
Prime Minister

Minister for the Environment,
Sustainable Development and Climate Change

Chairperson,
Environment and Resources Authority

L.N. ---- of 2019

**ENVIRONMENT PROTECTION ACT
(CAP. 549)**

**Deliberate Release into the Environment of Genetically Modified Organisms (Amendment)
Regulations, 2019**

BY VIRTUE of the powers conferred by articles 54 and 55 of the Environment Protection Act, the Minister for the Environment, Sustainable Development and Climate Change, after consultation with the Environment and Resources Authority, has made the following regulations :-

Citation.
S.L. 549.60.

1. The title of these regulations is the Deliberate Release into the Environment of Genetically Modified Organisms (Amendment) Regulations, 2019 and they shall be read and construed as one with the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, hereinafter referred to as "the principal regulations".

Amends regulation 2 of the principal regulations..

2. In regulation 2 of the principal regulations thereof, immediately after the definition "competent authority" there shall be added the following proviso:

Cap. 449.

"Provided that issues relating to the deliberate release of genetically modified organisms for food and feed use and their placing on the market as outlined in Regulation (EC) No 1829/2003 on genetically modified food and feed, shall fall within the competency of the Food Safety Commission prescribed in the Food Safety Act."

Amends regulation 6 of the principal regulations.

3. Regulation 6 of the principal regulations shall be amended as follows:

(a) in the English text only, paragraph (c) of sub-regulation (2) shall be substituted with the following:

“(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*.”

(b) in the Maltese text only, following paragraph (b) of sub-regulation (2) there shall be added the following new paragraph:

“(ċ) in-notifika għandha tkun akkumpanjata mid-dokumenti rilevanti u kwlunkwe informazzjoni oħra meħtieġa kif speċifikat u meħtieġ mill-awtorità kompetenti. In-notifikant għandu jindika b’mod ċar jekk in-notifika tkunx ser tippreġudika xi każ ta’ infurzar, xi każ pendent quddiem il-qorti jew xi kawżi oħra li jkunu għandhom *sub-judice*.”

(c) In sub-regulation (7) for the words "sub-regulation (5)" wherever they occur there shall be substituted with the words "sub-regulation (6)";

Amends regulation 7 of the principal regulations.

4. Sub-regulation (3) of regulation 7 of the principal regulations shall be replaced by the following text:

“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 point 1 of Schedule IX.”

Amends regulation 12 of the principal regulations.

5. Regulation 12 of the principal regulations shall be amended as follows:

(a) in paragraph (e) of sub-regulation (2) for the words “regulation 14(4)” there shall be substituted the words “regulation 14(5)”;

(b) paragraph (j) of sub-regulation (2) shall be substituted with the following:

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

(c) in sub-regulation (5) for the words "the requirements laid down" there shall be substituted the words "the relevant requirements laid down";

(d) in paragraph (b) of sub-regulation (5) the word “to an application” there shall be substituted with the word “to a notification”;

(e) in paragraph (c) of sub-regulation (5) the words “regulation 13(b)” shall be substituted with the words “regulation 13(1)(b)”.

Amends regulation 13 of the principal regulations.

6. Regulation 13 of the principal regulations shall be amended as follows:

(a) in paragraph (b) of sub-regulation (1) the words “regulation 12(2)(h)” shall be substituted with the words “regulation 12(2)(i)”;

(b) immediately after sub-regulation (4) there shall be added the following new sub-regulation (5):

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

- (i) 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.
- (ii) Within thirty 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.
- (iii) 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.
- (iv) 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."

Amends regulation 14 of the principal regulations.

7. Regulation 14 of the principal regulations shall be amended as follows:

(a) in the English text only, in paragraph (b) of sub-regulation (1) thereof, for the words "ninety days" there shall be substituted the words "sixty days";

(b) sub-regulation (3) thereof shall be substituted by the following:

"(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 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 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."

Amends regulation 15 of the principal regulations.

8. Regulation 15 of the principal regulations shall be amended as follows:

(a) In sub-regulation (1) the words "the procedure set out in sub-regulations (2) to (5)" shall be substituted with the words "the procedure set out in sub-regulation (2) to (6)".

(b) In paragraph (d) of sub-regulation (4) the words "Schedule V" shall be substituted with the words "Schedule VI";

(c) sub-regulations (5) to (9) thereof shall be renumbered as sub-regulations (6) to (10) respectively;

(d) immediately after sub-regulation (4) thereof there shall be added the following new sub-regulation:

"(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.";

(e) in sub-regulation (7) as renumbered for the words "sub-regulation (4)(d)" wherever it occurs there shall be substituted with the words "sub-regulation (6)(b)."

(f) sub-regulation (8) thereof as re-numbered shall be substituted with the following:

"(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 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 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.”

Amends Regulation 16 of the principal regulations.

9. Immediately after sub-regulation (3) of regulation 16 of the principal regulations there shall be added the following new sub-regulation:

“(4) (i) 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.

(ii) 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).

(iii) Once the adjustment pursuant to paragraph (i) or (ii) is completed the competent authority shall duly inform the Commission, the Member States and the consent holder.”.

Adds new regulations 16A and 16B.

10. Immediately after regulation 16 of the principal regulations there shall be added the following new regulations:

“Measures restricting or prohibiting the cultivation in all or part of the Maltese territory.

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

- (a) environmental policy objectives;
- (b) town and country planning;

- (c) land use;
- (d) socioeconomic impacts;
- (e) avoidance of GMO presence in other products without prejudice to regulation 16B;
- (f) agricultural policy objectives; and
- (g) public policy.

(ii) The compelling grounds may be invoked individually or in combination, with the exception of paragraph (g) of sub-regulation (2)(i), 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 days, starting from the day that the draft measures are communicated to the Commission.
- (5) On the expiry of the seventy-five 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) (i) Once the competent authority adopts measures in accordance with this regulation it shall communicate such measures to the Commission, the other Member States and the consent holder without delay.

(ii) 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 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."

Amends regulation 17 of the principal regulations.

10. Regulation 17 of the principal regulations shall be amended as follows:

(a) sub-regulation (2) thereof shall be substituted by the following:-

"(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:

- (i) revise the notification, as required; and
- (ii) immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.";

(b) in sub-regulation (3) thereof immediately after the words "the provisions in regulation 14" there shall be added the words "and 15";

(c) In paragraph (b) of sub-regulation (4) the words "Schedule V" shall be substituted with the words "Schedule VI";

(d) In sub-regulation (5) for the words "sub-regulation (4)(b)(i)" whenever it occurs shall be substituted with the words "sub-regulation (4)(b)."

Amends regulation 18 of the principal regulations.

12. In sub-regulation (1) of regulation 18 of the principal regulations immediately after the words "regulations 14(2)," there shall be added the words "15(7)".

Amends regulation 19 of the principal regulations

13. In sub-regulation (1) of regulation 19 of the principal regulations the words "Without prejudice to this regulation, the competent authority may not prohibit, restrict or impede placing on market of any GMO, as or in products, which comply with these regulations except where," shall be substituted with the word "Where,".

Amends regulation 21 of the principal regulations

14. In regulation 21 of the principal regulations the words "regulation 2(1)" shall be substituted with the words "regulation 2".

15. Regulation 23 of the principal regulations shall be amended as follows:

(a) sub-regulation (3) to (7) shall be re-numbered as sub-regulations (5) to (9) respectively;

(b) sub-regulation (2) shall be substituted with the following new sub-regulation:

“(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 years, or to both such fine and imprisonment.

(c) immediately after sub-regulation (2), there shall be added the following new sub-regulations (3) and (4):

“(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 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*.”

Adds new regulation 26A.

16. Immediately after regulation 26 of the principal regulations there shall be added the following new regulation:-

“Free circulation of authorized GMOs.

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

Amends Schedule II of the principal regulations.

17. Schedule II of the principal regulation thereof shall be amended as follows:

Amends Section C of Schedule II.

- (i) Section C shall be substituted with the following text:

“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 of these regulation, 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 of these regulation 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 of these regulations 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 points (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 subcombinations 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 subcombinations, 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:

- the recipient or parental organism(s),
- the genetic modification(s), be it insertion or deletion of genetic material, and relevant information on the vector and the donor,
- the GMO,
- the intended release or use including its scale,

- the potential receiving environment(s) into which the GMO will be released and into which the transgene may spread, and
- 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 in accordance with the following six steps:

1. *Problem formulation including hazard identification*

The problem formulation shall:

- 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;
- identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under point (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:

- 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,
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors,
- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,
- effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

- disease affecting humans, including allergenic or toxic reactions,
- 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:

- (i) evidence from previous experiences;
 - (ii) available data sets or literature;
 - (iii) 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:

- the spread of the GMO(s) in the environment,
 - the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not,
 - phenotypic and genetic instability,
 - interactions with other organisms,
 - 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 of these regulations, 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.”

Amends Section D of Schedule II.

- (ii) The title and the introductory paragraph of Section D shall be substituted with the following:

“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 Section B and following the methodology described in Section C, and on the basis of the information required pursuant to Schedule III.”

Amends Section D.2 of Schedule II.

- (iii) Section D.2 shall be substituted with the following:

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

“Higher plants” shall mean plants which belong to the taxonomic group Spermatophytæ (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.”

Amends Schedule III of the principal regulations.

18. Schedule III of the principal regulation shall be substituted with the following:

“SCHEDULE III

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C of these regulations 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:

- (i) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;
- (ii) for notifications referred to in Part C of these regulations, 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.”

Amends Schedule III B of the principal regulations.

19. Schedule III B of the principal regulation shall be substituted with the following:

‘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 m²).
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) subspecies
 - (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:

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

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

— subcellular 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:
 - size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,
 - the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format,
 - in case of deletion, size and function of the deleted region(s),
 - subcellular 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,
 - 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,
 - sequence information in a standardised electronic format for both 5' and 3' flanking regions at each insertion site,
 - bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,
 - 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,
 - bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,
 - primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein,
 - 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:

- method(s) used for expression analysis together with their performance characteristics,
 - information on the developmental expression of the insert during the life cycle of the plant,
 - parts of the plant where the insert/modified sequence is expressed,
 - potential unintended expression of new ORFs identified under the seventh indent of point (ii), which raise a safety concern,
 - 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 point 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.”

Amends Schedule IV of the principal regulations.

- 20.** Schedule IV of the regulations shall be amended as follows:
 - (i) Point 1 shall be substituted with the following:

“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,”

(*) 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).”

(ii) Point 7 shall be substituted with the following:

“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,”

Date: 01 February 2019