Possible immediate 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.

7. Possible immediate or delayed effects on animal health and consequences for the feed or 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 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 any GMO release.

9. Possible immediate 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)

"Higher plants" means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer.

2. Plant to micro-organisms gene transfer.

3. Interactions of the GMHP with target organisms.

4. Interactions of the GMHP with non-target organisms.

5. Impacts of the specific cultivation, management and harvesting techniques.

6. Effects on biogeochemical processes.

7. Effects on human and animal health.

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SCHEDULE III

(Regulations 4, 5, 6, 7, 11 and 12)

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C shall, as a rule, include the information set out in Schedule III A, for GMOs other than higher plants, or in Schedule III B, for genetically modified higher plants.

The provision of a given subset of information listed in Schedule III A or in Schedule III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

(*a*) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;

(*b*) for notifications referred to in Part C, Annexes with detailed information on those studies, including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

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 perennial plants and trees, 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 Union.

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 any responsible scientist

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 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;
    (*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 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 any insert into the recipient or to delete a sequence;

(*c*) description of the insert 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 or inserted or deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(*a*) description of any genetic trait 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 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 any expressed protein;

(*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 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,
- 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 any purpose 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. any method 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 any site (in case of notifications under Part C of any site 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 any region 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 any proposed site 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*) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;

(*b*) post-release transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of postrelease selection leading to the expression of unexpected 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 any parental organism,

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

11. anticipated mechanism and result of interaction between the released GMOs and any target organism 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 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)

I. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7

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.

4. Information relating to the release;

(a) purpose of the release;

(b) foreseen date(s) and duration of the release;

(c) method by which the GMHP will be released;

(d) method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods;

(e) approximate number of plants (or plants per m^2).

5. Information relating to the site of release;

(a) location and size of the release site(s);

(b) description of the release site ecosystem, including climate, flora and fauna;

(c) presence of sexually compatible wild relatives or cultivated plant species;

(d) Proximity to officially recognised biotopes or protected areas which may be affected.

B. Scientific Information

1. Information relating to the recipient plant or, where appropriate, to the parental plants;

(a) complete name:

(i) family name;

(ii) genus;

(iii) species;

(iv) sub-species;

(v) cultivar or breeding line;

(vi) common name;

(b) geographical distribution and cultivation of the plant within the Union;

(c) information concerning reproduction:

(i) mode(s) of reproduction;

(ii) specific factors affecting reproduction, if any;

(iii) generation time;

(d) sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species;

(e) survivability:

(i) ability to form structures for survival or dormancy;

(ii) specific factors affecting survivability, if any;

(f) dissemination:

(i) ways and extent of dissemination;

(ii) specific factors affecting dissemination, if any;

(g) where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts;

(h) potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation.

(a) Information relating to the genetic modification:

(i) description of the methods used for the genetic modification;

(ii) nature and source of the vector used;

(iii) source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the GMHP:

(i) general description of the trait(s) and characteristics which have been introduced or modified;

(ii) information on the sequences actually inserted/deleted:

(aa) size and copy number of all insert(s) and methods used for its/their characterisation;

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

(cc) sub-cellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination;

(iii) parts of the plant where the insert is expressed;

(iv) genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of the molecular characterisation.

3. Information on specific areas of risk.

(a) Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.

(c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.

(d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.

(e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.

(f) Potential interactions with the abiotic environment and the adverse environmental effects thereof.

(g) Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.

(h) Conclusions on the specific areas of risk.

4. Information on control, monitoring, post-release and waste treatment plans

(a) Any measures taken, including:

(i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;

(ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.

(b) Description of methods for post-release treatment of the site.

(c) Description of post-release treatment methods for the genetically modified plant material including wastes.

(d) Description of monitoring plans and techniques.

(e) Description of any emergency plans.

(f) Description of the methods and procedures to:

(i) avoid or minimise the spread of the GMHPs beyond the site of release;

(ii) protect the site from intrusion by unauthorised individuals;

(iii) prevent other organisms from entering the site or minimise such entries.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO REGULATION 12

A. General information.

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

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

3. Designation and specification of the GMHP.

4. Scope of the notification:

(a) cultivation;

(b) other uses (to be specified in the notification).

B. Scientific Information.

1. Information relating to the recipient plant or, where appropriate, to the parental plants.

(a) Complete name:

(i) family name;

(ii) genus;

(iii) species;

(iv) subspecies;

(v) cultivar/breeding line;

(vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:

(i) mode(s) of reproduction;

(ii) specific factors affecting reproduction, if any;

(iii) generation time.

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

(e) Survivability:

(i) ability to form structures for survival or dormancy;

(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination;

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation.

(a) Information relating to the genetic modification.

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the genetically modified plant.

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

(ii) Information on the sequences actually inserted or deleted:

(aa) size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation;

(bb) the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format;

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

(dd) sub-cellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination;

(ee) in the case of modifications other than insertion or deletion, function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification;

(ff) sequence information in a standardised electronic format for both 5′ and 3′ flanking regions at each insertion site;

(gg) bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes;

(hh) all Open Reading Frames, (hereafter referred to as "ORFs") within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA. ORF is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame;

(ii) bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects;

(jj) primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein;

(kk) bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.

(iii) Information on the expression of the insert:

(aa) method(s) used for expression analysis together with their performance characteristics;

(bb) information on the developmental expression of the insert during the life cycle of the plant;

(cc) parts of the plant where the insert/modified sequence is expressed;

(dd) potential unintended expression of new ORFs identified under sub-sub-paragraph (gg) of sub-paragraph (ii), which raise a safety concern;

(ee) protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of molecular characterisation.

3. Comparative analysis of agronomic and phenotypic characteristics and of composition.

(a) Choice of conventional counterpart and additional comparators.

(b) Choice of sites for field studies.

(c) Experimental design and statistical analysis of data from field trials for comparative analysis:

(i) description of field studies design;

(ii) description of relevant aspect of the receiving environments;

(iii) statistical analysis.

(d) Selection of plant material for analysis, if relevant.

(e) Comparative analysis of agronomic and phenotypic characteristics.

(f) Comparative analysis of composition, if relevant.

(g) Conclusions of comparative analysis.

4. Specific information for each area of risk.

For each of the seven areas of risk referred to in Section D.2 of Schedule II the notifier shall first describe the pathway to harm explaining in a chain of cause and effect how the release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

(a) Persistence and invasiveness including plant to plant gene transfer:

(i) assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;

(ii) assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;

(iii) conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.

(b) Plant to micro-organism gene transfer:

(i) assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;

(ii) conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment.

(c) Interactions of the GMHP with target organisms, if relevant:

(i) assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);

(ii) assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof;

(iii) conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.

(d) Interactions of the GMHP with non-target organisms:

(i) assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

The assessment shall also take into account the potential adverse effect(s) on relevant ecosystem services and on the species providing those services;

(ii) conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms.

(e) Impacts of the specific cultivation, management and harvesting techniques:

(i) for GMHPs for cultivation, assessment of the changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;

(ii) conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.

(f) Effects on biogeochemical processes:

(i) assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;

(ii) conclusions on adverse effects on biogeochemical processes.

(g) Effects on human and animal health:

(i) assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;

(ii) for GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;

(iii) assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;

(iv) conclusions on the effects on human and animal health.

(h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Schedule II and the risk management strategies proposed in accordance with item 5 of Section C.3 of Schedule II.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

Amended by:
L.N. 182 of 2019.

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 regulation 2 definition of "placing on the market". Technical guidance notes, as regards, *inter alia*, the description of how the product is intended to be used, may be developed in accordance with the regulatory procedure referred to Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Schedule. The labelling of exempted organisms as required by regulation 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 a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004[*]. After the consent any new commercial names should be provided to the competent 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 any supplier 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 any geographical area 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. methods for detection, identification and, where appropriate, quantification of the transformation event; samples of the GMO(s) and their control samples, and information as to the place where the reference material can be accessed. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register(s) referred to in Article 31(2) of the Directive 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

* Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

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 regulation 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 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 (Regulation 7)

The criteria referred to in regulation 7(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, pathogenecity) 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 regulations 13, 14, 15 and 17 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of any GMO 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 any release of the GMO in question as compared to any release of the corresponding non-modified organism, based on the environment risk assessment carried out in accordance with Schedule II.

5. A conclusion on whether any GMO in question should be placed on the market or as any product 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 environment risk assessment. 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 in the design of the monitoring plan referred to in regulations 12(2), 15(3), 16 (3) and 17. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Schedule.

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 environment risk assessment 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 environment risk assessment

B. General principles

Monitoring, as referred to in regulations 12, 15, 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 environment risk assessment,
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 environment risk assessment:
    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 environment risk assessment,
    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 IX

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 or deleted sequences or have the same inserted or 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 site on the following conditions:

- the taxononic status and biology of the recipient plants species is well known,
- information is available on the interactions of the recipient plant species in the ecosystems in which the experimental 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 any GMO,

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

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

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

(*b*) a statement evaluating the impacts and risks posed by any GMO 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 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 ninety 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 the notification is therefore rejected.

(7) (iii) For the purpose of calculating the ninety-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 or 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 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 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 fifteen 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 any release 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.