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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 457

Adopted 26 May 2009

Regulations Regarding Deliberate Release of Genetically Modified Organisms

[15 January 2013]

*Issued pursuant to
Section 5, Paragraph one, Clause 2 of the Law
On Circulation of Genetically Modified Organisms*

1. General Provisions

1. This Regulation prescribes:

1.1. the procedures for deliberate release of genetically modified organisms (hereinafter – release);

1.1.¹ the procedures for issuing, extending, amending and cancelling a permit, as well as for monitoring;

1.3. the procedures for providing information on circulation of genetically modified organisms;

1.3.¹ the procedures for restricting or prohibiting cultivation of genetically modified organisms;

1.4. public involvement in the decision-making process.

[15 January 2013; 10 February 2015; 27 October 2015]

2. This Regulation shall not apply to:

2.1. the contained use of genetically modified micro-organisms;

2.2. the placing on the market of genetically modified food and feed, to which Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed applies;

2.3. medicinal products which contain genetically modified organisms, consist of or are produced from them, the release of such medicinal products, except risk assessment for medicinal products in accordance with Paragraphs 16 and 17 of this Regulation;

2.4. carriage of genetically modified organisms by road, railway, inland waterways, sea or air.

[15 January 2013]

3. Prior to the commencement of the release of genetically modified organisms not permitted in the European Union, a person shall perform a risk assessment in accordance with the laws and regulations regarding the methodology for the risk assessment of genetically modified organisms in order to specify the potential effect of the particular genetically modified organism on human and animal health, or the environment, in which deliberate release of the genetically modified organism is intended, and shall receive a written permit for the release of genetically modified organisms from the State scientific institute “Institute of Food Safety, Animal Health and Environment -“BIOR”” (hereinafter – the Institute).

[3 May 2011; 15 January 2013; 10 February 2015]

4. In order to receive a written permit for the release of genetically modified organisms, a person shall submit a submission to the Institute which has been drawn up in accordance with the requirements referred to in Chapter 7 of this Regulation, and in accordance with the laws and regulations regarding the price list of the activities carried out within the scope of State administration tasks of the Institute shall cover expenses which are related to the preparation of an opinion on risk assessment of the relevant genetically modified organism.

[10 February 2015 / See Paragraph 2 of amendments]

5. The Institute shall, not later than within three working days after receipt of the submission, verify the conformity thereof with Paragraph 54 of this Regulation and send it to the Scientific Expert Commission, as well as inform the public in accordance with the procedures laid down in Chapter 5 of this Regulation.

[10 February 2015]

6. If the submission does not conform to the requirements referred to in Paragraph 54 of this Regulation or, in accordance with the documents submitted, it is not possible to perform the risk assessment thoroughly, the Institute, with appropriate justification, may request the person to submit additional information or perform additional consultations, including with the public. The time period necessary for the provision of additional information or consultations shall not be included in the time period referred to in Paragraphs 9, 20, 27, and 39 of this Regulation.

[10 February 2015]

7. The Institute, upon consulting with the person, shall decide on granting of the status of restricted accessibility to particular information included in the submission on the basis of the Freedom of Information Law and shall not disclose this information to the third person.

[10 February 2015]

8. The following information shall not be considered as restricted access information:

8.1. the given name, surname, address of the person (for a legal person – the name and legal address);

8.2. the description of the genetically modified organism, which allows the identification thereof;

8.3. the purpose of the release of the genetically modified organism, the place and anticipated use thereof;

8.4. the monitoring programme and emergency action plan;

8.5. the environmental risk assessment of the genetically modified organism.

9. The Scientific Expert Commission shall, within 60 days after receipt of a submission, prepare and submit to the Institute an opinion on the risk evaluation of genetically modified

organisms and the monitoring programme (hereinafter – risk assessment opinion). A decision to issue a permit or to refuse to issue it is taken on the basis of the opinion.
[10 February 2015]

10. The Scientific Expert Commission shall, not later than within five working days, prepare a report on the opinions expressed and recommendations submitted by the public (hereinafter – report on the public opinion). The Institute, in order to survey the public opinion, may extend the deadline referred to in Paragraphs 20, 27 and 39 of this Regulation, by not longer than 30 days.
[10 February 2015]

11. The Institute shall, not later than within one working day after receipt of the risk assessment opinion and the report on the public opinion, send them to the Supervisory Council of Genetically Modified Organisms.
[10 February 2015]

12. The Supervisory Council of Genetically Modified Organisms shall, within 15 working days after receipt of the risk assessment opinion and report on the public opinion, submit a proposal of recommendatory nature to the Institute regarding the issuance of a permit for the release of the particular genetically modified organism.
[10 February 2015]

13. The Institute, taking into account the risk assessment opinion, the public opinions expressed, also the report on the public opinion and the proposals of the Supervisory Council of Genetically Modified Organisms, shall issue a written permit or a decision to refuse to issue a permit, indicating the grounds for refusal. If the relevant local government expresses substantiated arguments and does not support the release into the environment of genetically modified organisms for trials (hereinafter – release into the environment), the Institute shall issue a decision to refuse to issue a permit.
[3 May 2011; 15 January 2013; 10 February 2015]

14. If the purpose of the use of the genetically modified organism is changed, the person shall submit a new submission to the Institute.
[10 February 2015]

15. If, during review of the submission or after receipt of the permit, the person has obtained new information or if the genetically modified organisms or the components obtained therefrom have changed so that they may have harmful effects on human and animal health or the environment, the person shall:

15.1. take measures to protect human and animal health or the environment;

15.2. inform the Institute, the Food and Veterinary Service and the State Environmental Service regarding the changes in these genetically modified organisms or the components thereof;

15.3. review the measures indicated in the submission.

[10 February 2015]

16. Medicinal products which contain genetically modified organisms, or consist of or are produced from them, shall be used for clinical trials in accordance with the laws and regulations regarding the procedures for performing clinical trials on medicinal products and the procedures for assessing conformity with the requirements of good clinical practice.

17. The Institute shall, not later than within 90 days after receipt of a submission regarding the use of such medicinal products for a clinical trial, which contain genetically modified organisms or consist of or are produced from them, send the risk assessment opinion to the person who submitted the submission.

[10 February 2015]

2. Issuance of Permits for the Release into the Environment of Genetically Modified Organisms

18. *[15 January 2013]*

19. The Institute shall, not later than within 30 days after receipt of the submission, send the summary referred to in Sub-paragraph 54.6 of this Regulation to the European Commission.

[10 February 2015]

19.¹ If release into the environment of the same genetically modified organism or the same combination of genetically modified organisms is intended in different places, but with the same purpose and in a specific time period, a person may submit one submission to the Institute.

[15 January 2013; 10 February 2015]

20. The Institute shall, not later than within 90 days after receipt of the submission and evaluation of the proposals submitted by the competent authorities of other Member States, if any, take a decision in accordance with the procedures laid down in Paragraph 13 of this Regulation.

[10 February 2015]

21. The following shall be indicated in a permit:

21.1. the identity of the genetically modified organism to be released into the environment;

21.2. the conditions for the release into the environment of the genetically modified organism;

21.3. the monitoring requirements, including the performance deadlines of the monitoring programme.

22. The Institute shall submit to the European Commission a substantiated proposal on the application of different procedure for the issuance of a permit, if sufficient experience has been acquired on the release into the environment of the specific genetically modified organism and it conforms to the following criteria:

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

22.2. there is substantiated information that the release into the environment of the genetically non-modified organism (recipient), or, in the relevant cases, the parental organism in a specific ecosystem does not harm human and animal health or the environment;

22.3. information is available on interaction of particular relevance involving genetically non-modified organisms (recipients), or, in relevant cases, the parental organisms, in the particular ecosystem;

22.4. such methods are used for the anticipated way of release into the environment, which are similar to those methods of releasing into the environment of genetically modified organisms for which a permit has already been issued, and the results obtained do not attest that there are adverse effects on human and animal health or the environment;

22.5. complete information on the genetic structure of all vector systems and inserts, which may be used for the identification of genetically modified organisms and the progeny thereof, is available, as well as the amount of deletions is known, if the genetic modification is related to deletions of genetic material;

22.6. the genetically modified organism does not cause greater adverse effects on human and animal health or the environment, in comparison with the relevant non-modified (recipient) organism or, in the relevant cases, the parental organism. The ability to be released into the environment uncontrollably, to adopt other non-related ecosystems and transfer the genetic material to other organisms in the environment does not cause harm to human and animal health or the environment.

[15 January 2013]

23. After the decision of the European Commission to apply a different procedure, which has been taken in accordance with the legislation of the European Union on the procedures for exercising the powers conferred on the European Commission, the Institute shall, within three working days, issue a written permit or a substantiated reason for the refusal to issue a permit to the person.

[10 February 2015]

24. If the Institute receives information on the adverse effects caused by the genetically modified organism to be released into the environment on human and animal health or the environment, it shall act as follows after consultation with the Food and Veterinary Service or the State Environmental Service:

24.1. request the person to change the conditions for the release into the environment;

24.2. temporarily suspend or prohibit the release into the environment;

24.3. inform the public regarding the decision taken.

[10 February 2015]

3. Issuance of Permits for the Placing on the Market of Genetically Modified Organisms

25. A person who wishes to commence the placing on the market of such genetically modified organisms, for which a permit has not been issued in the European Union, shall include the following in the submission in addition to the information referred to in Paragraph 54 of this Regulation:

25.1. information in accordance with Chapter 8 of this Regulation. The person, on the basis of the results obtained during the period of time when the genetically modified organisms were released into the environment, or taking into account the scientifically substantiated information which certifies that the placing on the market and use of the genetically modified organisms does not pose a risk to human and animal health or the environment, has the right to request permission from the Institute not to include the information referred to in Paragraph 70 of this Regulation in the submission;

25.2. the conditions for the placing on the market of the genetically modified organism, including specific conditions for use and storage;

25.3. the anticipated period of validity of the permit;

25.4. a monitoring programme in accordance with Chapter 9 of this Regulation, including proposals regarding the time period for the implementation of the monitoring programme;

25.5. proposals for the labelling and packaging in accordance with the requirements referred to in Chapter 8 of this Regulation and Regulation (EC) No 1830/2003 of the European Parliament and of the Council on 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products from genetically modified organisms and amending Directive 2001/18/EC;

25.6. data or results on the release of the particular genetically modified organism or the same combination of genetically modified organisms, if it has been notified previously to any of the competent authorities of Member States or is notified at the specific time or if the person is deliberately releasing the particular genetically modified organism in any European Union Member State or outside it.

[15 January 2013]

26. If the submission contains all the information referred to in Paragraph 25 of this Regulation, the Institute shall, not later than within three working days, send the summary referred to in Sub-paragraph 54.6 of this Regulation to the European Commission and the competent authorities of other Member States.

[10 February 2015]

27. The Institute shall, not later than within 90 working days after receipt of the submission, send the risk assessment opinion to:

27.1. the person who submitted the submission;

27.2. the European Commission.

[10 February 2015]

28. The Institute, in addition to the information referred to in Paragraph 27 of this Regulation, shall send information to the European Commission, on the basis of which it is recommended to issue a permit for the placing on the market of the specific genetically modified organism, or information on the basis of which it is recommended not to issue a permit for the placing on the market of the specific genetically modified organism – not sooner than 15 days after sending of the risk assessment opinion to the person and not later than 105 days after receipt of the submission.

[10 February 2015]

29. The risk assessment opinion shall be applied to the anticipated use and the proposed monitoring programme of the genetically modified organism. The following shall be indicated in the risk assessment opinion:

29.1. the conditions in accordance with which the specific genetically modified organism may or may not be placed on the market. If it is indicated in the risk assessment opinion that the specific genetically modified organism may not be placed on the market, the Institute shall provide reasoned substantiation;

29.2. indications of the non-modified (recipient) organism which relate to the risk assessment of the specific genetically modified organism, as well as the potential adverse effects on human and animal health or the environment which may be caused by releasing the non-modified organism (recipient);

29.3. a description of the genetic modification of the genetically modified organism;

29.4. an assessment on whether the genetic modification has been described in sufficient amount in order to gather information on the potential adverse effects on human and animal health or the environment;

29.5. in accordance with the environmental risk assessment to identify new potential adverse effects on human and animal health or the environment, which may be caused by the placing on the market of the particular genetically modified organism. The potential adverse effects shall be determined by comparing the genetically modified organism with the corresponding non-modified organism;

29.6. the specific matters of the environmental risk assessment, on which the opinion of the European Commission and the competent authorities of other Member States is requested.

[15 January 2013]

30. If the person withdraws the submission after receipt of the risk assessment opinion, he or she may resubmit the submission to a competent authority of a different Member State.

31. If the Scientific Expert Commission has prepared a risk assessment opinion, indicating that the genetically modified organism may be placed on the market, and if, not later than within 60 days after sending of the risk assessment opinion, no reasoned objections have been received from the European Commission and from the competent authorities of other Member States, or if an agreement has been reached on the objections received within 105 days after sending of the risk assessment opinion, the Institute shall issue a written permit to the person for the placing on the market of the genetically modified organism.

[10 February 2015]

32. If the European Commission or any competent authority of a European Union Member State expresses and maintains objections in accordance with Paragraphs 31 and 36 of this Regulation, a decision shall be taken in accordance with the legislation of the European Union on the procedures for exercising the powers conferred on the European Commission.

33. If the European Commission takes a decision to issue a permit, the Institute shall, not later than within three working days after taking of this decision, issue a written permit to the person for the placing on the market of the genetically modified organism.

[10 February 2015]

34. A permit for the placing on the market of the genetically modified organism shall be issued for the time period which is indicated in the submission, but not longer than for 10 years.

35. The following shall be indicated in a permit:

35.1. the territory in which the permit is applicable, as well as the identity and unique identifier of the genetically modified organism to be placed on the market;

35.2. the term of validity of the permit;

35.3. the conditions for the placing on the market of the genetically modified organism, including the specific requirements for the use, processing and packaging of the genetically modified organism, as well as the specific conditions for the protection of the environment, ecosystem and geographical areas;

35.4. accessibility by the Institute to control samples, anticipating the observance of the relevant requirements for confidentiality;

35.5. the labelling requirements in accordance with Chapter 8 of this Regulation;

35.6. the monitoring requirements in accordance with Chapter 9 of this Regulation;

35.6.1. the deadlines for the implementation of the monitoring programme;

35.6.2. specific instructions (if necessary) for traders or users of genetically modified organisms and for growers of genetically modified crops;

35.6.3. if genetically modified crops are cultivated – other information which is necessary at the specific cultivation site.

[3 May 2011; 10 February 2015; 27 October 2015]

36. If the Institute has received information on the adverse effects on human and animal health or the environment, caused by the genetically modified organism to be placed on the market:

36.1. prior to the issuance of a written permit, it shall, not later than within three working days, send this information to the European Commission and to the competent authorities of other Member States. The Institute may consider unresolved issues with the

competent authorities of European Union Member States, in order to reach an agreement within 75 days prior to the issuance of a written permit;

36.2. after issuance of a written permit, it shall, not later than within 60 days, send a proposal to the European Commission on the change of permit conditions (if it is necessary). If substantiated objections have not been received within 60 days after sending of information or if an agreement has been reached regarding the objections expressed within 75 days after sending of information, the Institute shall take a decision on the change in permit conditions, notify them to the person and shall, within 30 working days after taking of the decision, inform the European Commission and the competent authorities of other Member States thereof.

[10 February 2015]

37. The person, upon commencement of the cultivation of genetically modified crops, after receipt of the written permit from the Institute, shall ensure the implementation of the requirements specified for the co-existence of genetically modified crops in accordance with the laws and regulations regarding ensuring co-existence of genetically modified crops.

[10 February 2015]

4. Extension of Permits for the Placing on the Market of Genetically Modified Organisms

38. In order to extend a permit for placing on the market of a genetically modified organism, a person shall submit a relevant submission to the Institute (if the original permit has been issued by the Institute) at least nine months prior to the expiry of the term of validity of the permit. The following shall be appended to the application:

38.1. the original permit or a copy thereof;

38.2. a report prepared in accordance with the submitted monitoring programme on the results of monitoring in the previous period of release;

38.3. any other latest information which is available and relates to the potential adverse effects of the genetically modified organisms on human and animal health or the environment;

38.4. the conditions for amending or supplementing of the original permit (if such are provided for), as well as the conditions that are related to the subsequent monitoring and the term of the permit.

[10 February 2015]

39. If the submission conforms to Paragraph 38 of this Regulation, the Institute shall, not later than within 90 days after receipt of the submission, send the risk assessment opinion to the person who submitted the submission and send the submission or a copy thereof and the risk assessment opinion to the European Commission, indicating that:

39.1. the placing on the market of the specific genetically modified organism may continue, and the conditions for the release;

39.2. the placing on the market of the respective genetically modified organism should be discontinued.

[10 February 2015]

40. If the Scientific Expert Commission has prepared a risk assessment opinion, indicating that the genetically modified organism may continue to be placed on the market, and if no reasoned objections have been received from the European Commission and from the competent authorities of other Member States not later than within 60 days after sending of the risk assessment opinion, or if agreement has been reached on the objections received within 75 days after sending of the risk assessment opinion, the Institute shall, not later than

within three working days, issue a written permit to the person for further placing on the market of the genetically modified organisms.

[10 February 2015]

41. If the European Commission or any competent authority of a European Union Member State expresses and maintains objections, a decision shall be taken in accordance with the legislation of the European Union on the procedures for exercising the powers conferred on the European Commission.

42. If the European Commission takes a decision to issue a permit, the Institute shall, not later than within three working days after taking of this decision, issue a written permit to the person for subsequent placing on the market of the genetically modified organisms.

[10 February 2015]

43. The extended permit for the placing on the market of the genetically modified organisms shall be issued for a time period of up to 10 years.

44. If the term of validity of the original permit has not expired, the person may continue to place the genetically modified organisms on the market until the receipt of the extended permit, in accordance with the conditions indicated in the original permit.

4.¹ Restriction or Prohibition of Cultivation of Genetically Modified Organisms

[27 October 2015]

44.¹ The Ministry of Agriculture shall, within 45 days after it has received an opinion on risk assessment by the competent authority of the European Union Member State or an opinion of the European Food Safety Authority in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council, notify the European Commission regarding the prohibition to cultivate the relevant genetically modified crop in Latvia or in a separate territory thereof.

44.² A person who has submitted a submission regarding cultivation of the relevant genetically modified crop shall, within 30 days after it has received information from the European Commission regarding prohibition to cultivate such crop, agree to the requirement regarding the prohibition to cultivate the genetically modified crop indicated in the submission or reject it.

44.³ If the person who has submitted a submission agrees to the requirement regarding the prohibition to cultivate the genetically modified crop indicated in the submission in the particular territory in accordance with Paragraph 44.¹ of this Regulation, it is indicated in the permit that it is prohibited to cultivate the relevant genetically modified crop in Latvia or in a separate territory thereof.

44.⁴ If the requirement referred to in Paragraph 44.¹ of this Regulation regarding prohibition to cultivate the relevant genetically modified crop in Latvia or in a separate territory thereof is notified to the European Commission after an opinion on risk assessment by the competent authority of the European Union Member State or an opinion of the European Food Safety Authority in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council is received, the time period indicated in Paragraphs 31 and 52 of this Regulation is extended by 15 days.

44.⁵ If the person who has submitted a submission rejects the requirement regarding the prohibition to cultivate the genetically modified crop indicated in the submission, the Ministry of Agriculture shall inform the European Commission regarding the planned restriction or prohibition to cultivate genetically modified crop or group of crops. Such information may be submitted to the European Commission prior to the issuance of the permit referred to in Paragraph 31 of this Regulation.

44.⁶ The Ministry of Agriculture shall, within 75 days after sending of the information referred to in Paragraph 44.⁵ of this Regulation to the European Commission, ensure that:

44.⁶ 1. a restriction or prohibition to cultivate the relevant genetically modified crop or group of crops is not accepted;

44.⁶ 2. cultivation of the relevant genetically modified crop or group of crops is not commenced. The Ministry of Agriculture shall inform the State Plant Protection Service regarding the planned restriction or prohibition.

44.⁷ A decision to restrict or prohibit cultivation of the relevant genetically modified crop or group of crops shall be taken after expiry of the time period referred to in Paragraph 44.⁶ of this Regulation. The decision may be taken from the day when the permit for the release of the relevant genetically modified crop or group of crops enters into effect, as well as throughout the term of validity of the permit.

44.⁸ The Ministry of Agriculture shall prepare and, according to specific procedures, submit to the Cabinet a draft order regarding restriction or prohibition to cultivate in Latvia genetically modified crop or group of crops previously permit in the European Union. The group of crops shall be determined according to the variety of crops or intrinsic properties thereof.

44.⁹ The Cabinet shall justify the decision to restrict or prohibit cultivation of the relevant genetically modified crop or group of crops with one or several reasons that are referred to in Section 5, Paragraph four, Clause 2 of the Law On Circulation of Genetically Modified Organisms. The criteria applied shall not be in contradiction with the opinion on risk assessment.

44.¹⁰ The Ministry of Agriculture shall inform the European Commission, the competent authorities of European Union Member States, and the person who submitted the submission regarding the decision taken in relation to restriction or prohibition to cultivate the relevant genetically modified crop or group of crops, as well as publish the decision on the website of the Ministry of Agriculture.

44.¹¹ In order to re-include Latvia or part of its territory in the territory of cultivation of genetically modified crop:

44.¹¹1. the Ministry of Agriculture shall submit a submission to the competent authority of the European Union Member State regarding inclusion of the relevant territory in the territory of cultivation of genetically modified organism;

44.¹¹2. the Cabinet shall revoke the decision to restrict or prohibit cultivation of genetically modified crop, and the Ministry of Agriculture shall inform the European Commission and the competent authorities of European Union Member States thereof without delay.

5. Public Involvement in the Decision Taking Process

45. The Institute shall post the following information on the website thereof in the State Information System – in the Register of Genetically Modified Organism Circulation (hereinafter – Register):

45.1. not later than within three working days after receipt of a submission:

45.1.1. the environmental risk assessment referred to in Sub-paragraph 54.5 of this Regulation;

45.1.2. the information referred to in Sub-paragraph 54.6 of this Regulation;

45.1.3. other documents submitted by a person, to which the status of restricted access has not been assigned;

45.2. not later than within three working days after receipt of a risk assessment opinion:

45.2.1. the risk assessment opinion;

45.2.2. the time period by which the public may express its opinion and provide proposals indicating the place of submission thereof;

45.3. not later than within three working days after taking of a decision:

45.3.1. the decision, including the conditions referred to in the permit, in accordance with Paragraphs 21 and 35 of this Regulation and the report on the public opinion;

45.3.2. the information on the locations for the release into the environment of genetically modified organisms;

45.3.3. the information on the locations for the cultivation of genetically modified crops;

45.4. not later than within three working days after receipt of the report – a report on the results of the release into the environment or market monitoring.

[3 May 2011; 15 January 2013; 10 February 2015]

46. Any person, within 30 days after insertion of the risk assessment opinion into the Register, may express his or her opinion and submit written proposals to the Institute on the release of the genetically modified organisms.

[15 January 2013]

46.¹ The relevant local government, within the territory of which release into the environment of genetically modified organisms is intended, shall, within 30 days after inserting of the risk assessment opinion in the Register, express the opinion thereof and submit written proposals to the Institute on the release into the environment of the genetically modified organism.

[3 May 2011; 10 February 2015]

47. If information is received regarding the adverse effects on human and animal health or the environment caused by the genetically modified organisms to be released or regarding a prohibited placing on the market of the genetically modified organisms, the Institute shall, within one day after receipt of information, inform the public by inserting information on the website of the Institute, publishing it in the official gazette *Latvijas Vēstnesis* [the official Gazette of the Government of Latvia] and in the newspaper of the relevant administrative area or populated area, on the website thereof, as well as by notifying on the television and radio.

[3 May 2011; 15 January 2013; 10 February 2015]

6. Duties and Rights of the Institute

[10 February 2015]

48. The Institute shall, within three working days after receipt of a submission regarding release of genetically modified organisms, inform thereof the Ministry of Agriculture, the Ministry of Environmental Protection and Regional Development, the Food and Veterinary Service, the State Plant Protection Service, the State Environmental Service and the local government, in the territory of which release of genetically modified organisms is intended.

[10 February 2015]

49. Once every three years the Institute shall prepare and submit to the European Commission a report on the measures that have been taken when implementing this Regulation. A short review on the experience acquired in working with the placing on the market of the genetically modified organism in accordance with this Regulation shall be included in the report.

[10 February 2015]

50. If there are threats to human and animal health or the environment, the Institute shall take a decision to prohibit the release into the environment for trials and placing on the market of the particular genetically modified organism or specify restrictions thereon and send the relevant information to the European Commission and the competent authorities of other Member States. Information regarding the decision taken shall include whether and how the conditions for release of the genetically modified organism into the environment for trials and placing on the market specified in the permit should be amended or that the release into the environment for trials and placing on the market of the particular genetically modified organism should be prohibited. The Institute shall additionally submit a reasoned opinion, indicating the latest scientific statements therein on which the decision taken is substantiated, and shall inform the public regarding taking of the decision.

[10 February 2015]

50.¹ If a request of the competent authority of the European Union Member State to include the European Union Member State or part of its territory in the territory of cultivation of genetically modified crop is received, the Institute shall update the permit accordingly and inform the European Commission, the competent authorities of European Union Member States, and the submitter of the submission.

[27 October 2015]

51. The Institute shall, within 30 days after receipt of the summary of the submission sent by the competent authority of another Member State on the release into the environment of the genetically modified organisms, prepare proposals or reasoned objections and submit them directly to the competent authority of the Member State or the European Commission. The Institute may request that the competent authority of the particular Member State sends the entire submission or a copy thereof, if it is necessary for the preparation of proposals or arguments.

[10 February 2015]

52. The Institute shall, within 60 days after receipt of a risk assessment opinion sent by the competent authority of another Member State on the placing on the market of the genetically modified organism, prepare proposals or reasoned objections and submit them directly to the competent authority of the Member State or to the European Commission. The Institute may request that the competent authority of the particular Member State sends the entire submission or a copy thereof, if it is necessary for the preparation of proposals or arguments.

[10 February 2015]

53. The Institute shall submit the following to the European Commission:

53.1. within 30 days after issuance of a permit – information on the decision taken on the release into the environment of the genetically modified organisms (if a permit has not been issued, a reasoned opinion shall be provided);

53.2. within 30 days after issuance of a permit – information on the decision taken on the placing on the market of the genetically modified organisms (if a permit has not been issued, a reasoned opinion shall be provided), as well as inform the competent authorities of other Member States thereof;

53.3. information on the monitoring results of the release of the genetically modified organisms;

53.4. once a year – a list of the issued and non-issued permits for the release into the environment of the genetically modified organisms in accordance with the different procedure referred to in Paragraph 22 of this Regulation;

53.5. not later than within three working days – information on the prohibited placing on the market of the genetically modified organisms, as well as inform the competent authorities of other Member States.

[15 January 2013]

7. Information to be Included in a Submission for the Release of Genetically Modified Organisms

[15 January 2013]

54. The following information shall be included in a submission for the release of genetically modified organisms:

54.1. the given name, surname, address of the person (for a legal person – the name and legal address);

54.2. the given name, surname, qualification and work experience of the responsible scientist;

54.3 the title of the submission;

54.4. information in accordance with Sub-chapter 7.1 or 7.2 of this Regulation;

54.5. the environmental risk assessment of the genetically modified organisms, carried out in accordance with the laws and regulations regarding the risk assessment methodology of the genetically modified organisms;

54.6. a summary of information in accordance with the requirements referred to in Annex 1 to this Regulation, if it is intended to release the genetically modified organism into the environment, or in accordance with the requirements referred to in Annex 2 to this Regulation, if it is intended to place the genetically modified organism on the market;

54.7. other information related to the specific genetically modified organism and which the person considers important, or reference to information previously published by other persons, if it is not restricted access information or the referred to person has given written consent to the use of the information.

[15 January 2013]

55. A person need not include all the information referred to in Sub-chapters 7.1 and 7.2 of this Regulation in the submission. The content of the submission shall be co-ordinated with the Institute, taking into account the specific character of each particular case.

[10 February 2015]

56. Sub-chapter 7.1 of this Regulation shall apply to the release of all types of genetically modified organisms, except genetically modified higher plants (hereinafter – higher plants).

[15 January 2013]

57. Sub-chapter 7.2 of this Regulation shall apply to the release of higher plants.

[15 January 2013]

58. Within the meaning of this Regulation higher plants are plants belonging to taxonomic groups of angiosperms (*Angiospermae*) and gymnosperms (*Gymnospermae*).

7.1. Information to be Included in a Submission for the Release of Genetically Modified Organisms (Except Higher Plants)

[15 January 2013]

59. Information on the genetically modified organism:

59.1. characteristics of the donor, the recipient or (where appropriate) the parental organism:

59.1.1. scientific name;

59.1.2. taxonomic status;

59.1.3. other names (for example, usual name, strain name);

59.1.4. phenotypic and genetic markers;

59.1.5. degree of relatedness between donor and recipient or degree of relatedness between parental organisms;

59.1.6. detection techniques;

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

59.1.8. description of the geographic distribution and the natural habitat (including information on natural predators, preys, parasites and competitors, symbionts and hosts);

59.1.9. organisms with which transfer of genetic material is known to occur in natural conditions;

59.1.10. genetic stability and factors affecting it;

59.1.11. pathological, ecological and physiological qualities:

59.1.11.1. classification of hazard;

59.1.11.2. generation time in natural ecosystems, sexual and asexual reproductive cycles;

59.1.11.3. information on survival, including seasonability and the ability to form survival structures in unfavourable environmental conditions, for example, seeds, spores, sclerotia;

59.1.11.4. pathogenicity; infectivity, toxicity, virulence, allergenicity, carrier (vector) of the pathogen, possible vectors, host range including non-target hosts. Possible activation of latent viruses (pro-viruses). Ability to colonise other organisms;

59.1.11.5. antibiotic resistance and potential use of these antibiotics in humans and domestic animals for prophylaxis and therapy;

59.1.11.6. involvement in environmental processes, for example, primary production, nutrient turnover, decomposition of organic matter, respiration;

59.1.12. nature of indigenous vectors;

59.1.12.1. sequence of nucleotides;

59.1.12.2. frequency of mobilisation;

59.1.12.3. specificity;

59.1.12.4. presence of antibiotics and other genes of resistance;

59.1.13. information on previous genetic modifications;

59.2. characteristics of the vector:

59.2.1. nature and source of the vector;

59.2.2. sequence of transposons, vectors and other non-coding genetic segments used to construct a new hereditary material in the relevant modified organism;

59.2.3. frequency of genetic mobilisation of the used vector or genetic transfer capabilities and methods for determination thereof;

59.2.4. information on the minimum part of the deoxyribonucleic acid (hereinafter – DNA) structure of the vector necessary for the intended function;

59.3. description;

59.3.1. description of the genetic modification:

59.3.1.1. methods used in the genetic modification;

59.3.1.2. methods used to construct and introduce the insert into the recipient or to cause the deletion of a sequence of DNA nucleotides;

59.3.1.3. description of the structure of the insert or vector;

59.3.1.4. the possibility of presence of unknown nucleotide sequences in the structure of the insert and information on the minimum part of the DNA structure of the vector necessary for the intended function;

59.3.1.5. methods and criteria used in selection;

59.3.1.6. nucleotide sequence, functional identity and location in a genome of the relevant altered, inserted or deleted nucleic acid segments, particularly in relation to any potential hazard of the modified organisms;

59.3.2. description of the genetically modified organism obtained:

59.3.2.1. description of genetic traits or phenotypic characteristics, particularly description of such new traits and characteristics which may be expressed in the modified organism or the expression of which is not possible;

59.3.2.2. structure and amount of any vector or donor nucleic acid remaining in the final structure of the genetically modified organism;

59.3.2.3. genetic stability of the organism;

59.3.2.4. intensity and level of expression of the new genetic material.

Method and sensitivity of the measurement;

59.3.2.5. activity of the expressed proteins (albuminoids);

59.3.2.6. description of the isolation and identification methods, including techniques for identification and isolation of the insert and the vector;

59.3.2.7. sensitivity, reliability (in quantitative terms) and specificity of the isolation and identification techniques;

59.3.2.8. information on the previous release or use of genetically modified organisms;

59.3.2.9 considerations related to health matters:

59.3.2.9.1. toxic and allergenic effects of the inactivated genetically modified organisms or their metabolic products;

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

59.3.2.9.3. capacity for colonisation;

59.3.2.10. if the organism is pathogenic to humans who are immunocompetent:

59.3.2.10.1. diseases caused and mechanism of pathogenicity thereof, including invasiveness and virulence;

59.3.2.10.2. communicability;

59.3.2.10.3. infective dose;

- 59.3.2.10.4. host range and possibility of alteration thereof;
- 59.3.2.10.5. possibility of survival outside of human host;
- 59.3.2.10.6. presence of carriers or means of uncontrolled dissemination;
- 59.3.2.10.7. biological stability;
- 59.3.2.10.8. antibiotic resistance patterns;
- 59.3.2.10.9. allergenicity;
- 59.3.2.10.10. availability of appropriate therapies;
- 59.3.2.11. other hazards related to the genetically modified organism.

60. Conditions and environment of the release of genetically modified organisms:

60.1. information on the release:

- 60.1.1. description of the intended release, the purposes thereof and the products to be obtained;
- 60.1.2. foreseen dates of the release and time planning for the release, including the frequency and duration of releases;
- 60.1.3. preparation of the site previous to the release;
- 60.1.4. size of the release site;
- 60.1.5. methods to be used for the release;
- 60.1.6. quantity of genetically modified organisms to be released;
- 60.1.7. the intended changes at the release site (type and method of cultivation, modification of the composition of the soil, irrigation or other activities);
- 60.1.8. worker protection measures to be taken during the release;
- 60.1.9. treatment of the intended release site after completion of activities with genetically modified organisms;
- 60.1.10. elimination of genetically modified organisms or discontinuation of activities to be performed with them after discontinuation of the release;
- 60.1.11. results of the previous release of genetically modified organisms and information on them, particularly information on their release at different scales and in different ecosystems;

60.2. information on the environment (both regarding the release site and the surroundings):

- 60.2.1. geographical location and grid reference of the release site (in the submission for placing on the market of genetically modified organisms the site of release shall be the foreseen area of the use of the product);
- 60.2.2. physical and biological proximity to humans, flora and fauna;
- 60.2.3. proximity to protected biotopes of European significance, specially protected natural territories or the nearest sites for extracting drinking water;
- 60.2.4. economic activity of inhabitants, which is based on the natural resources of the relevant region;
- 60.2.5. climatic characteristics of the region likely to be affected;
- 60.2.6. geographical, geological and soil characteristics;
- 60.2.7. flora and fauna, including crops, livestock and migratory species;
- 60.2.8. target and non-target ecosystems likely to be affected;
- 60.2.9. comparison of the natural habitat of hosts and the release site;
- 60.2.10. any known or planned development or changes in land use at the release site of genetically modified organisms, which could influence the environment of the release site.

[15 January 2013]

61. Interaction between the genetically modified organisms and the environment:
- 61.1. characteristics affecting the ability of genetically modified organisms to survive, propagate and disseminate freely:
 - 61.1.1. biological features which affect survival, propagation and dissemination of the genetically modified organisms;
 - 61.1.2. known or predicted environmental conditions, which may affect the survival, propagation and dissemination of the genetically modified organisms (for example, wind, water, soil, temperature, pH);
 - 61.1.3. sensitivity to specific factors of the impact;
 - 61.2. impact on the environment:
 - 61.2.1. predicted site of release of the genetically modified organisms;
 - 61.2.2. studies of the behaviour, characteristics of the genetically modified organisms and their ecological impact carried out in simulated natural environment, for example, in growth rooms, cultivation facilities, greenhouses;
 - 61.2.3. genetic transfer capability:
 - 61.2.3.1. delayed (post-release) transfer of genetic material from the genetically modified organism to other organisms of the relevant ecosystem;
 - 61.2.3.2. delayed (post-release) transfer of the genetic material from indigenous organisms to the genetically modified organism;
 - 61.2.4. likelihood that after release of the genetically modified organisms the natural selection might cause the expression of unexpected or undesirable traits in the genetically modified organism;
 - 61.2.5. measures employed to ensure and verify genetic stability. Description of such genetic traits, which may prevent or minimise dispersal of genetic material. Methods used to prove genetic stability;
 - 61.2.6. routes of biological dispersal, known or potential modes of interaction and factors facilitating the dispersal, including, for example, inhalation, ingestion, surface contact;
 - 61.2.7. description of ecosystems, in which the genetically modified organisms might disseminate;
 - 61.3. possible environmental impact of the genetically modified organisms:
 - 61.3.1. potential for excessive population increase;
 - 61.3.2. competitive advantages of the genetically modified organisms in relation to the unmodified recipients or parental organisms;
 - 61.3.3. identification and description of the target organisms;
 - 61.3.4. anticipated mechanism and result of interaction between the genetically modified organisms and the target organisms;
 - 61.3.5. identification and description of non-target organisms which may be inadvertently affected, and the mechanisms for the prevention of this impact;
 - 61.3.6. potential changes in biological interaction or in host range after release of the genetically modified organisms;
 - 61.3.7. known or predicted impact on other organisms in the environment, the impact on the level of competitor population – preys, hosts, symbionts, predators, parasites and pathogens;
 - 61.3.8. known or predicted involvement of the genetically modified organisms in biogeochemical processes;
 - 61.3.9. other potential significant impact of the genetically modified organisms on the environment.

[15 January 2013]

62. Information on monitoring, control, waste treatment plans and emergency action plans:
- 62.1. monitoring techniques:

- 62.1.1. methods for tracing the genetically modified organisms and for monitoring of their effects;
- 62.1.2. specificity, sensitivity and reliability of the monitoring techniques to identify the genetically modified organism and distinguish it from the donor, recipient or parental organisms;
- 62.1.3. techniques for detecting transfer of the modified genetic material to other organisms;
- 62.1.4. duration of monitoring and frequency of control measures;
- 62.2. emergency action plans:
 - 62.2.1. methods and procedures to avoid or minimise the dissemination of the genetically modified organisms beyond the release site thereof or the designated area of use;
 - 62.2.2. methods and procedures to restrict the release site of the genetically modified organisms and to prevent access by unauthorised persons;
 - 62.2.3. methods and procedures to prevent other undesirable organisms from entering the release site of the genetically modified organisms;
- 62.3. waste treatment:
 - 62.3.1. type of waste;
 - 62.3.2. expected amount of waste;
 - 62.3.3. potential risk factors;
 - 62.3.4. description of waste treatment envisaged;
- 62.4. action in emergency situations:
 - 62.4.1. methods and procedures to be used for control of the genetically modified organisms if uncontrolled dissemination thereof occurs;
 - 62.4.2. methods for re-cultivation and renewal of the areas utilised;
 - 62.4.3. methods for disposal or sanitation of plants, animals and soil that were exposed to the effect of the genetically modified organisms during or after release of the genetically modified organisms;
 - 62.4.4. methods for the isolation of the area where the uncontrolled dissemination of the genetically modified organisms has occurred;
 - 62.4.5. plan for protecting human health and the environment in case undesirable consequences occur during the release of the genetically modified organisms.

[15 January 2013]

7.2. Information to be Included in a Submission for the Release of Higher Plants

[15 January 2013]

- 63. Information relating to the recipient or (if necessary) parental plants:
 - 63.1. complete name – family, genus, species, sub-species, cultivar or breeding line and the common name;
 - 63.2. information concerning reproduction:
 - 63.2.1. mode of reproduction;
 - 63.2.2. special factors affecting reproduction (if any);
 - 63.2.3. generation time;
 - 63.2.4. sexual compatibility with other cultivated or wild plant species;
 - 63.3. survivability:
 - 63.3.1. ability to form structures for survival or dormancy;
 - 63.3.2. specific factors affecting survivability (if any);
 - 63.4. uncontrolled dissemination abilities:
 - 63.4.1. ways and extent of uncontrolled dissemination, for example, an estimation of how viable pollen or seeds declines with distance;

- 63.4.2. specific factors affecting uncontrolled dissemination (if any);
 - 63.5. geographic distribution of the plant;
 - 63.6. in the case of plant species not normally grown in the Member State where the release of the genetically modified organisms is intended, description of the natural habitat of the plant (including information on natural predators, parasites, competitors and symbionts);
 - 63.7. potential significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.
64. Information describing the genetic modification:
- 64.1. description of the methods used for the genetic modification;
 - 64.2. nature and source of the vector used;
 - 64.3. size, origin, taxonomic belonging (name) of donor organism, component of the genome to be transferred in the modification and the function thereof.
65. Information describing the genetically modified plant:
- 65.1. description of the traits which have been introduced or modified;
 - 65.2. information on the inserted or deleted nucleotide sequences:
 - 65.2.1. size and structure of the insertion or deletion, as well as the methods used in the modification, including information on the vector used in the formation of the genetically modified plant hybrids or on retention of the molecule parts of any other vector in the modified plant;
 - 65.2.2. in case of deletion – size and function of the deleted region;
 - 65.2.3. location of the insertion place in the plant cells (integrated in chromosomes, DNA of chloroplasts, mitochondria, or maintained in a non-integrated form), as well as methods for its determination;
 - 65.2.4. number of copies inserted;
 - 65.3. information on the expression of the inserted genetic information:
 - 65.3.1. information on the type of expression of the insert and methods used for its characterisation;
 - 65.3.2. parts of the plant where the insert is expressed (for example, roots, stem, pollen);
 - 65.4. difference of the plant from the recipient plant in:
 - 65.4.1. mode or rate of reproduction;
 - 65.4.2. ability of uncontrolled dissemination;
 - 65.4.3. survivability;
 - 65.5. genetic stability of the insert and phenotypic stability of the plant;
 - 65.6. possibility of transfer of the genetic material from the plant to other organisms;
 - 65.7. information on any toxic, allergenic or other harmful effects on human and animal health or the environment, if it occurs during the process of genetic modification;
 - 65.8. information on the safety of the plants to animal health, particularly regarding toxic, allergenic or other harmful effects arising from the genetic modification, where the plant is intended to be used in animal feedstuffs;
 - 65.9. if possible, characteristics of the mechanism of interaction between the plant and target organism;
 - 65.10. potential interaction with the abiotic environment;
 - 65.11. potential interaction with different biotic environmental factors;
 - 65.12. description of detection and identification techniques for the plants;
 - 65.13. information on similar experience of release of the plants (if any).
66. Information on the site of release of plants (only in relation to the release into the environment of genetically modified organisms):

- 66.1. location and size of the release site;
 - 66.2. description of the release site ecosystem, including description of climate, flora and fauna;
 - 66.3. presence of such related wild plants or cultivated plant species that are sexually compatible with the particular genetically modified organism;
 - 66.4. proximity to the protected biotopes of European significance and specially protected natural territories.
67. Information relating to the release of plants (only in relation to the release into the environment of genetically modified organisms):
- 67.1. purpose of the release;
 - 67.2. foreseen start time for release (month, quarter);
 - 67.3. methods for the release of genetically modified plants;
 - 67.4. methods for preparing and managing the release site prior to, during and after the release of genetically modified organisms, including cultivation practices and harvesting methods;
 - 67.5. approximate number of plants (or number of plants per square metre).
68. Information on monitoring, control measures after release and waste treatment:
- 68.1. precautionary measures:
 - 68.1.1. determination of distance to the biotope where related species of the specific plant can be found;
 - 68.1.2. any measures to minimise or prevent dispersal of the pollen or seeds of plants;
 - 68.2. description of post-treatment methods of the plant release site;
 - 68.3. description of methods (after the release thereof) to be used for treatment of the plant material (including waste);
 - 68.4. monitoring programme and description;
 - 68.5. description of emergency plans;
 - 68.6. measures and methods to protect the release site.

[15 January 2013]

8. Additional Information to be Included on the Labelling of Genetically Modified Organisms and in the Submission for Placing on the Market of Genetically Modified Organisms

69. In addition to the information referred to in Sub-Chapters 7.1 and 7.2 of this Regulation the following shall be indicated in the submission for placing on the market of genetically modified organisms:
- 69.1. commercial name of the product which consists of, contains or is obtained from a genetically modified organism, and names of the genetically modified organisms in the composition of the referred to product, any specific designations, names or codes used by a person to identify the genetically modified organism;
 - 69.2. the given name, surname, address of the person registered in the European Union (for a legal person – name and legal address) who is responsible for the placing on the market (regardless of whether it be the manufacturer, the importer or the distributor);
 - 69.3. the given name, surname and address of the supplier of control samples (for a legal person – name and legal address);
 - 69.4. description of use of the genetically modified organism, in which the differences between the genetically modified organism and the relevant genetically non-modified organism in use shall be highlighted;

69.5. geographical area or types environment where the genetically modified organism is intended to be used, also including, where possible, information on the estimated scale of use;

69.6. intended type of use, for example, industry, agriculture, skilled trades or unlimited placing in retail trade;

69.7. information on the genetic modification which can be used for the detection of the specific genetically modified organism. This information shall indicate, where appropriate, the competent authority, to which samples of the genetically modified organism or its genetic material and details of nucleotide sequences, or other type of information which is necessary to identify the genetically modified organism and its progeny, for example, the methodology for identifying the genetically modified organisms, including data on the release into the environment demonstrating the specificity of the methodology, has been submitted. It shall be indicated which is restricted access information and should not be placed in the Register;

69.8. proposed labelling of the genetically modified organisms on the label or in an accompanying document. It shall be indicated on the labelling how to access the information in the publicly accessible part of the Register. The labelling shall include the following information, at least in the form of a summary:

69.8.1. commercial name of the product which consists of, contains or is obtained from the genetically modified organism;

69.8.2. a statement “This product contains a genetically modified organism”;

69.8.3. the name of the genetically modified organism;

69.8.4. the information referred to in Sub-paragraph 69.2 of this Regulation.

70. In addition to the information referred to in Paragraph 69 of this Regulation, in accordance with Sub-paragraph 25.1 of this Regulation, the following shall be indicated:

70.1. protection measures in case of uncontrolled or accidental release of genetically modified organisms;

70.2. specific instructions or recommendations for storage of genetically modified organisms and other activities involving them;

70.3. specific instructions on monitoring and reporting in accordance with a monitoring programme;

70.4. proposed restrictions in the permit for the use of genetically modified organisms, for example, in relation the territory and purposes of the use of the genetically modified organism;

70.5. proposed type of packaging. The packaging shall be such as to prevent accidental spread of genetically modified organisms during storage and release thereof;

70.6. estimated amount of production or import in the European Union;

70.7. proposed additional labelling requirements. The information referred to in Sub-paragraphs 69.4, 69.5, 70.1, 70.2, 70.3 and 70.4 of this Regulation shall be included in summarised form.

[15 January 2013; 27 October 2015]

9. Development and Monitoring of the Monitoring Programme for the Placing on the Market of Genetically Modified Organisms

71. A person shall develop a monitoring programme for the placing on the market of genetically modified organisms for each individual case, taking into account the environmental risk assessment, the modified characteristics of the relevant genetically modified organism, the intended use and receiving environment thereof.

72. An environmental risk assessment of genetically modified organisms shall be performed prior to the commencement of monitoring for an efficient and general monitoring programme in accordance with the laws and regulations regarding the methodology for risk assessment of genetically modified organisms.

73. The objectives of a monitoring programme shall be:

73.1. to confirm that the environmental risk assessment concerning the potential adverse effects of genetically modified organisms or their use, is correct;

73.2. to identify the adverse effects of the genetically modified organisms not specified in the environmental risk assessment or their use on human and animal health or the environment.

74. The main principles for the development of a monitoring programme shall be as follows:

74.1. monitoring shall be performed after receipt of a permit for the placing on the market of genetically modified organisms;

74.2. the interpretation of the data collected by monitoring shall be considered in the light of other environmental conditions and activities. Where changes in the environment are observed, further environmental risk assessment shall be considered to establish whether:

74.2.1. they are a consequence of the use of genetically modified organisms;

74.2.2. they are other environmental factors, which have not been initiated by the placing on the market of genetically modified organisms;

74.3. upon developing a monitoring programme, information and data shall be used which has been obtained by performing monitoring of the release of genetically modified organisms into the environment.

75. A monitoring programme shall have the following main sections:

75.1. strategy;

75.2. methodology;

75.3. analysis, report, revision.

76. Upon developing a monitoring programme:

76.1. each case shall be evaluated separately, taking into account the environmental risk assessment;

76.2. the characteristics of the genetically modified organism, the characteristics and scale of the intended use and the specific environmental conditions where the genetically modified organisms are intended to be deliberately released, shall be taken into account;

76.3. general monitoring shall be incorporated and, if necessary, case-specific monitoring focusing on determination of the adverse effects identified in the environmental risk assessment, taking into account that:

76.3.1. case-specific monitoring shall be carried out for a sufficient time period to detect immediate and direct effects and, where appropriate, delayed and indirect effects, which have been identified in accordance with the environmental risk assessment;

76.3.2. when implementing general monitoring, where appropriate, existing monitoring programmes shall be used, for example, biological diversity, soil quality, plant pest and disease monitoring programmes;

76.4. observation, in a systematic manner, of genetically modified organisms in the ecosystem and the interpretation of these observations with respect to safety to human and animal health or the environment shall be planned;

76.5. the person responsible for the performance of the tasks specified in the monitoring programme, for the development and implementation of the monitoring programme shall be determined, as well as it shall be ensured that the persons and the Institute

are informed on the observed adverse effects on human and animal health or the environment. Time and intervals for reports on the monitoring results shall be indicated;

76.6. mechanisms for the identification and confirmation of any observed adverse effects and an opportunity for a person or the Institute to take measures in order to protect human and animal health or the environment shall be intended.

[3 May 2011; 15 January 2013; 10 February 2015]

77. In specific cases, case-specific monitoring shall be included in a monitoring programme, with the help of which the potential effects of the placing on the market of genetically modified organisms shall be identified, which have been identified in accordance with the environmental risk assessment.

78. General monitoring shall also be included in the monitoring programme, with the help of which the unforeseeable or accidental adverse effects of genetically modified organisms shall be determined. Specific effects shall be anticipated on the basis of the environmental risk assessment and the scientific information available. The potential effects shall be identified in good time, planning general monitoring accordingly.

79. Taking into account the instructions referred to in this Chapter, the cost-efficiency of case-specific monitoring and general monitoring shall be evaluated. The monitoring programme shall be developed on the basis of the latest scientific reports and practices.

80. When interpreting the results of monitoring, the existing environmental conditions and activities performed for the determination of the base line, shall be taken into account. General and environmental monitoring programmes may be used similarly. If unforeseen changes are observed in the environment, the option for further risk assessments shall be considered in order to determine whether the changes established are the consequences of the placing on the market of genetically modified organisms or other factors. In this regard, protection measures for human and animal health or the environment shall also be considered.

9.1. Monitoring Strategy

81. It is important to determine in the monitoring strategy the potential effects which may occur during the placing on the market of the genetically modified organism, the level up to which it should be monitored and an appropriate method and monitoring time period.

82. The probability that the genetically modified organism will cause direct, indirect, immediate or delayed adverse effects shall be considered in the monitoring strategy, taking into account the intended use and the receiving environment thereof.

83. It shall be determined in the monitoring strategy how the potential adverse effects identified in the environmental risk assessment according to the use and the receiving environment of the genetically modified organism shall be confirmed. For this purpose, the conclusions and assumptions made in the environmental risk assessment shall be taken into account on the basis of the scientific assessment and the opinion of the Scientific Expert Commission. Moreover, matters arising during the process of the environmental risk assessment and unclear matters, for example, the potential effects of genetically modified organisms which may occur only upon releasing genetically modified organisms in large quantities, shall also be included in the monitoring strategy.

84. Any general information relating to the particular genetically modified organism, including data and information obtained during the release into the environment of the

genetically modified organism, as well as information from scientific publications and appropriate comparable evidence obtained during another release of the genetically modified organisms may be used in the development of the monitoring programme. Data obtained from available risk assessments and monitoring of the release into the environment shall be particularly useful.

85. The monitoring method:

85.1. shall describe the method of the monitoring strategy, paying particular attention to the main potential risks and the establishment of a cyclic monitoring process in order to continuously improve the quality of the monitoring programme;

85.2. shall ensure the means for detection of the potential adverse effects of the genetically modified organism at early stage of expression. Any timely detection of adverse effects related to the genetically modified organism allows more rapid reassessment and implementation of measures in order to minimise any consequences in the environment.

86. The development of a monitoring programme for genetically modified organisms shall take place gradually, taking into account the existing data, monitoring methodology, as well as the extent of the release of the genetically modified organisms. The results obtained during deliberate release of the genetically modified organism shall be evaluated in the first phase. In developing a monitoring programme for the placing on the market of genetically modified organisms, the information obtained when performing the monitoring of the release into the environment of the genetically modified organisms shall be used.

[15 January 2013]

87. The existing observation programmes may also be adapted for the needs of monitoring of genetically modified organisms in order to ensure comparability and to reduce expenditure for resources related to designing the method. It shall apply to the existing environmental monitoring programmes in agriculture and preservation of biological diversity, to long-term ecological monitoring programmes, to soil observation and veterinary studies. A person shall agree with the specific competent authorities on the adaption of such existing programmes to the monitoring programme.

88. Paragraph 84 of this Regulation shall apply to case-specific monitoring and general monitoring according to the objectives specified in this Chapter, but also allow the application of other types of monitoring.

89. In the case-specific monitoring method:

89.1. the potential adverse effects on human and animal health or the environment identified in the environmental risk assessment shall be analysed, taking into account the different locations, soil types and climatic conditions of the genetically modified organisms;

89.2. a precise period of time, during which results are obtained, shall be determined.

90. The first phase of case-specific monitoring shall be the determination of the objectives of the monitoring strategy. The assumptions which have been laid out in the environmental risk assessment on the potential adverse effects of the genetically modified organisms or their use shall also be determined, and in specific cases they shall be confirmed by case-specific monitoring. If the non-existence of a risk or an insignificant risk has been identified in the conclusions of the environmental risk assessment, case-specific monitoring shall not be necessary.

91. The potential adverse effects identified in the environmental risk assessment shall be included in the monitoring programme, taking into account that the assumptions relating to these effects may be confirmed or rejected as a result of monitoring.

92. If cultivation of genetically modified crops is anticipated, monitoring in relation to the transfer of pollen and the resistance of the genetically modified crop shall be evaluated. The level of the likelihood of such occurrence shall also depend on the extent of the use of the genetically modified crop and the receiving environment, including the proximity and scale of genetically non-modified related crops and related wild species.

[3 May 2011]

93. The potential environmental risk resulting from genetically modified organisms, which are approved for import and recycling only, may be assessed and completely contained, if the genetically modified organisms are not released into the environment and if they do not have the tendency to disseminate.

94. The potential effect on human and animal health and the environment resulting from the release of genetically modified organisms shall depend on the traits of the genetically modified organism and its specific genetic modifications, for example, the potential effect caused by the transfer of pollen from genetically modified crops to genetically non-modified crops or related wild plants depends, for the most part, on whether the genetically modified crops cross or self-pollinate. The presence of related wild plants shall also be considered.

[15 January 2013]

95. Any further effects, for example, the potential development of resistance against *Bacillus thuringiensis* (hereinafter – Bt) toxin for insects, is related only to the genetically modified organisms, which have been modified for excretion of this specific toxin. It is different with the genetically modified organisms which have been modified only for resistance against herbicides because these genetically modified organisms do not contain the gene of Bt toxin.

96. It shall also be important to supervise the potential transfer of genes of resistance against antibiotics and the possible consequences which might be caused by the genetically modified organisms containing the antibiotic resistance gene as a transformation marker.

97. After determination of the objectives, on the basis of the potential adverse effects, the parameters shall be identified for achievement of these objectives. The parameters and the methods for measuring and assessment thereof should be valid and adequate for this purpose.

98. The basis for general monitoring shall be periodic observation, and it shall be used in order to identify the unforeseen adverse effects or use of the genetically modified organisms, which has not been indicated in the environmental risk assessment but is harmful to human and animal health or the environment. It shall include observation of phenotypic characteristics and also allow for more detailed analyses.

99. In general monitoring:

99.1. any indirect, delayed and cumulative adverse effects shall be identified and registered, which have not been mentioned in the risk assessment;

99.2. a longer period of time and as large area as possible shall be used.

100. The type of general monitoring (including location, area and any measurable parameters) shall depend, for the most part, on which unforeseen adverse effects are being studied, for example, in order to supervise such unforeseen adverse effects on the cultivated ecosystem as

changes in biological diversity and the cumulative effect of multiple releases and interaction in the environment, a different general monitoring method may be required than in order to supervise the effects of the transfer of other genes.

101. Traditional periodic monitoring practices may be used in general monitoring, for example, agricultural crop or plant protection monitoring, monitoring of medicinal products, and ecological monitoring, environmental observation and biological diversity retention programmes. The monitoring programme may also include information on how the particular information was acquired, which the third persons have collected during the traditional periodic monitoring, or how the information referred to has become available to the person.

102. If traditional periodic monitoring is used in general monitoring, both such practice and changes, which are necessary thereto in order to perform the relevant general monitoring, shall be described.

103. The determination of the baseline condition of the receiving environment shall be a prerequisite for the identification and evaluation of the changes observed during monitoring. The baseline is a reference point with which any effect caused by placing on the market of genetically modified organisms may be compared. Therefore, the baseline shall be determined prior to any attempt to detect and supervise any effect. Monitoring of parallel areas of genetically modified organisms and such comparable areas, in which there are no genetically modified organisms, may be alternative, and it may have significance if the environment is particularly dynamic.

104. Information based on the systems for adequate observation of the environment regarding condition of the receiving environment may be necessary before fulfilment of the measures for introduction of the monitoring programme and the environmental policy. Programmes shall be provided for in the environmental observation plan for taking into account proved, credible and possible relationship of ecosystems, and they may be useful in order to determine:

104.1. the environmental condition and changes therein;

104.2. reasons for changes;

104.3. the anticipated environmental development.

105. Indicators of the condition of the receiving environment may include animals, plants and micro-organisms from different groups of organisms and ecosystems. The relevant indicators may be assessed on the basis of the characteristics and the parameters of the relevant genetically modified organism to be controlled. Sexual compatibility of other organisms with genetically modified organisms may also have significance. The relevant indicator species shall have several possible parameters of measurement or variables of suitability, including similarity of growth rate, number, biomass, reproduction ability, increase or decrease rate of population and genetic diversity.

106. It is useful to evaluate the baselines in relation to changes in management practice, which result from the use of the genetically modified organism. They may include changes in the use of pesticides in cultivation of such crop species that are genetically modified for tolerance against herbicides and resistance against insects. In considering a monitoring programme for crops which have been genetically modified for tolerance against herbicides, the use of herbicides in genetically non-modified crops may be evaluated, which is accepted as a component of the relevant baseline.

107. Monitoring shall be carried out in such period of time, which is sufficiently long in order to detect, where necessary, not only the potential immediate effects, but also delayed effects that have been identified in the environmental risk assessment. Coherence between the anticipated level of the risk and the duration of release shall also be considered. A longer period of release may increase the risk of cumulative effects. If immediate effects are not expressed during a longer period, monitoring may be concentrated on delayed and indirect effects, also evaluating whether the monitoring programme is applied to a period of time which is after the co-ordinated period of time. It may occur, for example, if the genetically modified organism is specifically sustainable in the environment.

108. The anticipated time period of the monitoring programme, including the potential frequency of control and the interval of review of the monitoring programme, shall be indicated. The possibility of expression of any such effects as set out in the environmental risk assessment shall be taken into account, for example, any adverse effects caused by the release of the genetically modified organisms, reproduction and sustainability or survivability thereof in the environment after placing thereof on the market shall be evaluated. For genetically modified microbes which are deliberately released in accordance with biological treatment programmes, this period may be days or months, but for some crop species it may be several years. The possibility of dissemination and sustainability of modification sequences themselves shall be considered also in relation to crossing with related plants.

[15 January 2013]

109. Control planning shall mainly depend on the type of effects to be supervised, for example, the effects caused by the transfer of pollen is only expressed after flowering, therefore, it is practical to investigate the territory prior to flowering in order to evaluate the proportion of related plants. Similarly occurrence of volunteer plants in subsequent growing seasons shall be supervised only in relation to the time period of dissemination of seeds and sustainability and germination of subsequent seed banks.

110. Prior visits shall also be necessary prior to the commencement of monitoring in order to determine relevant baselines.

111. A term shall be specified for the time periods of the monitoring programme, they shall be revised and amended in accordance with the results obtained during implementation of the monitoring programme.

112. A person shall submit the monitoring programme to the Institute in accordance with Sub-paragraph 25.4 of this Regulation. Suitability of the submitted monitoring programme shall be one of the criteria, according to which any submission for placing on the market of genetically modified organisms is considered. The monitoring programme shall be evaluated on the basis of whether it is adequate in relation to the implementation of the requirements specified in this Regulation.

[10 February 2015]

113. *[3 May 2011]*

114. The duties in relation to case-specific monitoring and to general monitoring shall be determined in the monitoring programme. The abovementioned monitoring shall be components of the monitoring programme. A person shall be responsible for the implementation of monitoring, however, involvement of the third persons – consultants and growers – in monitoring, shall be allowed in order to perform different tasks specified in the monitoring programme. The competent authorities of the European Commission and other

Member States may be involved in general monitoring. When employing the third persons or entering into a contract with them for the performance of monitoring, a plan for involvement of these persons shall be explained in detail in the monitoring programme.

115. The Institute may perform additional monitoring. Additional monitoring may be case-specific monitoring or general monitoring. The purpose of such monitoring shall be to provide the risk manager with an opportunity to take relevant measures without delay, if undesirable or unidentified effects occur in accordance with the environmental risk assessment performed. However, additional monitoring cannot replace monitoring for which the person is responsible.

[10 February 2015]

116. It shall be possible to expand the existing monitoring or general monitoring programmes, applying them to the possible adverse effects resulting from the placing on the market of genetically modified organisms. These programmes shall include agricultural, food, biological diversity, long-term ecological monitoring programmes, as well as environmental observation monitoring and veterinary surveillance monitoring programmes, for example, in a seed cultivation monitoring programme, in which the certification rules of the Organisation for Economic Co-operation and Development (hereinafter – OECD) are observed and, therefore, periodic supervision and control of rural and surrounding areas is included, the parameters indicated may be adapted for monitoring on the field.

117. In the sale of genetically modified seeds it shall be possible to introduce an additional service in which the merchant or hired consultants perform at least one of the types of general monitoring. Instructions which relate to monitoring and notification may be distributed to growers who buy genetically modified seeds, and conditions of sale or use may be defined in the contract regulations.

118. Instructions shall be developed so that growers and agricultural consultants might study the main unforeseen changes or effects, for example, the dissemination and introduction of volunteer plants which grow in adjacent areas. In such conditions it shall be anticipated that monitoring of adverse effects may be included in periodic practice and that it is used in order to determine the means for plant protection used in agriculture for restricting pests, plant pathogens and weeds.

9.2. Monitoring Methodology

119. On the basis of the environmental risk assessment for each case separately, the parameters and elements to be controlled shall be identified, taking into account changes performed in the genetically modified organism. The suitability of monitoring for the anticipated effects on target organisms shall also be evaluated, for example, monitoring of populations of corn borers in relation to the cultivated Bt corn varieties.

120. Elements which are not specific may also be considered as a component of the monitoring programme, for example:

120.1. effects on organisms, which are not target organisms and have resulted from a modification, including development of resistance in related wild organisms or pest organisms, changes in range of host organisms or distribution of pest organisms and viruses, as well as development of new viruses;

120.2. distribution, dissemination and resistance in the environment or ecosystems, which is not the target environment or ecosystems;

120.3. frequency, method and intensity of crossing with sexually compatible, related wild organisms in natural populations;

120.4. unexpected changes in basic behaviour of organism, for example, changes in reproduction, number of progeny, growing and survivability of seeds;

120.5. changes in biological diversity, for example, number or composition of species.

121. Information on the place and scale of area where monitoring will take place may be included in the monitoring programme. It may be indicated separately by Member States, geographical areas, territories, land parcels or, if necessary, other areas.

122. The areas and samples to be controlled shall be identified (including areas and samples intended for recording or control) in relation to the potential effects resulting from the placing on the market of genetically modified organisms. Any areas and samples intended for recording or control shall be sufficiently typical of the environment and conditions of use in order to derive important conclusions, moreover, the methodology for sample taking shall be scientifically and statistically justified. Significant information on changes of indicators may be obtained from data justified in such a way, and thus the possibility to detect the effects increases.

123. In areas to be controlled (for example, in relation to genetically modified crop species), in determining habitats selected for monitoring, traits of such species (typical and modified), as well as reproduction and dissemination thereof, and types of ecosystems, which may be affected, may be considered. Significant areas of monitoring shall include the selected agricultural areas where crops are grown for commercial purposes and the surrounding habitats.

124. Monitoring shall also be applied to adjacent or neighbouring cultivated and non-cultivated areas, as well as areas where volunteer plants are monitored after harvesting, and specially protected natural territories. Some types of habitats, for example, areas having disorders, and plant communities rich in species may be more susceptible to invasion than others. Areas, in which there are disorders, with low vegetation and profusion of plants and grasses, shall be particularly suitable for monitoring because they are widely distributed, are often found close to more intensively cultivated agricultural areas, are typical of roadsides, ditches and field sides where accidental seed losses and distribution occur more frequently at the beginning.

125. Monitoring shall also be considered in relation to the possibility if transfer of the genetic material to related biological and genetically non-modified crops takes place. Therefore, it shall be evaluated to what extent these crops are cultivated in adjacent or neighbouring areas.

126. The anticipated frequency of control and surveillance shall be indicated in the monitoring programme. It may include a schedule, in which the time and number of intended visits to the territory is indicated. Taking into account Paragraphs 107, 108, 109, 110, 111, 123, 124 and 125 of this Regulation, it shall be evaluated at which time the potential adverse effects are expressed more and which areas should be monitored.

127. It shall be necessary to explain and identify monitoring of the parameters and elements referred to in Paragraph 119 of this Regulation, including taking and analysis of samples. If standard methodology specified by the standards of the European Committee for Standardisation and the OECD methods for the monitoring of genetically modified organisms in the environment is applicable, they shall be observed and the source of the methodology shall be indicated. The methods to be used in monitoring shall be scientifically justified and

valid for the release of genetically modified organisms in conditions in which they are used, therefore, the characteristics of the methods, such as selectivity, specificity, repeatability, any restrictions, sensitivity, as well as access of the specific control samples, shall be evaluated.

[15 January 2013]

128. It shall be indicated in the monitoring programme, in what way the methodology is updated in accordance with the selected monitoring method or strategy.

129. In developing an appropriate methodology for sample taking and analysis, statistical analysis may also be used in order to specify optimal dimensions of samples and the shortest time periods of monitoring for detection of the relevant effects with the necessary statistical accuracy.

130. It shall be indicated in the monitoring programme in relation to case-specific monitoring and general monitoring, how, who and how often data is collected and processed. It shall be particularly important if the third persons are employed or hired for the collection of data. A person, upon collecting and registering data, shall rest upon a previously specified action and standard documents in order to ensure continuity (for example, shall use standardised registration forms or ensure direct registration of data in standardised spreadsheets). A person shall also explain how the data is processed, how information is received from the third persons, for example, from consultants or growers.

9.3. Analysis, Notification and Review

131. Time periods and intervals for the notification of the results of monitoring, as well as the frequency of data review and performance of general analysis thereof shall be indicated in the monitoring programme.

132. In evaluation of the monitoring result data, if necessary, a statistical analysis with relevant values of standard deviation shall be included so that justified subsequent decisions could be taken, including decisions on whether the conclusions explained in the risk assessment are correct. The accuracy of the assessment shall mainly be determined by how correct the baselines and control samples are, which relate to the receiving environment. Statistical analysis shall also provide information on whether the specific methodology, including sample taking and analysis, is appropriate.

133. In evaluating the results of monitoring and research, it may be determined whether it is necessary to supervise other parameters indicated in the monitoring programme. The previous conclusions shall also be checked (particularly if there is evidence of potential unfavourable effects on susceptible habitats and organism groups).

134. Data collected throughout the monitoring shall be interpreted pursuant to other existing environmental conditions and measures. If changes are observed in the environment, subsequent assessment shall be necessary in order to determine whether these are the consequences of genetically modified organisms or use thereof or such changes have been caused by such environmental factors, which are not the placing on the market of genetically modified organisms. Baselines, which are used in this aspect for comparison, shall be re-assessed.

135. The structure of the monitoring programme shall be such that results of case-specific monitoring, general monitoring and additional research may be unequivocally used, taking a decision on the renewal of a permit for the placing on the market.

136. A person shall ensure implementation of the monitoring programme in accordance with the conditions specified in the permit for the placing on the market of genetically modified organisms and, taking into account the intervals specified in the permit, submit a report on the results of monitoring of placing on the market of genetically modified organisms to the Institute, the European Commission and competent authorities of other Member States, in accordance with the conditions referred to in the permit in compliance with Annexes 2.¹ and 2.² to this Regulation.

[3 May 2011; 10 February 2015]

136.¹ A person shall reflect the information compiled in the report referred to in Paragraph 136 of this Regulation, using diagrams, pictures and tables and, if necessary, provide also statistical data. If it is not possible to specify the information requested in the relevant permit or monitoring programme, a detailed substantiation shall be provided.

[3 May 2011]

137. It shall also be indicated in the monitoring programme how the appropriate information, gathered during the specific period or during periodic monitoring, shall be ensured to a person and the competent authorities of other Member States.

138. A person shall ensure the transparency of the results and shall determine in the monitoring programme how the information collected shall be submitted or published. It may be performed, for example:

138.1. by information sheets provided for growers and other concerned persons;

138.2. by seminars, in which information is presented and exchanged with the concerned persons;

138.3. by archived documents of internal use of a merchant;

138.4. by placing information on the Internet websites of a merchant;

138.5. by publishing information in sectoral and scientific publications.

139. The person shall review the information and conditions specified in the submission.

140. A monitoring programme shall not be considered as statistics. It shall be essential to revise the monitoring plan and methodology related thereto after appropriate intervals and, if necessary, update and adjust it.

141. The Institute, on the basis of the monitoring report submitted by a person, is permitted to adjust the monitoring programme after the first monitoring period. The person shall be responsible for the revised monitoring programme.

[10 February 2015]

142. The Institute, upon reviewing the monitoring programme, shall check the efficiency and quality of data collection, the taking of measurements and sample taking and analysis. In revising the monitoring programme, the efficiency of monitoring criteria in relation to assessments shall also be assessed, as well as any issues resulting from risk assessment shall also be evaluated.

[10 February 2015]

143. If specific models are used for forecasting, evaluation based on the collected data may be performed and a later calculation may be carried out. If necessary, upgrades and development of sample taking and analysis shall be taken into account.

144. After such revision, correction of methods, relevant adaptation or improvement of monitoring objectives and monitoring programme shall be necessary.

10. Drawing Up of Reports on the Results of Monitoring the Release into the Environment of Genetically Modified Organisms

145. In accordance with the conditions specified in the permit for the release into the environment of genetically modified organisms, a person, in observance of the intervals specified in the permit, which are based on the environmental risk assessment, shall submit a report to the Institute (if possible, by using electronic mail) on the results of monitoring the release into the environment of genetically modified organisms (hereinafter – report) in accordance with the sample specified in Annex 3 to this Regulation.

[10 February 2015]

146. The sample report shall only apply to one permit for release which is identified according to the submission number.

147. A person shall submit a final report and, if necessary, a final report of post-release monitoring, as well as an intermediary report of post-release monitoring. Reports shall be prepared in accordance with the sample report.

148. The final report shall be submitted after the last harvesting of the genetically modified crops. Additional reports shall not be required, if post-release monitoring is not provided for in the submission.

149. The final report of post-release monitoring shall be submitted upon completion of post-release monitoring. If necessary, the Institute shall indicate in the permit the duration of the post-release monitoring, as well as the schedule for the submission of intermediary reports of post-release monitoring.

[10 February 2015]

150. The Institute may request additional information from a person which confirms the results of the release into the environment of genetically modified organisms, for example, a register or intermediary reports which should be submitted during the release into the environment of the genetically modified organisms.

[10 February 2015]

151. The person shall reflect the information compiled in the report referred to in Paragraph 145 of this Regulation, using diagrams, pictures and tables, and, if necessary, provide also statistical data. If it is not possible to specify the information requested in the relevant permit or monitoring programme, a detailed substantiation shall be provided.

[3 May 2011]

152. If the release into the environment of genetically modified organisms has taken place in several sites, several times and has been perennial, a person shall provide a general overview on measures implemented and consequences observed throughout the period of co-ordination.

Informative Reference to European Union Directives

[27 October 2015]

This Regulation contains legal norms arising from:

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

2) Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

Prime Minister – Minister for Children,
Family and Integration Matters

V. Dombrovskis

Acting for the Minister for Agriculture –
Minister for Environment

R. Vējonis

Information Summary On the Release into the Environment of Genetically Modified Organisms

PART 1 Genetically Modified Organisms which are not Higher Plants

A. General Information

1. More detailed information on the submission

a) the Member State in which the submission is submitted
b) the number of the submission
c) the date of confirmation of the submission
d) the title of the submission
e) the anticipated period of release

2. Person

Name of the authority or company

3. Characteristics of the genetically modified organism

a) indicate whether the genetically modified organism is: viroid [] ribonucleic acid (hereinafter – RNA) virus [] deoxyribonucleic acid (hereinafter – DNA) virus [] bacteria [] fungus [] animal [] • mammal [] • insect [] • fish [] • another animal [] specify species, class other, specify (state, species and class)
b) the taxonomic identity (genus and species) of the genetically modified organism
c) the genetic stability indicated in Sub-paragraph 59.1.10 of this Regulation ¹

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4. Is the same person planning to release the same genetically modified organism elsewhere in the European Union?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, indicate the state code (codes)	

5. Has the same person informed of the release of the same genetically modified organism elsewhere in the European Union?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, indicate: <ul style="list-style-type: none">• the submission Member State• the submission number	

6. Has the same person informed of the release of the same genetically modified organism outside the European Union?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, indicate: <ul style="list-style-type: none">• the submission Member State• the submission number	

7. Summary on the potential effects of the release into the environment of the genetically modified organism

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B. Information Relating to the Recipient or Parental Organisms, from which Genetically Modified Organisms are Obtained

8. Nature of the recipient or parental organism

Indicate whether the recipient or parental organism is: viroid [] RNA virus [] DNA virus [] bacteria [] fungus [] animal [] <ul style="list-style-type: none">• mammal []• insect []• fish []• another animal [] (specify species, class) others, specify
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9. Name

a) order and higher unit (in relation to animals)
b) genus
c) species
d) subspecies
e) line or strain
f) pathotype (biotype, ecotype, race etc.)
g) common name

10. Geographical release of the organism

a) organisms indigenously or otherwise introduced into the State in which the report is compiled: yes [] no [] not known []

b) indigenous organisms or organisms, which have otherwise dispersed in other European Union States: 1) yes [] If yes, indicate the type of ecosystem in which it can be found: the Atlantic Ocean [] the Mediterranean Sea [] the boreal ecosystem [] the Alps [] the continent [] Macronesia [] 2) no [] 3) not known []
c) is it often used in the state in which the submission is being drawn up? yes [] no []
d) is it often stored in the state in which the submission is being drawn up? yes [] no []

11. Natural biotope of the organism

a) if the organism is a micro-organism: in water [] living freely in soil []
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in soil in relation to plant root systems [] in relation to plant leaf or stem systems [] in relation to animals [] others, specify
b) if the organism is an animal – natural biotype or common agro-ecosystem

12.a) Detection methods

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12.b) Identification methods

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13. Is the recipient organism classified in accordance with the legal acts of the European Union on human and animal health or environmental protection?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, specify	

14. Is a living or non-living recipient organism (including its extracellular products) noticeably a pathogen or harmful in any other way?

Present []	Not present []	Not known []
If yes, specify: a) which of the organisms: for humans [] for animals [] for plants [] for others []		
b) provide the appropriate information indicated in Sub-paragraph 59.1.11.4 of this Regulation ¹		

15. Information on reproduction

a) lifespan in natural ecosystems
b) lifespan in an ecosystem where release will take place
c) mode of reproduction: sexual reproduction [] non-sexual reproduction []
d) factors affecting reproduction

16. Survivability

a) ability to form structures which aid survivability or dormancy:

- 1) endospores []
- 2) cysts []
- 3) sclerotia []
- 4) asexual spores (fungi) []
- 5) sexual spores (fungi) []
- 6) eggs []
- 7) chrysalis []
- 8) larvae []
- 9) others, specify

b) significant factors affecting survivability

17.a) Modes of uncontrolled dissemination

17.b) Factors affecting uncontrolled dissemination

18. Previous genetic modifications of the recipient or parental organism, the release of which has already been notified to the state in which the submission is being draw up (indicate the submission number)

C. Information Relating to the Genetic Modification

19. Type of the genetic modification

- a) genetic material insertion []
- b) genetic material deletion []
- c) nucleotide substitution []
- d) cell fusion []
- e) other, specify

20. Anticipated result of the genetic modification

24. Composition of the insert

a) composition of the insert
b) source of each part forming the insert
c) the intended function of each part forming the insert in the genetically modified organism
d) the location of the insert in the host: <ul style="list-style-type: none">• on a free plasmid []• integrated in a chromosome []• others, specify
e) does the insert contain parts the product or function of which is not known? yes [] no [] If yes, specify

D. Information on the Organism from which the Insert is Obtained

25. Indicate whether it is

viroid [] RNA virus [] DNA virus [] bacteria [] fungus [] animal [] <ul style="list-style-type: none">• mammal []• insect []• fish []• another animal [] specify species, class others, specify

26. Complete name

a) order and higher unit (in relation to animals)
b) name of family (in relation to plants)
c) genus
d) species
e) sub-species
f) line or strain

g) cultivar or breeding line
h) pathotype (biotype, ecotype, race etc)
i) common name

27. Is a living or non-living organism (including its extracellular products) noticeably a pathogen or harmful in any other way?

Yes []	No []	Not known []
If yes, specify:		
a) which of the organisms:		
for humans []		
for animals []		
for plants []		
for others []		
b) is the nucleotide sequence of the donor related in any way to the pathogenic or harmful qualities of the organism?		
yes [] no [] not known []		
If yes, provide the appropriate information indicated in Sub-paragraph 59.1.11.4 of this Regulation ¹		

28. Is the donor organism classified in accordance with the laws and regulations regarding labour protection requirements when coming into contact with biological substances?

[] Yes	[] No
If yes, specify	

29. Does the donor and recipient organism exchange with genetic material by natural methods?

[] Yes	[] No	Not known []
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E. Information Relating to the Genetically Modified Organism

30. Genetic features and phenotypes of the recipient or parental organism, which have changed as a result of the genetic modification

a) does the genetically modified organism differ from the recipient according to survivability?
yes [] no [] not known []
Specify
b) does the genetically modified organism differ in any way from the recipient according to mode and rate of reproduction?

yes [] no [] not known []
Specify
c) does the genetically modified organism differ in any way from the recipient according to uncontrolled options for dissemination?
yes [] no [] not known []
Specify
d) does the genetically modified organism differ in any way from the recipient according to pathogenicity?
yes [] no [] not known []
Specify

31. Genetic stability of the genetically modified organism

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32. Is a living or non-living genetically modified organism (including its extracellular products) noticeably a pathogen or harmful in any other way?

Yes []	No []	Not known []
If yes, specify:		
a) which of the organisms:		
for humans []		
for animals []		
for plants []		
for others []		
b) provide the appropriate information indicated in Sub-paragraph 59.1.11.4. of this Regulation ¹		

33. Description of identification and detection methods

a) techniques used for detection of genetically modified organisms in the environment
b) techniques used for identification of genetically modified organisms in the environment

F. Information Relating to the Release

34. Purpose of release (including any expected significant potential effects on the environment)

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35. Does the release site differ from the natural biogeocenosis or ecosystem in which the recipient or parental organism is regularly used, stored or detected?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, specify	

36. Information on the release and the surrounding territory

a) geographical location (administrative region, if necessary, the co-ordinates)
b) scale of the site (m ²): 1) actual site of release (m ²) 2) wider site of release (m ²)
c) distance to the protected biotopes of European significance or specially protected natural territories (including sites for taking drinking water), which might be affected
d) flora and fauna, including crops, agricultural animals and migrating species, which may possibly interact with the genetically modified organisms

37. Method and scale of release

a) the number of the genetically modified organisms to be released
b) duration of activities
c) methods and procedures with which the release of the genetically modified organisms outside the site of release are delayed and minimised

38. Short description of general environmental conditions (weather, temperature etc.)

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Data acquired during the previous release of the same genetically modified organism (if any), particularly – data related to the potential effects on human and animal health or the environment caused by the release

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G. Interaction of Genetically Modified Organisms with the Environment and the Potential Effects on the Environment, if It Differs Significantly from the Recipient or Parental Organism

40. Name of the target organism (if necessary)

a) order and higher unit (in relation to animals)
b) name of family (in relation to plants)
c) genus
d) species
e) sub-species
f) line or strain
g) cultivar or breeding line
h) pathotype (biotype, ecotype, race etc)
i) common name

41. Anticipated mechanism and result of the interaction of the released genetically modified organisms and the target organism (if necessary)

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42. Any other potentially significant interaction in the environment with other organisms

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43. Is selection possible after release, for example, higher competitiveness or wider spread of the genetically modified organism?

Yes []	No []	Not known []
If yes, provide more detailed information		

44. Types of ecosystems to which the genetically modified organisms might disseminate from the release site and in which they might stay fixed

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45. Full name of the non-target organism which could indirectly significantly adversely affect the release of the genetically modified organisms (observing the nature of the receiving environment)

a) order and higher unit (in relation to animals)
b) name of family (in relation to plants)
c) genus
d) species
e) sub-species
f) line or strain
g) cultivar or breeding line
h) pathotype (biotype, ecotype, race etc)
i) common name

46. Probability of the exchange of genetic material *in vivo*

a) release from the genetically modified organisms to other organisms in the ecosystem
b) from other organisms to the genetically modified organisms
c) potential consequences of the gene transfer

47. Reference to the behaviour and nature of the genetically modified organisms, as well as the results of the research of ecological impact (if any), obtained in a simulated natural environment (for example, microcosms)

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48. Potential interaction of significance to the environment with biogeochemical processes (if different from the recipient or parental organism)

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H. Information Related to Monitoring

49. Methods for monitoring of the genetically modified organisms

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50. Methods for monitoring of ecosystem impact

51. Methods for detection of the transfer of the genetic material (from genetically modified organisms to other organisms)

52. Scale of monitoring area (m²)

53. Duration of monitoring

54. Frequency of monitoring

I. Information on the Post-release of the Genetically Modified Organisms and Waste Treatment

55. Treatment of the site after release

56. Post-release treatment of the genetically modified organisms

57.a) Type and amount of waste obtained

57.b) Waste treatment

J. Information on Emergency Plans

58. Methods and procedures for the control of the unforeseen uncontrolled dissemination of the genetically modified organisms

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59. Methods for elimination of the genetically modified organisms in potentially affected areas

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60. Methods for elimination of the plants, animals, soil and other environmental components or sanitary methods, which may be subjected to the effects during or after release

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61. Plans for the protection of human and animal health upon the occurrence of unfavourable consequences

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PART 2 Genetically Modified Organisms which are Higher Plants

A. General Information

1. More detailed information on the submission

a) the number of the submission
b) the date of confirmation of the submission
c) the title of the submission
d) the offered period of release

2. Person

Name of the authority or company

3. Is the same person planning the release of the same genetically modified plant in accordance with the Regulation¹ elsewhere in the European Union or outside the European Union?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, indicate the state code (codes)	

4. Has the same person informed of the release of the same genetically modified plant elsewhere in the European Union or outside the European Union?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, indicate the number of the notification	

B. Information on the Genetically Modified Plant

5. Identity of the recipient or parental plant

a) family
b) genus
c) species
d) sub-species (if necessary)
e) cultivar and breeding line (if necessary)
f) common name

6. Description of the inserted or modified traits and characteristics (including marker genes and previous modifications)

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7. Type of the genetic modification

a) genetic material insertion
b) genetic material deletion
c) nucleotide substitution
d) cell fusion
e) other, specify

8. If insertion of the genetic material has taken place, please indicate the source of the insertion region and the function intended for each part in the composition

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9. If deletion or other modification of the genetic material has occurred, provide information on the function of the excluded or modified nucleotide sequences

10. Short description of the methods used in the genetic modification

11. If the recipient or parental plant is any of the forest tree species, indicate the modes and area of uncontrolled dissemination, as well as special factors affecting the dissemination

C. Information Relating to the Release into the Environment

12. Purpose of the release (including any appropriate information available in this phase), for example, agronomic objectives, hybridisation inspection, changed survivability or uncontrolled dissemination, inspection of effects on the target organisms or non-target organisms

13. Geographical location of the release site

14. Scale of the site (m²)

15. Data acquired during the previous release of the same genetically modified organism (if any), particularly – data related to the potential effects on human and animal health or the environment caused by the release

D. Summary on the Potential Effects of the Release into the Environment of the Genetically Modified Plants

In particular note whether the characteristics indicated might directly or indirectly provide a greater selective benefit to natural environments, as well as explain the anticipated positive impact on the environment

E. Short Description of the Measures Taken by a Person in Order to Control Threats (Including Isolation Created for Limiting Dispersion), for Example, Proposals for Monitoring and Monitoring Performed After Harvesting of Crops

F. Summary of the Planned Field Trials for Release into the Environment which (in a Specific Case) will be Installed in Order to Obtain New Data on the Effects of the Release on Human and Animal Health or the Environment

Signature² _____

Date² _____

Place for a seal²

Notes.

¹ Cabinet Regulation No. 457 of 26 May 2009, *Regulations Regarding Deliberate Release of Genetically Modified Organisms*.

² The details “signature”, “date” and “place for a seal” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding the drawing up of electronic documents.

Acting for the Minister for Agriculture –
Minister for the Environment

R. Vējonis

Information Summary on the Placing on the Market of Genetically Modified Organisms

PART 1 **Genetically Modified Organisms which are not Higher Plants**

A. General Information

1. More detailed information on the submission

a) the Member State in which the submission is submitted
b) the number of the submission
c) name of the product (commercial name and other names)
d) the date of acknowledgement of the receipt of the submission

2. Person

a) the given name, surname or name of the person
b) address of the person
c) the person is: local producer [] importer []
d) if import takes place: 1) the given name, surname or name of the producer 2) address of the producer

3. Characteristics of the genetically modified organism in the composition of the product

Name and nature of the genetically modified organism in the composition of the product: [] genetically modified crops for use in food [] food which consists of genetically modified crops or contains genetically modified crops [] food obtained from genetically modified crops or containing components which have been obtained from genetically modified crops [] genetically modified crops for use in animal food [] animal food which consists of genetically modified crops or contains genetically modified crops [] animal food obtained from genetically modified crops or containing components which

have been obtained from genetically modified crops <input type="checkbox"/> import and processing (placing on the market) <input type="checkbox"/> seeds and plant reproduction material for cultivation in the European Union (placing on the market)
--

4. General description of the product

a) type of the product
b) composition of the product
c) specificity of the product
d) types of users
e) any special conditions of use and handling to be regarded as the conditions of the permit applied
f) if necessary, the geographical regions of the European Union in which restriction of the placing on the market of the product is intended in accordance with the conditions of the permit applied
g) environmental types for which the product is not appropriate
h) the estimated potential annual demand: 1) in the European Union 2) in export markets for the goods of the European Union
i) unique identification code of the genetically modified organism

5. Has the same person submitted a submission in relation to the specific genetically modified organism, which the product contains, for the receipt of a permit for the release into the environment of the genetically modified organism?

Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, indicate the state and the number of the submission	
If not, provide a reference to risk analysis data which are based on the principles for the release into the environment of the genetically modified organisms	

6. Has the same person concurrently submitted a submission in relation to the specific genetically modified organism to another European Union Member State?

Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, specify	

7. Has another person placed on the market of the European Union another product with the same combination of genetically modified organisms?

Yes []	No []	Not known []
If yes, specify		

8. Summary of the results obtained during the previous or current release of the same combination of genetically modified organisms which was or is performed in a different ecosystem

9. Storage and processing instructions and recommendations, including any mandatory restrictions which should be considered as the conditions of the permit issued

10. Anticipated packaging

11. Any anticipated labelling requirements (additional to the general labelling requirements laid down in laws and regulations)

12. Measures which the person recommends in the event of unintentional release or misuse

13. Measures for waste disposal and treatment (if applicable)

B. Characteristics of the Genetically Modified Organism in the Composition of the Product

B.1. Information Relating to the Genetically Non-modified Organism (Recipient) or Parental Organism, from which the Genetically Modified Organism is Derived

14. Scientific name and common name

15. Phenotypic and genetic traits

16. Geographical distribution and natural habitat

17. Genetic stability and factors affecting it

18. Potential for genetic transfer and exchange with other organisms and the likely consequences of the gene transfer

19. Information on reproduction and factors affecting it

20. Information on survivability and factors affecting it

21. Ways of uncontrolled dissemination and factors affecting it

22. Interaction with the environment

23.a) Detection methods

23.b) Identification methods

24. Classification in accordance with the laws and regulations of the European Union relating to human and animal health or environmental protection

--

25.a) Pathogenic characteristics

--

25.b) Other harmful characteristics of the organisms living or dead, including extracellular products thereof

--

26. Characteristics and description of the known extrachromosomal genetic elements

--

27. Summary of the known history of previous genetic modifications

--

B.2. Information on the Genetic Modification

28. Methods used for the genetic modification

--

29. Characteristics of the vector

a) structure and source of the vector
b) description of the vector structure
c) genetic map and restriction map of the vector
d) data on nucleotide sequence
e) information on the degree, to which the vector contains sequence, the product or function area of which is not known
f) genetic transfer capabilities of the vector
g) frequency of mobilisation of the vector
h) part of vector, which remains in the genetically modified organism

30. Information on the insert

a) methods used to construct the insert
b) restriction sites
c) sequence of the insert
d) origin and function of each constituent part of the insert in the genetically modified organism
e) information on the degree, to which the insert is limited to the required function
f) location of the insert in the genetically modified organism

B.3. Information on Organisms (Donors) from which the Insert is Obtained

31. Scientific name and other names

--

32. Does the donor organism have pathogenic or harmful traits?

Yes []	No []
If yes, indicate the nature of the traits	

33. If the donor organism has any pathogenic or harmful traits, indicate whether the donated sequences are in any way involved in them

--

34. Classification in accordance with the laws and regulations of the European Union relating to human and animal health or environmental protection

--

35. State whether natural exchange of the genetic material between the donor organism and the recipient organism is possible or has been observed?

--

B.4. Information on the Genetically Modified Organism

36. Description of the genetic traits or phenotypic characteristics, if different from that of the recipient organism or the parental organism

--

37. Genetic stability of the genetically modified organism, if different from that of the recipient organism or the parental organism

38. Rate and level of expression of the new genetic material

39. Activity of synthesised proteins

40.a) Description of the methods used for detection of the genetically modified organisms, if they differ from the methods used for detection of the recipient organisms or parental organisms

40.b) Description of identification techniques used for differentiation of the genetically modified organism from the recipient organism and the parental organism

41. Health considerations

a) toxic or allergenic effects of the genetically modified organism and the metabolic products thereof, if they are significantly different from the toxic or allergenic effects of the recipient or parental organism and the metabolic products thereof

b) product hazards, if significant

c) comparison of the genetically modified organism with the donor, recipient or parental organism according to pathogenicity, if significantly different
--

d) capacity for colonisation, if significantly different from the recipient or parental organism
--

e) if the organism is more pathogenic than the recipient or parental organism in relation to humans, which do not suffer from immunodeficiency, provide the information indicated in Sub-paragraph 59.3.2.10 of this Regulation ¹
--

B.5. Interaction between the Genetically Modified Organisms and the Environment

42. Survival, reproduction and uncontrolled dissemination of the genetically modified organisms in the environment, if different from the survival, reproduction and dissemination into the environment of the recipient or parental organism

43. Environmental impact of the genetically modified organism, if different from the environmental impact of the recipient or parental organism

C. Predicted Behaviour of the Genetically Modified Organism, if Different from the Recipient or Parental Organism

C.1. Impact of the Genetically Modified Organism on the Environment

C.2. Effects of the Genetically Modified Organism on Human or Animal Health, if Different from the Effects of the Recipient or Parental Organism

D. Information on Previous Releases

D.1. History of Such Previous Release (if any), Regarding which a Submission has been Submitted in Accordance with Part 2 of the Regulation¹

44. Number of the submission

45. Release site

46. Purpose of the release

47. Duration of the release

48. Duration of post-release monitoring

49. Purpose of post-release monitoring

50. Conclusions on post-release monitoring results

51. Results of the release relating to any risk to human and animal health or the environment in accordance with Paragraph 145 of the Regulation¹

D.2. History of the Previous Release Occurring in the European Union or Outside the European Union

52. Release country

53. Authority overseeing the release

54. Release site

55. Purpose of the release

56. Duration of post-release monitoring

57. Purpose of post-release monitoring

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58. Conclusions on post-release monitoring

--

59. Results on release relating to any risk to human and animal health or the environment

--

D.3. History of Previous Activities Related to the Risk Assessment Prior to Placing on the Market

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E. Information Relating to the Monitoring Programme, Including Identified Traits, Characteristics and Uncertainties Relating to the Genetically Modified Organism or Interaction Thereof with the Environment that Should be Addressed in the Post-commercialisation Monitoring Programme

--

**PART 2
Genetically Modified Organisms which are Higher Plants**

A. General Information

1. More detailed information on the submission

a) the Member State of submission
b) the number of the submission
c) name of the product (commercial name and other names)
d) the date of acknowledgement of the receipt of the submission

2. Person

a) the given name, surname or name of the person
b) address of the person
c) the person is:

local producer [] importer []
d) if import takes place: 1) the given name, surname or name of the producer 2) address of the producer

3. General description of the product

a) name of the recipient and parental plant and the intended function of the genetic modification
b) method (seeds, cut flowers, vegetative parts etc.) by which the product may not be placed on the market in accordance with the conditions of the permit
c) anticipated use of the product and types thereof
d) any specific instructions and recommendations for use, storage, handling and processing, including mandatory restrictions to be regarded as the conditions of the issued permit
e) if necessary, the geographical regions of the European Union in which restriction of the placing on the market of the product is intended in accordance with the conditions of the permit applied
f) environmental types for which the product is not appropriate
g) any proposed packaging requirements
h) any anticipated labelling requirements (additional to the general labelling requirements specified in laws and regulations)
i) estimated potential demand 1) in the European Union 2) in export markets for the goods of the European Union
j) unique identification code of the genetically modified organism

4. Has a submission regarding the genetically modified higher plant referred to in the composition of the product been submitted for the receipt of the permit for the release into the environment of the genetically modified organisms?

Yes []	No []
If not, provide a reference to risk analysis data which are based on the principles for the release into the environment of the genetically modified organisms	

5.a) Has a submission regarding the product been concurrently submitted in another European Union Member State?

Yes []	No []
If not, provide a reference to risk analysis data which are based on the principles for the	

release into the environment of the genetically modified organisms

5.b) Has a submission regarding the product been submitted in a third country either concurrently or previously?

Yes []	No []
If yes, specify	

6. Has the same genetically modified higher plant been previously notified for marketing in the European Union?

Yes []	No []
If yes, indicate the notification number and Member State	

7. Measures recommended by the person if unintentional release or misuse has occurred, as well as measures for elimination and processing

--

B. Characteristics of the Genetically Modified Higher Plants in the Composition of the Product

B.1. Information Relating to the Genetically Non-modified (Recipient) Organism or (Respectively) the Parental Organism

8. Complete name

a) family name
b) genus
c) species
d) subspecies
e) cultivar or breeding line
f) common name

9.a) Information concerning reproduction

1) reproduction method
2) specific factors affecting reproduction, if any
3) generation length

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9.b) Sexual compatibility with other cultivated or wild plant species

--

10. Survivability

a) ability to form structures for survival or dormancy
b) specific factors affecting survivability (if any)

11. Uncontrolled dissemination

a) modes and scale of uncontrolled dissemination
b) specific factors affecting uncontrolled dissemination (if any)

12. Geographical distribution of the plant

--

13. In the case of plant species not normally grown in the European Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

--

14. Potential significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms

--

15. Phenotypic and genetic traits

--

B.2. Information Relating to the Genetic Modification

16. Description of the methods used for the genetic modification

--

17. Structure and source of the vector

--

18. Name, size, source of donor organism and intended function of each constituent fragment of the region for insertion

--

B.3. Information on the Genetically Modified Higher Plant

19. Description of the newly developed or modified characteristics

--

20. Information on actual nucleotide sequence insertions, deletions or modifications

a) sizes and structure of the insert, methods used for characterisation thereof, including information on any parts of the vector introduced in the genetically modified higher plant or any carrier or foreign DNA remaining in the genetically modified higher plant
b) if the deletion has been performed – the size and function of the deleted segment
c) location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion or maintained in a non-integrated form) and methods for detection thereof
d) number of copies and genetic stability of the insert
e) in case of modifications other than insertion or deletion, describe the 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

21. Information on the expression of the insert

a) information on the expression of the insert and methods used for characterisation thereof
b) parts of the plant where the insert is expressed (for example, roots, stem, pollen)

22. Information on how the genetically modified higher plant differs from the recipient plant, according to the following criteria

a) mode and rate of reproduction
b) the ability of uncontrolled dissemination
c) survivability

d) other differences

23. Potential for the transfer of the genetic material from the genetically modified higher plant to other organisms

24. Information on any adverse effects on human and animal health and the environment, arising from the genetic modification

25. Information on the safety of the genetically modified higher plant to animal health, where the genetically modified higher plant is intended to be used in animal feedstuffs, if different from that of the recipient or parental plant organism

26. Mechanism of interaction between the genetically modified higher plant and target organisms (if applicable), if different from that of the recipient or parental organism

27. Potential significant interactions with non-target organisms, if different from that of the recipient or parental organism

28. Description of detection and identification techniques for the genetically modified higher plant, to distinguish from the recipient or parental organism

B.4. Information on the Potential Effects of the Release of the Genetically Modified Higher Plants on the Environment

29. Potential environmental impact from the placing on the market of the genetically modified organism, if different from the potential effects caused by similar release of the recipient or parental organism

30. Potential environmental impact of the interaction between the genetically modified higher plant and target organisms (if applicable), if different from that of the recipient or parental organisms

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31. Potential environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organisms

a) effects on biological diversity in the area of cultivation
b) effects on biological diversity in other biogeocenoses
c) effects on pollinators
d) effects on endangered species

C. Information on Previous Releases

32. History of the previous release regarding which the same person has submitted a submission in connection with the release into the environment of the genetically modified organism

a) the number of the notification
b) conclusions of post-release monitoring
c) results of the release in respect to any risk to human and animal health or the environment (submitted to the competent authority in accordance with Paragraph 145 of these Regulations ¹)

33. History of the previous release which has been performed by the same person in the European Union or outside the European Union

a) release country
b) authority overseeing the release
c) release site
d) purpose of the release
e) duration of the release
f) purpose of post-release monitoring
g) duration of post-release monitoring
h) conclusions on post-release monitoring

i) results of the release in respect of any risk to human and animal health or the environment

D. Information Relating to the Monitoring Programme, Including Identified Traits, Characteristics and Uncertainties Relating to the Genetically Modified Organism or Interaction Thereof with the Environment that Should be Addressed in the Post-commercialisation Monitoring Programme

--

Signature² _____

Date² _____

Place for a seal²

Notes.

¹ Cabinet Regulation No. 457 of 26 May 2009, *Regulations Regarding Deliberate Release of Genetically Modified Organisms*.

² The details “signature”, “date” and “place for a seal” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding the drawing up of electronic documents.

Acting for the Minister for Agriculture –
Minister for the Environment

R. Vējonis

Report on the Results of Monitoring of Placing on the Market (Growing) of Genetically Modified Organisms (Sample)

1. General Information

1.1. Crop, trait _____

1.2. Number and date of the decision of the European Commission _____

1.3. Unique identifier _____

1.4. Reporting period: from XX/XX/XX to XX/XX/XX

1.5. Other monitoring reports have been submitted in relation to:
importation and processing: Yes No

food or feed: Yes No

2. Summary¹

3. Results of Monitoring

3.1. General monitoring:

3.1.1. Description of general monitoring²

3.1.2. Information on existing environmental monitoring programmes used in order to perform environmental impact monitoring during general monitoring and description of other methods³

3.1.3. Information on provided information and information on training of market participants, growers etc.⁴

3.1.4. Results of general monitoring⁵

3.1.5. Additional information⁶

3.1.6. Report on scientific publications in reviewed editions⁷

3.2. Case-specific monitoring

3.2.1. Description and results of case-specific monitoring (if necessary)⁸

3.2.2. Monitoring and notification of harmful effect in case of uncontrolled dissemination (if necessary)⁹

3.3. Final notes¹⁰

4. Summary of Results and Conclusions¹¹

5. Adaptation of the Monitoring Programme and the Relevant Methodology During Next Years¹²

Signature¹³ _____

Date¹³ _____

Place for a seal¹³

Annex
to the Report on
the Results of Monitoring of Placing
on the Market (Growing) of Genetically Modified Organisms

Report on scientific publications in reviewed editions

Some publications may include data which relate to several environmental risk assessment fields in compliance with Note 7 of this Annex. In such cases a separate table shall be created for each field (create as many tables as necessary).

Environmental risk assessment field

Publication	Summary of the research and results	Objective of protection	Parameter observed	Harmful effect	Opinions on initial environmental risk assessment

Notes.

¹ Summary on the acquired results of monitoring and general conclusions. The adaptation of the relevant monitoring programme methods shall be described on the basis of these results and conclusions.

² Description of general monitoring in which the following shall be specified:

- a) information on all methods used, including parameters observed, inspection methods, location and frequency;
- b) information on use of directory enquiries phone numbers;
- c) representatives of the undertaking in each European Union Member State;
- d) website address;
- e) information on the use of agricultural questionnaires or other monitoring methods;
- f) number of farmers who have filled in a questionnaire, place of growing and selection criteria of these farmers;
- g) third persons involved and selection criteria for these persons.

Growing area, where the monitoring is performed, shall be proportionate and representative against total area where genetically modified crops are grown. A person shall describe and provide more detailed information on proportionality and representativeness of the environment subject to monitoring, as well as criteria in accordance with which these areas are considered as representative and therefore selected for the monitoring.

³ Detailed information on all existing environmental monitoring programmes used in order to perform environmental impact monitoring during general monitoring. The following information shall be provided in relation to each identified existing environmental monitoring programme:

- a) name;
- b) Member States in which the existing environmental monitoring programmes operate and data whether such programmes operate in the local, regional or state level;
- c) website address;
- d) objective of protection;
- e) a way by which the information is collected for the existing environmental monitoring programme for the needs of general monitoring;
- f) procedures by which the person shall be notified regarding harmful effect;
- g) if necessary, data regarding any agreements entered into between a person, performer of the monitoring or third person;
- h) criteria used for selection of the existing environmental monitoring programme.

⁴ Data on information which is available for market participants and growers, especially on the spread of particular genetically modified crop in the European Union, on harmlessness of a product and main features thereof and regarding provisions in the field of monitoring. Data on how and when the availability of such information is ensured for market participants and growers and regarding the measures which have been performed in order to inform in due time regarding any changes in the existing information or regarding new information.

For Bt corn products and where it is specified in the environmental risk assessment, the data regarding organised education and training measures for farmers and information on a product

provided to them shall be provided in order to inform regarding the duty to prevent formation of insect resistance. Information on a product shall be appended to the report.

⁵ Results of general monitoring performed, including direct, indirect, delayed and cumulative effect observed and type of specially observed harmful effect and conclusions made. All parameters of the monitoring methodology, including location of monitoring, shall be analysed in detail, interpreted and discussed, at the same time demonstrating how these results substantiate conclusions.

If inquiry of farmers is performed, the analysis of the acquired results shall be provided in Annex to the report. If in accordance with the prepared questionnaire it is intended to provide the information of such type, the general information on agricultural holding, for example, information on use of fertilizers, crop rotation or productivity of crops, pests and diseases, use of pesticides and amount of weeds, occurrence of wild fauna and flora, as well as the information on a particular area, especially referring to the information which indicates to unforeseen effect, shall be included in the analysis. Correlation shall be determined comparing inquiries of regions or relating replies to the existing environmental monitoring programmes or to observations obtained by means of other supervision methods.

It shall be assessed whether the information obtained during the general monitoring is appropriate and useful for detection of direct, indirect, delayed and cumulative effect. Besides, the indicators (for example, edges of fields, groups of non-target species) regarding which additional or more qualitative data would be necessary shall be identified in the environmental risk assessment.

In order interpret data appropriately, this section of the report shall be as detailed as possible.

⁶ Additional information, if harmful or unintended effect is observed, for example, the relevant region or location, stage of vegetation period, measures for prevention of harmful effect of the activity or risk reduction, which might be or will have to be implemented in order to prevent harmful effect, as well as the information how it affects the environmental risk assessment, shall be indicated and other conclusions shall be written down. In order interpret data appropriately, this section of the report shall be as detailed as possible.

⁷ Scientific publications in reviewed editions shall be taken into account and analysed within the context of monitoring programme and monitoring results, preparing analysis of the report thereon; articles, reports and any additional researches or other sources of information relating to crop growing or combination of traits shall be taken into account.

These publications shall be registered, compiled and the information shall be specified in Annex to Report on the Results of Monitoring of Placing on the Market (Growing) of Genetically Modified Organisms. All relevant publications which have appeared during the reporting period shall be indicated in the literature report. If necessary, articles of conferences, reports and additional researches performed by a person and not scientifically reviewed may be submitted.

⁸ The requirements referred to in the environmental risk assessment and in the relevant permit regarding case-specific monitoring, as well as results of the monitoring performed, including detailed information on methods, frequency, duration, monitoring results, analysis and conclusions shall be specified. It shall be demonstrated in this section, how the information has been compiled and analysed in order to substantiate the conclusions. In order to interpret the data correctly, this section of the report shall be as detailed as possible. In order interpret data appropriately, this section of the report shall be as detailed as possible.

⁹ Report on measures implemented in order to perform monitoring of harmful effect in case of uncontrolled dissemination, if such monitoring is intended in the permit or existing monitoring programme, namely, the frequency of implementation of such monitoring, monitoring methodology used, measures for reduction of uncontrolled dissemination and elimination of pollution at the location of the procedure, where uncontrolled dissemination has occurred. Besides any observed unusual, harmful effect or effect related to genetically modified organism shall be noted.

¹⁰ Summary on the monitoring results obtained using questionnaires, existing environmental monitoring programmes or other supervision methods and persons involved, the literature report, as well as general conclusions. The information obtained from existing environmental monitoring programmes or using other supervision methods substantiating any aspect of the monitoring performed and providing complete report on replies provided for in questionnaires of farmers shall be included in the report, appending also a copy of the manual for completing a questionnaire and, if necessary, specifying references to them in the report.

¹¹ Summary on the acquired results of monitoring and general conclusions. It shall be clearly demonstrated in the summary, how the data obtained during the monitoring performed and interpretation of data substantiates these conclusions. In this section of the report a person shall specify the main data obtained in monitoring performed during previous years, in order to analyse and assess the possibility or probability of causing of mutual or cumulative effect which may be complicated to assess completely by the monitoring of one year.

¹² Assessment of the monitoring programme and the relevant methodology used for preparation of the report. The efficiency and deficiencies of the methodology used for determination of harmful effect shall be assessed, as well as it shall be indicated whether it is necessary to change or adapt the monitoring programme and the relevant methodology, taking into account the information of the monitoring in relation to the usefulness and quality of data obtained and uncertainty of results provided in the report.

¹³ The details “signature”, “date” and “place for a seal” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding the drawing up of electronic documents.

Report on the Results of Monitoring of Placing on the Market (Except Growing) of Genetically Modified Organisms (Sample)

1. General Information

1.1. Crop, trait _____

1.2. Number and date of the decision of the European Commission _____

1.3. Unique identifier _____

1.4. Reporting period: from XX/XX/XX to XX/XX/XX

1.5. Other monitoring reports have been submitted in relation to growing:

Yes No

2. Summary¹

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3. Use of Genetically Modified Organisms (Except Growing)

3.1. Import of goods in the European Union

3.1.1. Import of crops (genetically modified and non-modified) into the European Union according to the country of origin

Country of origin	Quantity (tons)	Assessment of the largeness of the part of the import formed by genetically modified organisms (if it is not possible to specify – approximate part of the grown in the country of origin)

3.1.2. Import of crops (genetically modified and non-modified) into the European Union according to the country of destination²

Country of destination	Quantity (in tons)

3.1.3. Analysis of the data provided for in Sub-paragraphs 3.1.1 and 3.1.2 of this Annex³

--

3.2. General monitoring

3.1.2. Description of general monitoring⁴

--

3.2.2. Information on those existing environmental monitoring programmes used during general monitoring, which are related to industry, environment, food and feed⁵

--

3.2.3. Information on the provided information and information on training of importers, traders, entrepreneurs, processors etc.⁶

--

3.2.4. Results of general monitoring⁷

--

3.2.5. Additional information⁸

--

3.2.6. Report on scientific publications in reviewed editions⁹

--

3.3. Case-specific monitoring

3.1.3. Description and results of case-specific monitoring (if necessary)¹⁰

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3.3.2. Processing (if necessary)¹¹

European Union Member State	Point of bringing in or place of growing	Processing point	Distance from the point of bringing in or place of growing	Transport used

3.3.3. Monitoring and notification of harmful effect in case of uncontrolled dissemination (if necessary)¹²

3.4. Final notes¹³

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4. Summary of Results and Conclusions¹⁴

--

5. Adaptation of the Monitoring Programme and the Relevant Methodology During Next Years¹⁵

--

Signature¹⁶ _____

Date¹⁶ _____

Place for a seal¹⁶

Annex
to the Report on
the Results of Monitoring of Placing
on the Market (Except Growing) of Genetically Modified Organisms

Report on scientific publications in reviewed editions

Some publications may include data which relate to several environmental risk assessment fields in compliance with Note 9 of this Annex. In such cases a separate table shall be created for each field (create as many tables as necessary).

Environmental risk assessment field

Publication	Summary of the research and results	Objective of protection	Parameter observed	Harmful effect	Opinions on initial environmental risk assessment

Notes.

¹ Summary on the acquired results of monitoring and general conclusions. The adaptation of the relevant monitoring programme methods shall be described on the basis of these results and conclusions.

² Actual not provisional data shall be specified (except regarding the largeness of the part of the import amount is formed by the genetically modified organism):

- a) exporting country where genetically modified crops are grown;
- b) amount of exported crops (genetically modified and non-modified) in tons;
- c) European Union Member States to which crops (genetically modified and non-modified) have been imported;
- d) amount of imported crops (genetically modified and non-modified) in tons.

³ The source of the provided data, information whether import during previous years has increased or decreased, and the reasons for such changes, the largest distributors of those crops in the European Union, the origin of which is not the European Union, as well as main importers of those crops in the European Union, the origin of which is not the European Union, shall be specified. Trends of changes in relation to the most significant importation markets in comparison to previous years and reasons for such changes shall be specified.

⁴ Description of general monitoring implemented, including data regarding methodology used (also observed parameters, data collection methods, types of places).

⁵ Information on those existing environmental monitoring programmes used during general monitoring which are related to the sector, environment, food and feed. The following information shall be provided in relation to each identified existing environmental monitoring programme:

- a) name specifying whether it is a programme related to industry, environment, food or feed;

- b) Member States in which the existing environmental monitoring programmes operate and data whether such programmes operate in the local, regional or state level;
- c) website address;
- d) objective of protection;
- e) a way by which the information is collected in the programme for the needs of general monitoring;
- f) procedures by which the person shall be notified regarding harmful effect;
- g) criteria in accordance with which the existing environmental monitoring programme has been selected.

⁶ Data on the information provided, for example, importers, traders, entrepreneurs, processors, on how and when the availability of such information is ensured and regarding the measures which have been performed in order to inform in due time regarding any changes in the existing information or regarding new information.

⁷ Results of general monitoring, including direct, indirect, delayed and cumulative effect observed and type of specially observed harmful effect and conclusions made. All parameters of the monitoring methodology, including location of monitoring, shall be analysed in detail, interpreted and discussed, at the same time demonstrating how these results substantiate conclusions. In order to interpret data appropriately, this section of the report shall be as detailed as possible.

⁸ Additional information, if harmful or unintended effect is observed. For example, the relevant region or location, stage of vegetation period, measures for prevention of harmful effect of the activity or risk reduction, which might be or will have to be implemented in order to prevent harmful effect, as well as the information, how it affects environmental risk assessment, and other conclusions shall be specified. In order to interpret data appropriately, this section of the report shall be as detailed as possible.

⁹ Scientific publications in reviewed editions shall be taken into account and analysed within the context of the monitoring programme and monitoring results in preparing analysis of the report thereon; articles of scientifically reviewed magazines, articles of conferences, reports and any additional researches or other sources of information relating to importing and processing and use of crop or combination of traits in food or feed shall also be taken into account. These publications shall be registered, compiled and the information shall be specified in Annex to the Report on the Results of Monitoring of Placing on the Market (Except Growing) of Genetically Modified Organisms.

All relevant publications which have appeared during the reporting period shall be indicated in the literature report. If necessary, articles of conferences, reports and additional researches performed by a person and not scientifically reviewed may be submitted.

¹⁰ The requirements referred to in the environmental risk assessment and in the relevant permit regarding case-specific monitoring, as well as results of the monitoring performed, including detailed information on methods, frequency, duration, monitoring results, analysis and conclusions shall be specified. It shall be demonstrated in this section how the information has been compiled and analysed in order to substantiate the conclusions. In order to interpret data appropriately, this section of the report shall be as detailed as possible.

¹¹ The information specified in this section shall be provided only if the monitoring is intended in a permit or monitoring programme in case of uncontrolled dissemination and in one of the following cases:

- a) if processing takes place outside the territory of the port of importation;
- b) in relation to places of processing of genetically modified crops grown in a Member State or the European Union.

¹² Report on measures implemented in order to perform monitoring of harmful effect in case of uncontrolled dissemination, if such monitoring is intended in the permit or existing monitoring programme, namely, the frequency of implementation of such monitoring, monitoring methodology used, measures for reduction of uncontrolled dissemination and

elimination of pollution at the location of the procedure, where uncontrolled dissemination has occurred. Besides any observed unusual, harmful effect or effect related to genetically modified organism shall be noted.

Such information shall be provided regarding:

a) ports in which genetically modified crops are imported and in case, if processing is taking place in the territory of the port;

b) places of processing specified in Sub-paragraph 3.3.2 of this Annex.

¹³ Summary on the monitoring results obtained using the existing environmental monitoring programmes, the literature report, as well as general conclusions. The information obtained from existing environmental monitoring programmes or using other supervision methods substantiating any aspect of the monitoring performed shall be included in the report, if necessary, specifying references to them in the report.

¹⁴ Summary on the acquired results of monitoring and general conclusions. It shall be clearly specified in the summary how the data obtained during the monitoring performed and interpretation of data substantiate these conclusions.

¹⁵ Assessment of the monitoring programme and the relevant methodology used for preparation of the report. The efficiency and deficiencies of the methodology used for determination of harmful effect shall be assessed, as well as it shall be indicated whether it is necessary to change or adapt the monitoring programme and the relevant methodology, taking into account the information of the monitoring in relation to the usefulness and quality of data obtained and uncertainty of results provided in the report.

¹⁶ The details “signature”, “date” and “place for a seal” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding the drawing up of electronic documents.

Sample Report on the Results of Monitoring of the Release into the Environment of Genetically Modified Organisms

1. General Information

1.1. Number of the notification (submission) of the European Union Member States:

B/XX/YY/ZZ, where

XX – abbreviation of the state name

YY – year of submission

ZZ – number allocated in order

1.2. Submitting state _____

1.3. Date and number of the permit _____

2. Status of the Report

Please indicate whether, according to this Annex, the current report is:

2.1. the final report

2.2. the post-release monitoring report:

2.2.1. the final report

2.2.2. the intermediary report

3. Characteristics of the Release

3.1. Scientific name of the recipient organism _____

3.2. Acronym or vectors¹ used in transformation (if the transformation identification number is not available) _____

3.3. Identification number if it is known _____

3.4. Please provide the following data, as well as indicate the field(s) layout:

Geographical location (administrative region, and, if necessary, the co-ordinates)	Scale of the release area ² (m ²)	Identity ³ and the approximate number of the genetically modified higher plants per event actually released (the number of seeds/plants per m ²)	Duration of the release (from... (day/month/year) to... (day/month/year))

4. Any Genetically Modified Organism on which the Person is Planning to Notify Later

4.1. Does the person intend to notify of the released transformation as for genetically modified organisms intended for placing on the market in accordance with the Community legislation at a later stage?

Yes

No

Unknown to date

If the answer is “yes” indicate:

- the state in which the submission will be submitted _____

- the purpose:

- for import
- for cultivation (for example, seed or planting material production)
- in food
- in fodder
- for use in pharmacy (or for processing for use in pharmacy)
- for processing
 - for use in food
 - for use in fodder
 - for industrial use
- for another purpose (specify)

5. Type of Release

Please select the main type(s) (in boxes), as well as sub-type(s) of the release. In case of release in several sites, several times and perennial release, please provide a general review on the release implemented throughout the period of co-ordination. Please mark the appropriate type.

5.1. Release for the purposes of research

5.2. Release for the purposes of improvement

- release screening
- proof of the concept (for example, testing of the new traits under the environmental conditions)
 - agronomic traits (for example, efficiency and selectivity of the plant protection product, yield capacity, germination capacity, crop establishment, plant vigour, plant height, susceptibility to climatic factors and diseases, etc.) (specify)
 - altered agronomic properties (for example, disease/pest/drought/frost-resistance, etc.) (specify)
 - altered quality properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify)
 - stability of the expression
 - reproduction of lines
 - study of hybrid growth
 - molecular farming

Molecular farming shall be the production of such substances (for example, proteins, pharmaceutical products) by plants, which have been genetically modified for a particular trait. Molecular farming may also be defined as the production of plant-synthesised pharmaceutical products, plant-made pharmaceutical products, plant-based protein production, etc.

- phyto-remediation

- other (specify)

5.3. Official testing []

- variety registration in the national variety catalogue
 - DUS (distinctness, uniformity and stability)
 - ACQ (assessment of cultivation qualities)
- other (specify)

5.4. Permission for the use of herbicide []

5.5. Release for sampling purpose []

5.6. Reproduction of seeds []

5.7. Release for the study of biological safety or risk assessment []

- vertical gene transfer studies
- crossing with conventional crops
- crossing with wild relatives
- horizontal gene transfer studies (gene transfer to micro-organisms);
- plant management due to uncontrolled dissemination
- potential changes in resistance or dispersal
- potential spread
- potential effects on target organisms
- potential effects on non-target organisms
- observation of resistant relatives
- observation of resistant insects
- other (specify)

5.8. Other mode of release []

(specify)

6. Method of the Release and Management, Result and Monitoring Measures in Relation to Any Risk to Human and Animal Health or the Environment

6.1. Risk management measures

Risk management measures implemented in order to avoid or minimise the spread or genetically modified organisms outside the site of dissemination, particularly the following measures:

- which were not originally notified in the submission
- which were applied in addition to the conditions in the permit
- which the permit required only under certain conditions (for example, dry periods, flooding)
- for which the permit allowed the person a choice among different measures

Mark the appropriate examples:

6.1.1. Until sowing or planting:

- clear labelling of the genetically modified seeds or planting material lot (separately from other seeds or tubers) (specify)

- segregation during the processing and transport of the seed or planting material (describe the method used), provide example(s) of containment in order to prevent uncontrolled spillage during the processing and transport

- elimination of superfluous seeds or planting material (describe the method used)
- temporary isolation (specify)
- transfer (specify previous crop)
- other (specify)

6.1.2. During the seeding or planting activities:

- the method of sowing or planting
- emptying and cleaning of the sowing or planting machinery in the field of release
- segregation during the sowing or planting (provide example of containment in order to prevent uncontrolled spillage during sowing or planting)
- other (specify)

6.1.3. During the release:

- distance of isolation (x metres):
 - from sexually compatible cultivated plant varieties
 - from sexually compatible wild relatives
- isolated planting (with the same or different crop, or with a genetically non-modified crop, x metres, etc.)
 - cage, net, fence or signpost (specify)
 - pollen trap (specify)
 - harvest of genetically modified inflorescences before flowering (indicate the frequency of the harvest)
 - harvest of bolters, relatives or hybrid plants (indicate the frequency of the harvest, x metres around the field of the genetically modified plants, etc.)
 - other (specify)

6.1.4. At the end of the release:

- harvest or elimination method (of crop or parts thereof) or other means (for example, the sampling and analysis of the sugar beet pulp) (specify)
- harvest or elimination prior to the ripeness of the seeds
- efficient removal of the plant parts
- segregated storage and transport of crop or waste (provide example of containment in order to prevent uncontrolled spillage of collected seeds, crops or waste)
- clean up of machinery at the release site
- final destination of waste, treatment of waste, surplus yield or plant products (specify)
- post-harvest treatment and cultivation of soil at the release site (describe the method for preparing and managing the release site at the end of the release, including soil cultivation practices)
- other (specify)

6.1.5. Post-harvest measures (please specify the post-harvest measures which were implemented at the release site):

- The frequency of visits (average indicator)
- The area monitored:
 - subsequent crops (specify)
 - crop rotation (specify)
 - fallow or no crop (specify)
 - superficial soil work or shallow ploughing

- false-sowing beds
- control of volunteer plants (specify intervals and duration)
- appropriate chemical treatment (specify)
- appropriate soil treatment (specify)
- other (specify)

6.1.6. Other measure (specify)

6.1.7. Emergency plan:

a) whether the release proceeded as planned:

Yes

No (describe for which reasons, for example, vandalism, climatic conditions, etc.)

b) whether measures had to be implemented in accordance with the emergency plan:

No

Yes (specify)

6.2. Post-release monitoring measures

As the existing sample report may be used for the final and post-release monitoring report, please distinguish clearly both types of report

Please, indicate whether:

- the post-release monitoring programme is commenced (if it is the final report – after the final harvest of the genetically modified higher plants)
- the post-release monitoring programme is continued (if it is the intermediary report of post-release monitoring)
- the post-release monitoring programme is completed (if it is the final report of post-release monitoring)
- no post-release monitoring programme is needed

The results of this monitoring shall provide for the confirmation or invalidation of earlier assumptions made in the risk assessment.

According to the aforementioned cases, please indicate which monitoring measures will be/are/were taken and where (at the release site/near the site (for example, on the field edges)). Please, be aware that all post-release monitoring measures taken during the whole post-release period should be indicated here.

Please indicate:

- monitoring measures on the site
 - duration
 - the frequency of visits (average)
 - the area monitored:
 - observation of resistant relatives
 - observation of resistant insects
 - control of volunteer plants (specify intervals and duration)
 - monitoring of gene flow (specify)
 - appropriate chemical processing and soil processing
 - other (specify)
- monitoring measures in adjacent areas:
 - duration
 - the frequency of visits (average)

- the area monitored:
 - observation of resistant relatives
 - observation of resistant insects
 - control of volunteer plants and monitoring of wild populations
(specify intervals and duration)
 - monitoring of gene flow (specify)
 - appropriate chemical processing and soil processing
 - other (specify)

6.3. Observation plan and method used

In this Paragraph the observation plan and the methods used shall be indicated in order to compile the consequences, which have to be reported in accordance with Sub-paragraph 6.4 of this Annex. Any amendments or modifications to the plan as proposed in the submission and the *SNIF* (Summary Notification Information Format) shall be specified in detail.

During the time between the date of submitting the submission and the final report, new scientific insights or methods may be developed, which cause a change in the methods used. In particular such modifications shall be specified in this Paragraph.

6.4. Consequences observed

6.4.1. Explanatory note

The results of the release shall be indicated in relation to the risk to human and animal health or to the environment, taking into account whether the results confirm that any risk has increased, decreased or remained the same.

The main objectives of the information given in this Paragraph are:

- to confirm or invalidate any assumptions regarding the occurrence and impact of potential consequences of the genetically modified organisms, which were identified in the environmental risk assessment;
- to identify the effects of the genetically modified organisms, which were not anticipated in the environmental risk assessment.

In the section on the effects and interaction of the genetically modified organisms, it shall be notified regarding:

- the risk to human and animal health;
- any other risk to the environment.

Particular attention shall be paid to unforeseen and accidental consequences (subsequently provided guidelines on consequences regarding which a person may notify). The consequences shall be considered taking into account the crop, the new traits, the receiving environment, as well as the conclusions of such environmental risk assessment, which has been carried out on a case-by-case basis.

In order to organise the data and to facilitate an efficient search within the given information, the person shall use, as far as possible, specific keywords to fill in the text fields under Paragraph 6 of this Annex, (particularly in Sub-paragraphs 6.4.2, 6.4.3 and 6.4.4). An updated list of such specific keywords is available on the Internet website <http://gmoinfo.jrc.it>.

6.4.2. Anticipated consequences

This section shall relate to the anticipated consequences or potential consequences, which were already identified in the environmental risk assessment of the submission and, therefore, could be anticipated.

A person has the duty to provide release information which confirms the assumptions of the environmental risk assessment.

6.4.3. Unforeseen consequences (without prejudice to handling of modification or new information).

Unforeseen consequences shall refer to effects on human and animal health or the environment, which were not foreseen or identified in the environmental risk assessment. This part of the report shall contain any information on unforeseen consequences or observations relevant for the original environmental risk assessment. In case of any observed unforeseen consequences or observations, this section shall be drawn up in as detailed form as possible in order to allow a proper interpretation of the information.

6.4.4. Other information

Persons shall be encouraged to supply information, which is outside the scope of the submission, but which may be relevant to the field trials in question. They may also include observations of beneficial effects.

7. Conclusion

In this chapter the person shall specify the conclusions drawn and the measures taken or to be taken on the basis of the results of the release with regard to further releases and, where appropriate, make reference to any kind of genetically modified organism the person intends to notify at a later stage.

The information provided in this report is not restricted access information. In accordance with the Regulation⁴ the Food and Veterinary Service may request both restricted access information and additional information from a person.

If the information is restricted access information, a summary of the generally accessible information shall be provided in Annex to the report or a general description, which will be made available to the public.

Signature⁵ _____

Date⁵ _____

Place for a seal⁵

Notes.

¹ In the case of small-scale field trials where several lines may be tested, the vectors used shall be mentioned, which give an insight in the newly introduced indicators and genetic elements. In the case of large (larger)-scale trials, the number of the events of release notified shall be limited to one or several events.

² Specify the scale of the genetically modified area and, where appropriate, the scale of the genetically non-modified area (for example, the border of the genetically non-modified area).

³ Vectors used.

⁴ Cabinet Regulation No. 457 of 26 May 2009, *Regulations Regarding Deliberate Release of Genetically Modified Organisms*.

⁵ The details “signature”, “date” and “place for a seal” of the document shall not be completed if the electronic document has been prepared in conformity with the regulatory enactments regarding the drawing up of electronic documents.

Acting for the Minister for Agriculture –
Minister for the Environment

R. Vējonis