# Draft law on the placing on the market of genetically modified organisms as or in products

**Chapter I. Objectives**

### Article 1. Subject

This Law lays down the rules for the placing on the European market of genetically modified organisms as or in products.

### Article 2. Definitions

For the purposes of this Law, the following definitions shall apply:

(1) ‘competent administration’: the Luxembourg Veterinary and Food Administration, hereinafter referred to as ‘ALVA’;

(2) ‘environmental risk assessment’: the assessment of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the placing on the market of genetically modified organisms (GMOs) may pose and carried out in accordance with Annex II of this Law;

(3) ‘online interface’: any software, including a website, part of a website or an application, as defined in Article 3(15) of Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004;

(4) ‘Minister’: the Minister responsible for Agriculture;

(5) ‘placing on the market’: the making available to third parties, free of charge or for consideration, of products composed in whole or in part of genetically modified organisms.

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

* The making available of genetically modified micro-organisms for activities governed by Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms, including for crop collections;
* The making available of GMOs other than the micro-organisms referred to in the first indent, intended to be used exclusively for activities subject to appropriate strict containment measures aimed at limiting the contact of these organisms with the whole population and the environment and ensuring a high level of safety for those organisms; the measures should be based on the same containment principles as those laid down in Directive 2009/41/EC;
* The making available of GMOs to be used exclusively for deliberate releases meeting the requirements laid down in the Law on the Marketing of Seeds and Plants and on the Co-existence of Genetically Modified, Conventional and Organic Crops;

(6) ‘notifier’: the person submitting the notification;

(7) ‘notification’: the presentation of the information required by this Law to the Minister responsible for Agriculture;

(8) ‘operator’: any person referred to in Article 3(29) of Regulation (EU) 2017/625 and subject to compliance with the obligations contained in this Law;

(9) ‘organism’: any biological entity capable of reproducing or transferring genetic material;

(10) ‘genetically modified organism’ (GMO): an organism, with the exception of human beings, whose genetic material has been modified in a manner that does not occur naturally by multiplication and/or natural recombination.

For the purposes of this definition:

1. Genetic modification shall be carried out at least by the use of the techniques listed in part one of Annex I A to this Law,
2. The techniques listed in part two of Annex I A to this Law are not considered to result in genetic modification;

(11) ‘product’: a preparation consisting of, or produced from, or containing a GMO or a combination of GMOs, placed on the market.

### Article 3. Exemptions

1. This Law shall not apply to organisms obtained by the techniques of genetic modification listed in Annex I B.
2. This Law shall not apply to the transport of GMOs by rail, road, inland waterways, sea or air.

### Article 4. **General** obligations

1. In accordance with the precautionary principle, GMOs may only be placed on the market in accordance with the provisions of this Law in order to avoid adverse effects on human health and the environment.
2. Anyone wishing to make a notification under this Law must conduct an environmental risk assessment beforehand. The information that may be necessary to carry out this assessment is described in Annex III.
3. The Minister shall, in the assessment referred to in paragraph 4 of this Article, pay particular attention to GMOs containing genes expressing resistance to antibiotics used for medical or veterinary treatments in the environmental risk assessment, with a view to identifying and gradually eliminating from GMOs antibiotic resistance markers that are likely to have adverse effects on human health and the environment.
4. A precise assessment on a case-by-case basis of potential adverse effects on human health and the environment which may result directly or indirectly from the transfer of genes from GMOs to other organisms shall be carried out by the notifier. This assessment shall be carried out in accordance with Annex II, taking into account the environmental impacts according to the nature of the organism introduced and the receiving environment.
5. The ALVA shall examine whether the notifications relating to the placing on the market comply with the requirements of this Law and whether the assessment provided for in paragraph 4 of this Article is satisfactory.
6. The ALVA shall organise official controls to ensure compliance with this law.

### Article 5. Scope of application

1. This Law shall not apply to GMOs as or in products to the extent that they are authorised by European legislation which provides for a specific environmental risk assessment, carried out in accordance with the principles set out in Annex II and on the basis of the information specified in Annex III, without prejudice to the additional requirements laid down in the legislation, and which lays down requirements for risk management, labelling, monitoring, where appropriate, public information and a safeguard clause at least equivalent to those contained in this Law.
2. This Law shall not apply to GMOs as or in products to the extent that they are authorised by Regulation (EC) No 726/2004, provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II and on the basis of the type of information specified in Annex III, without prejudice to other relevant requirements for risk assessment and management, labelling, monitoring, public information and a safeguard clause provided for in Community legislation on medicinal products for human and veterinary use.

## Chapter 2. Placing on the market of GMOs as or in products

### Article 6. Notification procedure

1. Prior to the placing on the market of a GMO or a combination of GMOs as or in products, a notification shall be submitted to the Minister.
2. The Minister shall acknowledge receipt of the notification by taking note of the date of the notification and shall immediately forward the summary of the dossier referred to in paragraph 3(h) to the competent authorities of the other Member States and to the European Commission.

The ALVA shall examine without delay whether the notification complies with paragraph 3 and, if necessary, request additional information from the notifier.

1. The notification shall contain:
2. the information required in Annexes III and IV. This information shall take into account the diversity of the sites of use of GMOs as or in products and shall include the data and results obtained from previous releases as part of research and development on the consequences of the release on human health and the environment;
3. the environmental risk assessment and the conclusions required in Annex II, Section D;
4. the conditions for placing the product on the market, including the specific conditions of use and handling;
5. the proposed duration of the authorisation should not exceed 10 years;
6. a monitoring plan in accordance with Annex VI, including a proposal for the duration of that plan. This period may differ from the duration proposed for the authorisation;
7. a proposal for labelling that meets the requirements specified in Annex IV. The labelling shall clearly indicate the presence of one or more GMOs. The words ‘This product contains genetically modified organisms’ must appear on a label or on an accompanying document;
8. a proposal for packaging which shall comprise the requirements specified in Annex IV;
9. a summary of the dossier, the model of which is laid down in Council Decision 2002/812/EC of 3 October 2002 referred to above, to be forwarded to the European Commission and the Member States for information.

If, on the basis of the results of a release notified under European law 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 does not pose a risk to human health or the environment, he may propose to the Minister responsible for Agriculture not to provide all or part of the information required in Annex IV, Section B.

The notification referred to in paragraph 1 shall be submitted in accordance with the established standard data formats.

1. The notifier shall include in this notification information on the data or results from releases of the same GMO or the same combination of GMOs previously or currently notified and which it has carried out or is carrying out inside or outside the European Union.
2. 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.
3. A separate notification is necessary for a GMO or a combination of GMOs to be used for purposes other than those specified in the notification.
4. If new information concerning the risks that the GMO poses to human health or the environment has become available before written authorisation is granted, the notifier shall immediately take the necessary measures to protect human health and the environment and inform the Minister responsible for Agriculture. The notifier shall also review the information and conditions specified in the notification.

The measures and information procedures referred to in this paragraph shall be specified by Grand-Ducal regulation.

### Article 7. Assessment report

1. Upon receipt of the notification referred to in Article 6, the Minister shall issue to the notifier an acknowledgement of receipt stating the date of its registration.

The ALVA shall examine without delay whether the dossier is complete and where it considers that one of the elements of the file is incomplete or irregular, it shall invite the notifier to complete or regularise the dossier.

1. Within 90 days from the date of registration of the application, the ALVA shall prepare an assessment report which shall be forwarded by the Minister to the notifier.

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

1. The content of the assessment reports shall be laid down in the provisions of Annex V to this Law and shall indicate:
2. whether the GMO(s) concerned is to be placed on the market and under what conditions, or,
3. if this or these GMO(s) are not to be placed on the market.

### Article 8. Standard procedure

1. The Minister may, at any time, by a reasoned request, invite a notifier to provide him with additional information, make observations, or make reasoned objections to the placing on the market of the GMOs concerned within 60 days of the date of dissemination of the assessment report.
2. In the event that it is decided that the GMO(s) should not be placed on the market, the Minister shall reject the application, on the opinion of ALVA, and inform the notifier of the reasons for his decision.
3. In the absence of any reasoned objection within 60 days of the date of publication of the assessment report, or where any objections have been lifted within 105 days from the same date, the Minister shall issue the marketing authorisation for the GMO or the combination of GMOs by a ministerial order. The authorisation shall be issued for a maximum period of 10 years.

### Article 9. Renewal of the authorisation

1. Applications for renewal of an authorisation granted shall be examined under the same conditions as applications for authorisation, subject to the provisions of this Article.
2. The application for renewal shall be sent nine months before the date of expiry of the initial authorisation to the Minister. It shall include:
3. a copy of the marketing authorisation;
4. a report on the results of the monitoring referred to in Article 6(e);
5. any new information that has become available on the risks of the product to public health or the environment;
6. where appropriate, a proposal to amend or supplement the conditions for monitoring and the period of validity of the authorisation.
7. The Minister shall acknowledge receipt of the notification and take note of the date of receipt of the notification. She shall send the assessment report drawn up by ALVA to the notifier.

The assessment report shall specify:

1. whether the GMO(s) are to remain on the market and under what conditions, or,
2. if the GMO(s) should not remain on the market.
3. The Minister may request further information, make observations or raise reasoned objections within 60 days of the date of publication of the assessment report.
4. In the absence of any reasoned objection within 60 days of the date of publication of the assessment report, or where any objections have been lifted within 75 days from the same date, the Minister shall, on the advice of the ALVA, grant the renewal of the authorisation. The period of validity of the authorisation shall, as a general rule, not exceed 10 years and may be limited or extended, where appropriate, for specific reasons.
5. The original marketing authorisation decision shall remain valid until a decision on its renewal has been made.

### Article 10. Community procedure in the event of objections

1. Where an objection is raised and maintained in accordance with Articles 8, 9 and 12, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 5 of Regulation (EU) No 182/2011.
2. Where a favourable decision has been taken to place the product on the market or renew the authorisation, the Minister shall issue the marketing authorisation for the GMO or combination of GMOs by ministerial order.

### Article 11. Authorisation

1. Where a written authorisation has been given for the placing on the market of a GMO as or in a product, it may be used without further notification throughout the territory of the European Union provided that the specific conditions of use and the environments and the geographical areas specified in those conditions are strictly adhered to.
2. The notifier may place the product on the market only if he has received written authorisation from the Minister in accordance with Articles 8, 9 and 10, and in accordance with the conditions required in that authorisation.

The authorisation shall explicitly specify:

1. its scope, in particular the identity of the GMO(s) to be placed on the market as or in products and their unique identifier;
2. its period of validity;
3. the conditions for placing the product on the market, including any specific conditions of use, handling and packaging of the GMO(s), as or in products, and conditions for the protection of particular ecosystems, environments or geographical areas;
4. the obligation of the notifier without prejudice to the confidential information referred to in Article 16 to keep control samples available to the ALVA;
5. labelling requirements, meeting the requirements laid down in Annex IV. The labelling must clearly indicate the presence of a GMO. The words ‘This product contains genetically modified organisms’ must appear on a label or on a document accompanying the product or other products containing the GMO(s);
6. the monitoring requirements specified in Annex VI, including the obligations to report to the Commission and the competent authorities, the timing of the monitoring plan and, where applicable, any obligations that may be imposed on the person selling the product or any user, including, for GMOs grown, regarding their location.
7. The Minister shall circulate the written authorisation and, where appropriate, the decision referred to in section 10 to the public and the ALVA shall monitor the conditions specified in the written authorisation to ensure that they are complied with. The information procedures referred to in this paragraph shall be specified by Grand-Ducal regulation.

### Article 12. Monitoring and processing of new information

1. After the placing on the market of one or more GMOs as or in products, the notifier shall ensure that monitoring and reporting are carried out in accordance with the conditions specified in the authorisation. Reports on this monitoring shall be sent to the Commission and to the competent authorities of the Member States.

On the basis of these reports, in accordance with the authorisation and within the framework of the monitoring plan specified in the authorisation, the Minister may, if he has received the initial notification, adapt the monitoring plan after the first monitoring period.

1. If, after the written authorisation has been given, new information from users or other sources has become available regarding the risks that the GMO(s) pose to human health or the environment, the notifier shall immediately take the measures necessary to protect human health and the environment and inform the Minister accordingly.

The measures and information procedures referred to in this paragraph shall be specified by Grand-Ducal regulation.

1. If information becomes available to the Minister which could have consequences for the risks posed by the GMO(s) to human health or the environment, or under the circumstances described in paragraph 2, he may avail himself of the provisions laid down in Article 8(1) if that information has become available before giving his written authorisation.
2. In order to ensure transparency, the results of the monitoring shall be made public. The procedures for the publication of the control results shall be defined by Grand-Ducal regulation.

### Article 13. Labelling of GMOs

1. GMOs placed on the market under this Law or issued pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed shall be labelled under the conditions laid down in Annex IV and, where appropriate, under the conditions laid down in Article 4.6 of Regulation (EC) No 1830/2003.
2. Labelling of products intended for direct processing and products with traces of GMOs present in a proportion not exceeding 0.9 %, provided that such traces are accidental or technically unavoidable, is not required.

### Article 14. Free movement

The Minister, on the advice of the ALVA, may restrict or suspend the placing on the market in the Grand Duchy of Luxembourg of GMOs, as or in products, if they do not comply with the requirements of this Law and its implementing regulations.

### Article 15. Safeguard clause

Where the ALVA or the Minister, by reason of new or additional information which has become available after the authorisation has been given and which affects the environmental risk assessment or because of the re-evaluation of existing information on the basis of new or additional scientific knowledge, has specific reasons to consider that a GMO as or in a product which has been properly notified and authorised in writing in accordance with this Law presents a risk to human health or the environment, the ALVA shall take the emergency measures referred to in Article 21 and the Minister responsible for Agriculture shall take the administrative measures referred to in Article 22.

### Article 16. Confidentiality

1. The notifier may submit to the Minister a request for confidential treatment of certain parts of the information submitted under this Law together with verifiable justification in accordance with paragraphs 3 and 6.
2. The ALVA shall assess the request for confidential treatment submitted by the notifier to the Minister.
3. At the request of the notifier, the Minister may grant confidential treatment only in respect of the following information, upon verifiable justification, where it is demonstrated by the notifier that their disclosure is likely to significantly harm his interests:
4. the information referred to in Article 39(2)(a), (b) and (c) of Regulation (EC) No 178/2002;
5. information on DNA sequences, with the exception of sequences used for the detection, identification and quantification of the transformation event; and
6. selection models and strategies.
7. After consultation with the notifier, the Minister shall, on the advice of the ALVA, decide on the information which shall be treated confidentially and inform the notifier thereof.
8. Confidential information notified or exchanged under this Law shall not be made public.
9. The relevant provisions of Articles 39(e) and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.
10. Notwithstanding paragraphs 3, 5 and 6 of this Article:
11. where urgent action is essential to protect human health, animal health or the environment, for example in emergency situations, the Minister may disclose the information referred to in paragraph 3; and
12. information which forms part of the conclusions of the scientific outputs provided by the relevant scientific committee(s) or of the conclusions of the assessment reports and which relates to the foreseeable effects on human health, animal health or the environment shall nevertheless be made public. In this case, Article 39(c) of Regulation (EC) No 178/2002 shall apply.
13. In the event of withdrawal of the notification by the notifier, the Minister shall respect confidentiality as granted in accordance with this Article. If the withdrawal of the notification takes place before the decision on the request for confidential treatment concerned is rendered, the Minister shall not make public the information for which confidential treatment has been requested.

## Chapter 3. Official controls

### Article 17. Competences

1. Official controls on GMOs placed on the market as or in products shall be carried out, at any stage of the production, processing, distribution and placing on the market of those GMOs, and at any stage of the manufacture, processing, distribution including storage and use of GMOs, by the ALVA, which verifies compliance with the provisions of this Law.
2. The ALVA may, where necessary, delegate certain specific tasks relating to its duties, as provided for in Articles 28 to 33 of Regulation (EU) 2017/625, after the agreement of the Minister.

### Article 18. Official controls

1. ALVA officials, as well as natural persons and delegated bodies designated in accordance with Article 17(2) shall be empowered to:
2. carry out their duty of monitoring and control at all stages of the placing on the market, labelling and packaging of GMOs placed on the market as or in products pursuant to this Law or issued pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed;
3. freely access operators’ premises, facilities, equipment and sites, including operators’ means of transport;
4. request communication of all registers, entries and documents relating to GMOs placed on the market as or in products covered by this Law, to take copies of them and to obtain a translation thereof in one of the three administrative languages;
5. access the data of the operators’ computer systems within the framework of the official controls provided for in this Law;
6. photograph GMOs, facilities, premises, sites, means of transport and all entries used;
7. take or obtain copies of information, data or documents, regardless of their storage media, including online interfaces;
8. carry out or have carried out technical and scientific measurements and examinations of the installations, premises, sites and means of transport used;
9. take, or have taken for examination or analysis, samples of the GMO, with the samples being taken against an acknowledgement of receipt.

The owner or holder of the samples taken shall have the right to request a repeat sample and shall be compensated at the current price of the samples, unless expressly waived;

1. require from the operator concerned and his staff all the information necessary to carry out official controls;
2. purchase or arrange test purchases of goods or services, if necessary anonymously or under a false identity, and inspect, analyse and test the goods and services;
3. The provisions of the first subparagraph shall not apply to products covered by Article 13.2.
4. The operator shall be entitled to request a second expert opinion at his own expense at any time in accordance with Article 35(1) and (2) of Regulation (EU) 2017/625.

A request for a second expert opinion made by the operator pursuant to the preceding subparagraph shall be without prejudice to the right of the ALVA to order the emergency measures referred to in Article 21 or the Minister to order the administrative measures referred to in Article 22 of this Law.

In the event of a dispute between the ALVA and the operators on the basis of the second expert opinion referred to in the first subparagraph of this paragraph, operators may request, at their own expense, the documentary examination of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory.

1. In carrying out their monitoring and control tasks, the officials referred to in paragraph 1 of this Article shall carry out official controls and report their presence to the operator or his representative.

These officials may be accompanied by:

* staff appointed by the competent authority of another Member State within the framework of the assistance provided for in Article 104 of Regulation (EU) 2017/625;
* an expert from the European Commission or another Member State of the Union acting within the framework of the controls provided for in Article 116 of Regulation (EU) 2017/625.

The operator shall have the right to accompany officials, natural persons and bodies designated in accordance with Article 17(2) carrying out official controls during the visit and shall facilitate the control operations carried out by them.

ALVA officials have the right to directly request the assistance of the law enforcement authority in carrying out their duties.

1. A written report shall be made on official control operations, findings, obligations and corrective measures to be implemented within set deadlines. A copy of the written report shall be issued to the operator.
2. The results of official controls shall be made public. The procedures for the publication of the control results shall be defined by Grand-Ducal regulation.

## Chapter 4. Fees for official controls and other official activities

### Article 19. Mandatory fees

A Grand-Ducal regulation shall determine the amount of fees, in accordance with the provisions of Articles 79, 81 and 82 of Regulation (EU) 2017/625, and specify the terms for the collection and payment of such fees, in accordance with the provisions of Articles 83 and 84 of [Regulation (EU) 2017/625](https://legilux.public.lu/eli/reg_ue/2017/625/jo).

### Article 20. Optional fees

A Grand-Ducal regulation shall determine the amount of fees, in accordance with the provisions of Article 80 of Regulation (EU) 2017/625, and specify the terms for the collection and payment of such fees, in accordance with the provisions of Articles 83 and 84 of [Regulation (EU) 2017/625](https://legilux.public.lu/eli/reg_ue/2017/625/jo).

## Chapter 5. Administrative measures

### Article 21. Emergency measures

1. The ALVA is authorised to order the emergency measures provided for in Articles 65 to 72 of Regulation (EU) 2017/625.
2. In the event of an established breach and where the GMO as a product or in a product is placed on the market or used in the territory of the Grand Duchy of Luxembourg, the ALVA may order any measures necessary to remedy the non-compliances and, in particular, the measures provided for in Article 138 of Regulation (EU) 2017/625.
3. The ALVA may attach to its decisions a periodic penalty payment with a daily amount of between EUR 200 and 2 000. The amount of the penalty payment shall take account of the economic capacity of the operator concerned and the seriousness of the breach detected.
4. As soon as the ALVA has found that the operator concerned has eliminated the non-compliances which were the subject of the measures provided for in paragraphs 1 and 2, the latter shall be lifted.
5. The order prescribed in accordance with paragraphs 1 and 2 shall be notified in writing or handed over to the operator. It shall be reasoned, take effect on the date of its notification and its duration shall depend on the nature, gravity and frequency of the non-compliance detected, with the operator against whom the measures have been taken being heard or summoned. In the event that the order has a period of validity, the period of validity may not exceed 30 days, renewable twice.
6. By way of derogation from paragraph 5, emergency orders prescribed pursuant to Article 138(2)(h) and (i) of Regulation (EU) 2017/625 shall be confirmed by a decision of the Minister within 48 hours, with the operator against whom the measures have been taken being heard or summoned.
7. The orders provided for in this paragraph shall be subject to an appeal for review before the Administrative Court. The costs incurred as a result of this order shall be borne by the operator. The recovery of costs and periodic penalty payments shall proceed as in public matters.

### Article 22. Administrative measures

1. In the event of non-compliance with the provisions of this Law, the Minister may close the business, operation, establishment, installation, online interface, premises or site, in whole or in part, and affix seals.
2. The measures taken by the Minister pursuant to paragraph 1 shall be subject to an appeal for review before the Administrative Court which shall make a judgment on the merits. Appeals must be brought within forty days of notification of the decision, otherwise entitlement will lapse.
3. As soon as the non-compliances which were the subject of the measures provided for in paragraph 1 have been found to have been eliminated, the latter shall be lifted.

## Chapter 6. Criminal offences and penalties

### Article 23. Investigation and recording of criminal offences

1. In addition to the members of the Grand-Ducal Police, acting as officers or agents of the judicial police, violations of this Law and its implementing regulations shall be recorded by the officials and staff members of the ALVA, falling within salary categories A, salary grades A1 and A2, salary category B, salary grade B1 and of the Customs and Excise Administration from the rank of principal brigadier.
2. In the performance of their duties, the officials and staff members referred to in paragraph 1 shall have the status of judicial police officers. They may exercise these functions throughout the territory of the Grand Duchy of Luxembourg. They shall record any infringements in reports that shall serve as evidence in the absence of proof to the contrary.
3. The officials and staff members referred to in paragraph 1 must have undergone special professional training in the investigation and recording of infringements and the criminal provisions of this Law.

The programme and duration of the training, as well as the assessment procedures shall be ordered by Grand-Ducal regulation.

1. Before taking up their duties, the officials and staff members referred to in paragraph 1 shall take the following oath before the President of the Luxembourg District Court: ‘ I swear to perform my duties with integrity, accuracy and impartiality.’

Article 458 of the Criminal Code applies to them.

### Article 24. Powers and prerogatives for the investigation and recording of criminal offences

1. Members of the Grand-Ducal Police of the rank of police officer and the officials and staff members referred to in Article 23(1) may have day and night access to facilities, premises, operator sites and means of transport used, subject to this Law and the regulations made under it, in the event of evidence suggesting that there is a serious breach of this Law and its implementing regulations.
2. The provisions of paragraph 1 shall not apply to premises used for housing.

However, and without prejudice to Article 33(1) of the Code of Criminal Procedure, in the event of serious indications that the origin of the offence is in premises intended for housing, a home visit may be carried out between 6:30 a.m. and 8:00 p.m. by two judicial police officers, members of the Grand-Ducal Police of the rank of police officer or the officials and staff members referred to in Article 19(1), acting under a mandate of the investigating judge.

1. In the exercise of the powers provided for in paragraphs 1 and 2, members of the Grand-Ducal Police of the rank of the police officer and the officials and staff members referred to in Article 23(1) shall be empowered to:
2. carry out their duty of monitoring and control at all stages of the placing on the market, labelling and packaging of GMOs placed on the market as or in products pursuant to this Law or issued pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed;
3. freely access operators’ premises, facilities, equipment and sites, including operators’ means of transport;
4. request communication of all registers, entries and documents relating to GMOs placed on the market as or in products covered by this Law, to take copies of them and to obtain a translation thereof in one of the three administrative languages;
5. access the data of the operators’ computer systems within the framework of the official controls provided for in this Law;
6. photograph GMOs, facilities, premises, sites, means of transport and all entries used;
7. take or obtain copies of information, data or documents, regardless of their storage media, including online interfaces;
8. carry out or have carried out technical and scientific measurements and examinations of the installations, premises, sites and means of transport used;
9. take, or have taken for examination or analysis, samples of the GMO, with the samples being taken against an acknowledgement of receipt.

The owner or holder of the samples taken shall have the right to request a repeat sample and shall be compensated at the current price of the samples, unless expressly waived;

1. require from the operator concerned and his staff all the information necessary to carry out official controls;
2. purchase or arrange test purchases of goods or services, if necessary anonymously or under a false identity, and inspect, analyse and test the goods and services;
3. in the event of a contravention or offence, seize and, if necessary, sequester the GMO placed on the market as or in products which was used to commit the offence or which was intended to be used to commit the offence, as well as records, entries and documents concerning it;
4. interview the operator concerned and his staff.

The seizure provided for in letter (k) may be maintained only if it is validated within eight days, not including Saturdays, Sundays and public holidays by order of the investigating judge.

The discharge of attachment pronounced by order of the investigating judge may be sought in any event, namely:

1. from the chamber of the Council of the district court during the investigation;
2. from the magistrate, in the case of a contravention;
3. from the criminal division of the district court when the case is referred to it by order for reference or by direct summons;
4. from the criminal division of the court of appeal if an appeal has been lodged or if an appeal in cassation has been lodged.

The petition shall be lodged with the Registry of the court called to adjudicate. A decision shall be taken as a matter of urgency and at the latest within eight days of the filing, with the public prosecutor and the accused or his defence counsel being heard in their oral explanations or duly summoned.

1. Any operator subject to the measures provided for in paragraph 3 shall, at the requisitioning of members of the Grand-Ducal Police of the rank of police officer and the officials and staff members referred to in Article 23(1), facilitate the operations carried out by them under this Law.
2. A report of the findings and operations shall be drawn up. A copy of the report shall be issued to the operator.
3. The costs incurred as a result of measures taken under this Article shall be included in the legal expenses and shall follow their outcome.

### Article 25. Sanctions

1. A notifier who acts in violation of Article 6(1), (3), (4) and (6), Article 9(1) and (2), Article 12(1) and (13) of this Law shall be punished by a fine of EUR 150 to 2 000.
2. The following persons shall be punished by imprisonment from eight days to six months and a fine of EUR 2 001 to EUR 50 000 or only one of these penalties:

* a notifier who acts in violation of Article 4(1), (2) and (4), Article 6(7), Article 11(1) and (2) and Article 12(3) of this Law;
* an operator who acts in violation of the administrative measures taken by the ALVA pursuant to Article 21 or by the Minister responsible for Agriculture under Article 22 of this Law.

1. The judge shall order, where appropriate, the confiscation of GMOs placed on the market as or in products, material, equipment and instruments used or intended to be used to commit the offence.
2. The judge may impose a ban on the placing on the market of GMOs for a period of three months to 15 years. This prohibition shall take effect from the day on which the decision which pronounced it acquires the authority of res judicata.
3. In the event of a repeat offence within a period of two years or fraud, the penalties may be increased to a maximum of double.

**Article 26. Fines**

In the event of contraventions provided for in Article 25(1), fines may be issued by officials of the Grand-Ducal Police authorised for that purpose, by the Director-General of the Grand-Ducal Police and, in the performance of their duties in connection with the recording of offences referred to in Article 24(1), by ALVA officials and staff members belonging to salary categories A, salary grades A1 and A2 and salary category B, salary grade B1.

The fine shall be subject to the condition that the offender must pay it within the 45-day period prescribed by the notice. The payment of the fine shall be made to the bank account indicated by the same notice.

The fine shall be replaced by a standard penalty notice:

1. if the offender has not paid within the specified time limit;
2. if the offender declares that they are unwilling or unable to pay the fine(s);

The amount of the fine and the modes of payment shall be determined by Grand-Ducal regulation which also determines the terms of application of this Article and which shall draw up a catalogue aggregating the contraventions according to the amount of the fines to be collected.

The amount to be collected may not exceed the maximum of the contraventions provided for in Article 25(1).

Payment of the fine within 45 days of detection of the infringement, plus reminder fees where applicable, shall have the consequence of halting any prosecution.

When the fine has been paid after that time, it shall be reimbursed in the event of acquittal, and shall be charged against the fine imposed and any legal expenses in the event of a conviction.

In this case, payment of the fine shall not prejudice the outcome of any legal action.

# ANNEX I A

# TECHNIQUES REFERRED TO IN ARTICLE 2(2)

**PART ONE**

Techniques of genetic modification referred to in Article 2(10)(a) are, inter alia:

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

**PART TWO**

Techniques referred to in Article 2(10)(b) 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 Annex I B, are:

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

# ANNEX I B

# TECHNIQUES REFERRED TO IN ARTICLE 3

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

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

# ANNEX II

# PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

This Annex 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 environmental risk assessment referred to in Articles 4 and 6.

With a view to contributing to a common understanding of the terms ‘direct, indirect, immediate and delayed’ when implementing 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, these 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 environmental 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 authorisations 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.

## Objective

The objective of an environmental risk assessment. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment which the placing on the market of GMOs may have. The environmental 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.

## General principles

In accordance with the precautionary principle, the following general principles should be followed when performing the environmental 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 environmental risk assessment. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data,
* the environmental 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 about the GMO and its effects on human health or the environment becomes available, the environmental risk assessment may need to be readdressed in order to:
* determine whether the risk has changed,
* determine whether there is a need for amending the risk management accordingly.

## Methodology

### C.1. General and specific considerations for environmental risk assessment

#### 1. Intended and unintended changes

As part of the identification and assessment of the potential adverse effects referred to in Section A, the environmental risk assessment 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 environmental risk assessment of notifications under this Law

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

1. the long-term interactions of the GMO and the receiving environment;
2. the characteristics of the GMO which become important on a long-term basis;
3. data obtained from repeated placings on the market of the GMO over a long period.

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

#### 3. Quality of the data

In order to carry out an environmental risk assessment for a notification under this Law, 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 environmental risk assessment why generating data by studies is not possible.

Where data generated outside Europe is provided in the environmental risk assessment, its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the environmental risk assessment for notifications under this Law shall comply with the following requirements:

1. where toxicological studies carried out to assess risk to human or animal health are provided in the environmental risk assessment, the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:
2. the requirements of Directive 2004/10/EC; or
3. the ‘OECD Principles on Good Laboratory Practice’ (GLP), if carried out outside the Union;
4. where studies other than toxicological studies are provided in the environmental risk assessment, they shall:
5. comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or
6. be conducted by organisations accredited under the relevant ISO standard; or
7. in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;
8. 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;
9. the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;
10. 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 environmental risk assessment;
11. 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 environmental risk assessment.

#### 4. Stacked transformation events in notifications under this Law

The following shall apply to the environmental risk assessment of a GMO containing stacked transformation events in notifications under this Law:

1. the notifier shall provide an environmental risk assessment for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;
2. the notifier shall provide an assessment of the following aspects:
3. the stability of the transformation events;
4. the expression of the transformation events;
5. the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;
6. 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 environmental risk assessment 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 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 environmental risk assessment, subject to Article 6(4).

### C.3. Steps in the environmental risk assessment

The environmental risk assessment referred to in Article 6 shall be conducted for each relevant area of risk referred to in Section D.1 or D.2 in accordance with the following six steps:

#### 1. Problem formulation including hazard identification

The problem formulation shall:

1. 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 use;
2. 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:

1. evidence from previous experiences;
2. available data sets or literature;
3. mathematical modelling;
4. 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;

1. 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 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;

1. formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);
2. 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. 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 environmental risk assessment.

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

#### 6. Overall risk assessment and conclusions

A qualitative and, where possible, quantitative assessment 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 assessment shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk assessment 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 this Law, the overall risk assessment shall also include an explanation of the assumptions made during the environmental risk assessment and 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 environmental risk assessment

Conclusions on the potential environmental impact in relevant receiving environments from 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 environmental risk assessment 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 Annex 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 the proposed release(s).
2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).
3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.
4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).
5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.
6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).
7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.
8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).
9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

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

‘Higher plants’ shall mean 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-organism gene transfer.
3. Interactions of the GMHP with target organisms.4. Interactions of the GMHP with non-target organisms.
4. Impact of the specific cultivation, management and harvesting techniques.
5. Effects on biogeochemical processes.
6. Effects on human and animal health.

# ANNEX III

# INFORMATION REQUIRED IN THE NOTIFICATION

Notifications of this Law shall, as a rule, include the information set out in Annex III A, for GMOs other than higher plants, or in Annex III B, for genetically modified higher plants.

The provision of a given subset of information listed in Annex III A or in Annex 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:

1. the summaries and results of the studies referred to in the notification, including an explanation about their relevance to the environmental risk assessment, where applicable;
2. for notifications referred to in this Law, 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 Annex to technical progress or developing guidance notes on this Annex. 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.

# ANNEX III A

# INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

## I. 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.

## 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:
12. classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
13. generation time in natural ecosystems, sexual and asexual reproductive cycle;
14. information on survival, including seasonability and the ability to form survival structures;
15. pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms; possible activation of latent viruses (proviruses); ability to colonise other organisms;
16. antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
17. involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
18. Nature of indigenous vectors:
19. sequence;
20. frequency of mobilisation;
21. specificity;
22. presence of genes which confer resistance.
23. History of previous genetic modifications.

### B. Characteristics of the vector

1. Nature and source of the vector.
2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO.
3. Frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination.
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

### C. Characteristics of the modified organism

1. Information relating to the genetic modification:
2. methods used for the modification;
3. methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
4. description of the insert and/or vector construction;
5. 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;
6. methods and criteria used for selection;
7. sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.
8. Information on the final GMO:
9. description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
10. structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
11. stability of the organism in terms of genetic traits;
12. rate and level of expression of new genetic material. Method and sensitivity of measurement;
13. activity of the expressed protein(s);
14. description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
15. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
16. history of previous releases or uses of the GMO;
17. considerations for human health and animal health, as well as plant health:
18. toxic or allergenic effects of the GMOs and/or their metabolic products;
19. comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
20. capacity for colonisation;
21. 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;

1. other product hazards.

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

### A. Information on the release

1. Description of the proposed deliberate release, including the purpose(s) and foreseen products.
2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases.
3. Preparation of the site previous to the release.
4. Size of the site.
5. Method(s) to be used for the release.
6. Quantities of GMOs to be released.
7. Disturbance on the site (type and method of cultivation, mining, irrigation, or other activities).
8. Worker protection measures taken during the release.
9. Post-release treatment of the site.
10. Techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment.
11. Information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

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

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

## IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOS AND THE ENVIRONMENT

### A. Characteristics affecting survival, multiplication and dissemination

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

### B. Interactions with the environment

1. Predicted habitat of the GMOs.
2. Studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments such as microcosms, growth rooms, greenhouses.
3. Genetic transfer capability:
4. postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;
5. postrelease transfer of genetic material from indigenous organisms to the GMOs.
6. Likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism.
7. Measures employed to ensure and to verify genetic stability. Description of genetic traits that may prevent or minimise the dispersal of genetic material. Methods for verifying genetic stability.
8. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.
9. Description of ecosystems to which the GMOs could be disseminated,
10. Potential for excessive population increase in the environment.
11. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s).
12. Identification and description of the target organisms, if applicable.
13. Anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable.
14. 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.
15. Likelihood of postrelease shifts in biological interactions or in host range.
16. Known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.
17. Known or predicted involvement in biogeochemical processes.
18. 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 monitoring their effects.
2. Specificity (to identify GMOs and to distinguish them from donor, recipient and, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.
3. Techniques for detecting the 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 applied to avoid and/or minimise the spread of GMOs beyond the site of release or designated area of use.
2. Methods and procedures applied to protect the site from intrusion by unauthorised persons.
3. Methods and procedures applied to prevent other organisms from entering the site.

### C. Waste treatment

1. Type of waste generated.
2. Expected amount of waste,
3. Description of the proposed treatment.

### D. Emergency response plans

1. Methods and procedures for controlling the GMOs in case of unexpected spread.
2. Methods for decontamination of the affected areas, e.g. 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.

# ANNEX 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 ARTICLES 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
5. Purpose of the release
6. Foreseen date(s) and duration of the release
7. Method by which the GMHP will be released
8. Method for preparing and managing the site before, during and after release, including cultivation practices and harvesting methods
9. Approximate number of plants (or plants per m2)
10. Information relating to the site of release
11. Location and size of the release site(s)
12. Description of the release site ecosystem, including climate, flora and fauna
13. Presence of sexually compatible wild relatives or cultivated plant species
14. 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
2. Complete name:
3. family name
4. genus
5. species
6. subspecies
7. cultivar or breeding line
8. common name
9. Geographical distribution and cultivation of the plant within the Union
10. Information concerning reproduction:
11. mode(s) of reproduction
12. specific factors affecting reproduction, if any
13. generation time
14. Sexual compatibility with other wild or cultivated plant species, including the distribution in Europe of compatible species
15. Survivability:
16. ability to form structures for survival or dormancy
17. specific factors affecting survivability, if any
18. Dissemination:
19. ways and extent of dissemination
20. specific factors affecting dissemination, if any
21. 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
22. Potential interactions of the plant, which are relevant for GMHP, with organisms present in the ecosystem where it is usually grown, or elsewhere, and information on its toxicity to humans, animals and other organisms
23. Molecular characterisation
24. Information relating to the genetic modification:
25. description of methods used for genetic modification
26. nature and source of vector used
27. source of the nucleic acid(s) used for the transformation, size and intended function of each constituent fragment of the region intended for insertion
28. Information relating to the GMHP:
29. general description of the trait(s) and characteristics introduced or modified
30. information about the sequences actually inserted or deleted:

* size and copy number of all insert(s) and methods used for its/their characterisation
* in case of deletion, size and function of 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

1. parts of the plant where the insert is expressed
2. genetic stability of the insert and phenotypic stability of the GMHP
3. Conclusions of the molecular characterisation
4. Information on specific areas of risk
5. Any change in the persistence or invasiveness of the GMHP and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof
6. Any change in the ability of GMHP to transfer genetic material to micro-organisms and the adverse environmental effects thereof
7. Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof
8. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof
9. Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof
10. Potential interactions with the abiotic environment and the adverse environmental effects thereof
11. Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification
12. Conclusions on the specific areas of risk
13. Information on control, monitoring, post-release and waste treatment plans
14. Any measures taken, including:
15. spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops
16. any measures to minimise or prevent the dispersal of any reproductive part of the GMHP
17. Description of methods for post-release treatment of the site
18. Description of post-release treatment methods for the genetically modified plant material including wastes
19. Description of monitoring plans and techniques
20. Description of any emergency plans
21. Description of the methods and procedures to:
22. avoid or minimise the spread of the GMHPs beyond the release site
23. protect the site from intrusion by unauthorised persons
24. prevent other organisms from entering the site or minimise such entries
25. Description of detection and identification techniques for the GMHP
26. Information about previous releases of the GMHP, if applicable

## II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13

### 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:
5. Cultivation
6. 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
2. Complete name:
3. family name
4. genus
5. species
6. subspecies
7. cultivar/breeding line
8. common name
9. Geographical distribution and cultivation of the plant within the Union
10. Information concerning reproduction:
11. mode(s) of reproduction
12. specific factors affecting reproduction, if any
13. generation time
14. Sexual compatibility with other wild or cultivated plant species, including the distribution within the Union of compatible species
15. Survivability:
16. ability to form structures for survival or dormancy
17. specific factors affecting survivability, if any
18. Dissemination:
19. ways and extent of dissemination
20. specific factors affecting dissemination, if any
21. 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
22. Potential interactions of the plant, which are relevant for GMHP, with organisms present in the ecosystem where it is usually grown, or elsewhere, and information on its toxicity to humans, animals and other organisms
23. Molecular characterisation
24. Information relating to the genetic modification:
25. description of methods used for genetic modification
26. nature and source of vector used
27. source of the nucleic acid(s) used for the transformation, size and intended function of each constituent fragment of the region intended for insertion
28. Information relating to the genetically modified plant:
29. description of the trait(s) and characteristics that have been introduced or modified
30. information on the sequences actually inserted or deleted:

* size and copy number of all detectable inserts, both partial and complete, and methods used for their characterisation
* organisation and sequence of genetic material inserted at each insertion site in a standardised electronic format
* in case of deletion, size and function of 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

1. 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 or 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

1. genetic stability of the insert and phenotypic stability of the GMHP
2. Conclusions of the molecular characterisation
3. Comparative analysis of agronomic and phenotypic characteristics and of composition
4. Choice of conventional counterpart and additional comparators
5. Choice of sites for field studies
6. Experimental design and statistical analysis of data from field trials for comparative analysis:
7. Description of field studies design
8. Description of relevant aspect of the receiving environments
9. Statistical analysis
10. Selection of plant material for analysis, if relevant
11. Comparative analysis of agronomic and phenotypic characteristics
12. Comparative analysis of composition, if relevant
13. Conclusions of comparative analysis
14. Specific information for each area of risk

For each of the seven areas of risk referred to in Section D.2 of Annex 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:

1. Persistence and invasiveness, including plant to plant gene transfer:
2. assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof
3. assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof
4. 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
5. Plant to micro-organism gene transfer:
6. assessment of the potential for transfer of newly inserted DNA from the GMHP to micro-organisms and the adverse effects thereof
7. conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to micro-organisms for human and animal health and the environment
8. Interactions of the GMHP with target organisms, if relevant:
9. assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s)
10. 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
11. conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms
12. Interactions of the GMHP with non-target organisms:
13. 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 take into account the potential adverse effect(s) on the relevant ecosystem services and on the species providing those services;

1. conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms
2. Impacts of the specific cultivation, management and harvesting techniques:
3. 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
4. conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques
5. Effects on biogeochemical processes:
6. 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
7. conclusions on adverse effects on biogeochemical processes
8. Effects on human and animal health:
9. assessment of potential direct and indirect interactions between the GMHP and persons working 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
10. 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
11. assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or material from that plant by animals
12. conclusions on the effects on human and animal health
13. Overall risk assessment 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 Annex II and the proposed risk management strategies in accordance with point 5 of Section C.3 of Annex II.

1. Description of detection and identification techniques for the GMHP
2. Information about previous releases of the GMHP, if applicable

# ANNEX IV

# ADDITIONAL INFORMATION

This Annex 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 products to be placed on the market, and GMO exempted under Article 2(5), second subparagraph. The labelling conditions of exempted organisms laid down in Article 13 shall be subject to the appropriate recommendations and restrictions on use.

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

1. Proposed commercial names for the products and names of the GMOs contained therein, and proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004. After authorisation, any new commercial names should be provided to the competent authority.
2. Name and full address of the person established in the territory of the European Union who is responsible for placing on the market, whether it be the manufacturer, the importer or the distributor.
3. Name and full address of the supplier(s) of control samples.
4. Description of how the product and the GMO as or in a product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted.
5. Description of the geographical area(s) and environmental type(s) in which the product is intended for use in the European Union, including, where appropriate, the 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 of 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.
8. Proposed labelling on a label or in an accompanying document. This information must include, at least in summarised form, a commercial name of the product, a statement that ‘This product contains genetically modified organisms’, the name of the GMO and the information referred to in point 2. The label should indicate how to access the information in the publicly accessible part of the register.

### B. In addition to the information referred to in point A, and in accordance with Article 6 of this Law, the following information shall be provided in the notification, if applicable:

1. the measures to be taken 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 and, if required, the competent authority, so that the competent authorities can be effectively informed of any adverse effect. These instructions should be consistent with Annex VI part C;
4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes;
5. proposed packaging;
6. estimated production in and/or imports to the European Union;
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.

# ANNEX V

# GUIDELINES FOR THE ASSESSMENT REPORTS

The assessment report provided for by Articles 6, 9, 11 and 12 should include in particular the following:

1. identification of the characteristics of the recipient organism which are relevant to the assessment of the GMO(s) in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism;
2. description of the result of the genetic modification in the modified organism;
3. assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment;
4. identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s), based on the environmental risk assessment carried out in accordance with Annex II;
5. A conclusion on whether the GMO(s) in question should be placed on the market as or in product(s) and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission shall be sought on specific issues of the environmental 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.

# ANNEX VI

# MONITORING PLAN

This Annex describes in general terms the objective to be achieved and the general principles to be followed to design the monitoring plan referred to in Articles 6(3), 11(2) and 12.

## A.   Objective

The objective of a monitoring plan is to:

* confirm that any assumptions made during the environmental risk assessment with regard to the occurrence and impact of potential adverse effects of the GMO or its use are correct, and
* identify the occurrence of adverse effects of the GMO or its use on human health or the environment that have not been anticipated in the environmental risk assessment.

## B.   General principles

The monitoring referred to in Articles 6, 11 and 12 shall take place after authorisation of the placing on the market of the GMO.

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 environmental 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(s) is expected to be released;
3. incorporate general monitoring for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the environmental risk assessment:
   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 environmental risk assessment;
   2. whereas monitoring could, if appropriate, make use of already established routine monitoring 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 monitoring practices will be made available to the authorisation 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; the plan must ensure that there is a route by which the authorisation 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 authorisation holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.