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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. 1078

Adopted 22 December 2008

**Methodology for the Risk Assessment of Genetically Modified Organisms**

*Issued pursuant to*

*Section 5, Paragraph one, Clause 3 of the Law On Circulation of Genetically Modified Organisms*

**I. General Provisions**

1. This Regulation prescribes the methodology for the risk assessment of genetically modified organisms.

2. The objective of the risk assessment of genetically modified organisms is to determine and assess the potential direct or indirect, immediate or delayed adverse effects thereof on human and animal health or the environment, which may be caused by deliberate release of specific genetically modified organisms (hereinafter – the release).

[*9 March 2010; 15 January 2013*]

3. [9 March 2010]

**II. General Principles of the Environmental Risk Assessment**

4. A person shall evaluate the environmental risk in accordance with precautionary principles, taking into account the general principles of the environmental risk assessment. Based on the environmental risk assessment, a person shall determine the appropriate measures of the risk management and the methods to be utilised.

[*9 March 2010*]

5. The general principles of the environmental risk assessment shall be as follows:

5.1. to identify the characteristics of a genetically modified organism which may cause potential adverse effects by taking into account the intended type of the release and use, to identify intended or unintended changes caused by genetic modification in accordance with Paragraph 12.1 of this Regulation. The characteristics of the genetically modified organism, which may cause potential adverse effects, shall be determined by comparing the characteristics of the genetically modified organism with the characteristics of such organism, which is not genetically modified and from which the genetically modified organism has been acquired;

5.2. to describe the environmental condition or the environmental baseline before the release of the genetically modified organism, while no (adverse) characteristics of the genetically modified organism can be identified. The baseline is the reference point wherewith subsequent changes are compared, which may be caused by the release of genetically modified organisms. The baseline shall be dependent on the receiving environment, as well as biotic and abiotic factors (for example, the preserved natural ecological environment, biological diversity, agricultural land or polluted land) or the combinations of different environmental conditions. If placing on the market of the genetically modified organism is intended, such environmental baseline shall be described, in which the release (cultivation) of the genetically modified organisms is intended;

5.3. to determine and indicate the long-term adverse effects and long-term cumulative effects of the genetically modified organism. Information regarding the long-term cumulative effects allows the assessment of the adverse effects of the genetically modified organism on human and animal health or the environment, including flora and fauna, soil fertility, degradation processes of organic matters, food chains, biological diversity and the resistance of organisms to antibiotics. Information and data regarding the long-term adverse effects shall be acquired over a continuous period of time by evaluating the following:

5.3.1. the interaction of the genetically modified organism with the receiving environment (an environment in which the release of the genetically modified organism is intended);

5.3.2. the characteristics of the genetically modified organism which may in the long-term have an adverse impact on human and animal health or the environment;

5.3.3. repeated cases of the release of the genetically modified organism;

5.3.4. the results of monitoring of the genetically modified organism or another genetically modified organism with a similar type of modification released and adverse effects thereof on human and animal health or on the environment;

5.4. to indicate the used environmental risk assessment methods and scientific publications regarding environmental risks. Environmental risks shall be analysed, using the guidelines of the European Food Safety Authority (guidelines available on the Internet website of the European Food Safety Authority http://www.efsa.europa.eu) and recognised scientific publications;

5.5. to indicate descriptions of the methods used, scientific publications, measurement calculations and measurement inaccuracies;

5.6. to indicate the measures of the risk management for the release of genetically modified organisms in order to determine data regarding the environmental baseline, if such data is not available. Data regarding the environmental baseline shall be such as to allow the evaluation of the significance of the risk for the relevant genetically modified organism. If the environmental risk assessment does not provide final answers to all matters to be examined due to the lack of data or if data is not available or is incomplete (particularly in relation to the potential long-term effects), measures of the risk management shall be taken in accordance with the precautionary principle in order to prevent adverse effects on human and animal health or the environment;

5.6.1 when preparing the environmental risk assessment on the release on the market of a genetically modified organism, the person shall compile already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the person shall justify in the environmental risk assessment why generating data by studies is not possible.

5.6.2 where data generated outside Europe is provided in the environmental risk assessment, its relevance to the receiving environment in the European Union shall be justified;

5.6.3 data provided in the environmental risk assessment on the release on the market shall conform to the following requirements:

5.6.31. where toxicological studies carried out to assess risk to human or animal health are provided in the environmental risk assessment, the person shall provide evidence to demonstrate that they were conducted in one of the following institutions which conform to:

5.6.31.1. the requirements for laboratory work quality and inspection;

5.6.31.2. the Principles on Good Laboratory Practice of the Organisation for Economic Co-operation and Development – on studies carried out outside the European Union;

5.6.32. where the results of the studies other than toxicological studies are provided in the environmental risk assessment, these studies shall conform to one of the following conditions:

5.6.32.1. the requirements for laboratory work quality and inspection;

5.6.32.2. be conducted by institutions accredited in conformity with the relevant standard of the International Organisation for Standardisation;

5.6.32.3. in the absence of a standard of the International Organisation for Standardisation, be conducted in accordance with internationally recognised standards;

5.6.33. information regarding the results obtained from the studies referred to in Sub-paragraphs 5.6.31 and 5.6.32 of this Regulation and regarding the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

5.6.34. the person shall specify, where possible, the scale of effect that each study performed intends to detect and shall justify it;

5.6.35. the selection of the sites for field studies shall be based on the relevant receiving environment and in view of the potential exposure and impact that would be observed where the genetically modified organism may be released and the selection of the relevant sites shall be justified;

5.6.36. the non-genetically modified comparator shall be appropriate for the relevant receiving environment and shall have a genetic background comparable to the genetically modified organism and also shall be a justified choice of comparable material;

5.7. when performing activities, to observe the step by step nature thereof. At first activities shall be commenced in enclosed premises, for example, in greenhouses, thus determining the potential adverse effects of the genetically modified organism on human and animal health or the environment;

5.8. to perform a separate environmental risk assessment for each genetically modified organism and the type of use and release thereof. The data of a similar genetically modified organism may be used in the environmental risk assessment, which has similar characteristics and a similar interaction with the environment;

5.9. to indicate the potential adverse effects of the genetically modified organism on other genetically modified organisms, which were or are being released;

5.9.1 the following conditions shall apply to genetically modified organisms containing stacked transformation events in the environmental risk assessment on the release on the market:

5.9.11. the person shall provide the environmental risk assessment for each single transformation event in the genetically modified organism or refer to already submitted notifications for those single transformation events;

5.9.12. the person shall provide the assessment of the following aspects:

5.9.12.1. the stability of the transformation events;

5.9.12.2. the expression of the transformation events;

5.9.12.3. the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

5.9.13. where the progeny of the genetically modified organism can contain various subcombinations of the stacked transformation events, the person shall provide a scientific rationale justifying that there is no need to provide experimental data for the relevant subcombinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data;

5.10. to perform a repeat environmental risk assessment and inform the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR””, if:

5.10.1. new information is obtained and there is reason to believe that the risk to human or animal health or the environment has changed;

5.10.2. it is necessary to perform changes to measures of risk management;

5.10.3. during analysis of the monitoring results, risks of the genetically modified organism have been identified.

[*9 March 2010; 15 January 2013; 10 February 2015; 26 February 2019*]

**III. Environmental Risk Assessment**

6. A person shall assess the environmental risk for each genetically modified organism individually, using the environmental risk assessment guidelines (guidelines available on the Internet website of the European Food Safety Authority http://www.efsa.europa.eu), scientific publications and the latest scientific conclusions.

7. The following shall be included in the environmental risk assessment:

7.1. information regarding the relevant genetically modified organism in accordance with Paragraphs 8 and 8.1 of this Regulation;

7.2. an opinion on the impact of the genetically modified organism on human and animal health or the environment in accordance with Paragraph 9 of this Regulation;

7.3. a summary of the environmental risk assessment in accordance with Paragraph 10 of this Regulation.

[*26 February 2019*]

8. The information regarding a genetically modified organism shall contain a detailed analysis of the following:

8.1. recipients, donors, vectors and parental organisms used in the genetic modification;

8.2. the process of the genetic modification, indicating whether insertion or deletion has been performed, as well as information regarding the vectors and donors used;

8.3. the structure of the genetically modified organism;

8.4. the intended form of release, the scale and usage thereof;

8.5. the potential receiving environment into which the genetically modified organism will be released and into which the transgene may spread;

8.6. the interaction between the characteristics referred to in this Paragraph.

[*26 February 2019*]

8.1 The environmental risk assessment on each risk factor referred to in Sub-paragraphs 9.1 and 9.2 of this Regulation has the following six steps:

8.11. problem formulation, including hazard identification:

8.11.1. identify any changes linked to the genetic modification by comparing the characteristics of the genetically modified organism with those of the chosen non-genetically modified comparator under the corresponding conditions of the release and use;

8.11.2. identify the potential adverse effects of the genetically modified organism on human and animal health or the environment which are linked to the changes which have been identified in accordance with Sub-paragraph 8.11.1 of this Regulation. Potential adverse effects shall not be discounted on the basis that they are unlikely to occur. Potential adverse effects will vary from case to case and may include, for example:

8.11.2.1. effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations and it may cause decline in biodiversity;

8.11.2.2. altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;

8.11.2.3. compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example, by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine;

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

8.11.2.5. diseases affecting humans, including allergenic or toxic reactions;

8.11.2.6. diseases affecting animals and plants, including toxic and also allergenic reactions in animals;

8.11.3. where potential long-term adverse effects of a genetically modified organism are identified, they shall be assessed in the form of literature or theoretical studies using at least one of the following methods:

8.11.3.1. evidence from previous experiences;

8.11.3.2. available data sets or literature;

8.11.3.3. mathematical modelling;

8.11.4. identify the relevant assessment measurements. The potential adverse effects which could impact the identified assessment measurements shall be considered in the next steps of the risk assessment;

8.11.5. identify and describe the exposure pathways or other mechanisms through which adverse effects may occur. Adverse effects may occur directly or indirectly through different exposure pathways or other mechanisms, for example:

8.11.5.1. the spread of the genetically modified organism in the environment;

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

8.11.5.3. phenotypic and genetic instability;

8.11.5.4. interactions with other organisms;

8.11.5.5. changes in management, including, where applicable, in agricultural practices;

8.11.6. formulate testable hypotheses and define relevant measurement endpoints to allow, where possible, a quantitative evaluation of the potential adverse effects;

8.11.7. consider possible sources of uncertainties, including knowledge gaps and methodological limitations;

8.12. hazard characterisation:

8.12.1. the magnitude of each potential adverse effect shall be evaluated by assuming that such an adverse effect will occur and that the magnitude is likely to be influenced by the receiving environment into which the genetically modified organism is intended to be released, by the scale and conditions of the release;

8.12.2. where possible, the evaluation shall be expressed in quantitative terms by using categories “high”, “moderate”, “low” or “negligible” for describing thereof and an explanation of the scale of effect represented by each category shall be provided;

8.13. exposure characterisation:

8.13.1. the likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment and intended use of the plant shall be taken into consideration;

8.13.2. if the evaluation is expressed in qualitative terms, the categories “high”, “moderate”, “low” or “negligible” shall be used for the description of the exposure and an explanation of the scale of effect represented by each category shall be provided;

8.14. risk characterisation:

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

8.14.2. if a quantitative or semi-quantitative estimation is not possible, a qualitative estimation of the risk shall be provided by using the categories “significant consequences”, “moderate consequences”, “insignificant consequences” or “negligible consequences” and an explanation of the scale of effect represented by each category shall be provided;

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

8.15. risk management strategies:

8.15.1. if risk factors are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed;

8.15.2. the possibility for the reduction of the relevant risk factor hazard or the exposure, or both, shall be included in the description of risk management strategies and they shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the environmental risk assessment;

8.15.3. the consequent reduction in overall risk shall be quantified where possible;

8.16. overall risk evaluation and conclusions:

8.16.1. a qualitative and, where possible, quantitative evaluation of the overall risk of the genetically modified organism shall be made by taking into account the results of the risk factor characterisation, the proposed risk management strategies and the associated levels of uncertainty;

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

8.16.3. the overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the genetically modified organism and, where appropriate, the monitoring of the efficacy of the proposed risk management measures;

8.16.4. for notifications for the purpose of the release on the market, the overall risk evaluation shall also include an explanation of the assumptions made during the environmental risk assessment and of the nature and magnitude of uncertainties associated with the risk factors and also a justification of the risk management measures proposed.

[*26 February 2019*]

9. In the opinion regarding the adverse effect of the genetically modified organism on human and animal health or the environment, the following shall be indicated:

9.1. regarding genetically modified organisms which are not higher plants:

9.1.1. the probability that in the intended environment of release, the genetically modified organism will become persistent and invasive in natural habitats;

9.1.2. all selectively favourable or unfavourable characteristics acquired by the genetically modified organism and the probability that they may be expressed under the intended conditions of release;

9.1.3. information regarding the ability of the genetically modified organism:

9.1.3.1. to transfer genes to other species;

9.1.3.2. to transfer all selective or unfavourable characteristics to other species existing in the receiving environment;

9.1.4. the potential immediate and delayed adverse environmental impact, which occurs to the genetically modified organism upon direct or indirect interaction with the target organism;

9.1.5. the potential immediate and delayed adverse environmental impact, including the level of competitors, victims, hosts, symbionts, predators, parasites and pathogens in the population, which occurs upon direct or indirect interaction of the genetically modified organism with a non-target organism;

9.1.6. the potential immediate and delayed adverse effects on human health, which occur upon direct or indirect interaction of the genetically modified organism with persons who work with genetically modified organisms or are present in the place of release thereof;

9.1.7. the potential immediate and delayed adverse effects on animal health and the consequences of such effect on the food chain, which occur when using genetically modified organisms and products acquired therefrom for animal food;

9.1.8. the potential immediate and delayed adverse effect on biogeochemical processes, which occurs to the genetically modified organism upon direct or indirect interaction thereof with a non-target organism in the environment of release of the genetically modified organism;

9.1.9. the potential immediate and delayed direct and indirect adverse environmental impact, which occurs due to the risk management measures of specific genetically modified organisms, if they differ from the measures, which are used in the risk management of the genetically non-modified organism;

9.2. regarding the highest genetically modified plants:

9.2.1. persistence and invasiveness of the genetically modified higher plant, including plant to plant gene transfer;

9.2.2. plant to micro-organisms gene transfer;

9.2.3. interaction of the genetically modified higher plant with target organisms;

9.2.4. interaction of the genetically modified higher plant with non-target organisms;

9.2.5. impact of the specific cultivation, management and harvesting techniques;

9.2.6. effect on biogeochemical processes;

9.2.7. effect on human and animal health.

[*26 February 2019*]

10. In accordance with the laws and regulations regarding deliberate release of genetically modified organisms a person shall draw up a summary or the environmental risk assessment. The following shall be indicated in the summary:

10.1. each characteristic of the genetically modified organism, which may cause the potential adverse effect and the significance of this effect;

10.2.the potential probability of occurrence of the adverse effect, which is based on the risk combination of each potential adverse effect determined, as well as the cumulative effect of other genetically modified organisms;

10.3. the level of inaccuracy of analyses performed.

[*15 January 2013*]

**IV. Assessment of Adverse Effects of the Genetically Modified Organism**

11. In order to determine the adverse effect of the genetically modified organism, a person shall assess and indicate the characteristics of the genetically modified organism, which cause or could cause an adverse effect to human and animal health or the environment. The genetically modified organism has adverse effects if it has, for example, the following characteristics:

11.1. it causes human, animal and plant diseases, including allergic or toxic effect;

11.2. it causes an effect on the species of the receiving environment, including specially protected species, population dynamics, changes in biotopes and the genetic variety of each population;

11.3. it causes susceptibility to pathogens which promote the spread of infectious diseases or the development of new reservoirs or carriers;

11.4. it promotes or initiates the development of new sources or vectors of infection;

11.5. it causes a negative effect on prophylactic, medical and medicinal activities, veterinary medicine or plant protection (for example, gene transfer, which causes resistance to antibiotics used in medicine or veterinary medicine);

11.6. it causes an effect on biogeochemical cycles, especially the circulation of carbon and nitrogen, which takes place in the soil upon decomposition of organic substances;

11.7. it causes an effect on biological diversity.

[*9 March 2010*]

12. Adverse effects of each genetically modified organism shall be characterised by a specific type of effect:

12.1. the direct effect. It refers to primary effect on human and animal health or the environment, which does not occur through a causal chain of events. Any effects, which are caused by a genetically modified organism that has been transformed with a specific aim (for example the direct effect of Bt toxin on target organisms or the pathogenic effect of the genetically modified micro-organism on human health) shall not be regarded as the form of direct effects;

12.2. the indirect effect. This occurs through causal chain of events and activities (for example, as a result of the interaction of different organisms, changes in transfer of genetic material or use of the genetically modified organism, or as a result of changes in risk management measures). If the indirect effect of the genetically modified organism is established with delay (for example, if the reduction of the population of target insects affects the population of other insects), it shall be necessary to evaluate the risk management measures for assessment of such adverse effects;

12.3. the immediate effect. This is observed during release of the genetically modified organism (for example, an insect which feeds on such parts of the genetically modified plant, which is prone to resistance against relevant insects, dies or human beings with a weakened immune system develop an allergy after contact (exposure) with a specific genetically modified organism). The immediate effect may be direct or indirect;

12.4. the delayed effect. The consequences of such an effect may only be determined in the long-term after commencement of the release of the genetically modified organism. It may be both a direct or indirect effect (for example, the characteristics of the genetically modified organism, which determine the invasive nature thereof, are analysed in several generations or a probability is determined that the hybrids of closely related genetically modified crop may become invasive in ecosystems). If the genetically modified organism has specific risks of delayed adverse effects or studies regarding delayed effects of the genetically modified organism have not been performed previously, monitoring of specific indicator species shall be envisaged, which will promote the assessment of the delayed effect and risks thereof. Appropriate measures (for example, monitoring) may be used in the determination of such effects;

12.4.1 long-term effect. Long-term effect resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to genetically modified organisms or from an extensive use of a genetically modified organism in time and space;

12.5. the cumulative long-term effect. The cumulative long-term effect of genetically modified organisms may be assessed if continuous monitoring of environmental base line has been performed. Studies of cumulative long-term effects shall be included in the monitoring programme of the relevant genetically modified organism, taking into account the objectives of the release of the genetically modified organism. If the genetically modified organism is in interaction with human beings, animals, flora, fauna, soil or other objects of biological diversity, during the release thereof, environmental monitoring of sensitive objects shall be performed. Micro-organisms, plants and animals shall be included as sensitivity indicators in the monitoring programme of such genetically modified organisms, which contain genes that code resistance against antibiotics or are tolerant against herbicides.

[*15 January 2013; 26 February 2019*]

12.1 Each change of a genetically modified organism is characterised by a specific type of changes:

12.11. intended changes. These are changes which are introduced with intention and which fulfil the original objectives of the genetic modification;

12.12. unintended changes. These are consistent changes which go beyond the intended changes resulting from the genetic modification;

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

[*26 February 2019*]

13. The adverse effect of the genetically modified organism, which is determined in accordance with Paragraph 12 of this Regulation, shall be characterised by the significance of such adverse effects on human and animal health or the environment. The determined adverse effect of the genetically modified organism shall be evaluated, taking into account the usage and type of release of the genetically modified organism. The consequences caused by adverse effects shall be divided as follows:

13.1. significant consequences which in the short-term or long-term cause significant changes to one or more species, including endangered species and recipient species. The decrease in the number or complete destruction of such species, which causes an adverse effect on the functioning of the ecosystem and other related ecosystems, shall be included in such changes. Such changes are irreversible in the short-term, and any recovery of the ecosystem may be slow;

13.2. moderate consequences which cause significant changes in the density of the population of other organisms, but do not cause changes, which might result in complete destruction of species or any significant impact on the endangered species or acquiring species. Temporary and significant changes to populations shall be regarded as moderate consequences if these changes are reversible. The effect of moderate consequences may be continuous if there is no substantial adverse effect on the functioning of the ecosystem;

13.3. minor consequences which cause insignificant changes in the density of the population of other organisms but do not cause complete destruction of population of other organisms or species that would adversely affect the functioning of the ecosystem. Organisms, which might be affected, may be organisms which in the short-term or long-term belong to non-endangered species that are not the acquiring species;

13.4. minimal consequences which do not cause significant changes in any population of the environment or ecosystem.

14. The characteristics of the genetically modified organism, which may cause an adverse effect, shall be evaluated as follows:

14.1. in relation to human and animal health or the environment, taking into account:

14.1.1. the size of the area in which the release of the genetically modified organism is intended;

14.1.2. the crossing possibilities of the genetically modified organism with other organisms outside the boundaries of the release;

14.2. in relation to the environmental base line. The environmental base line may be affected by:

14.2.1. the structure of the genetically modified organism;

14.2.2. the type of adverse effects;

14.2.3. the number of the distributed genetically modified organisms;

14.2.4. the environment in which the release of the genetically modified organism is intended;

14.2.5. the probability of occurrence of adverse effects;

14.2.6. the conditions of release;

14.2.7. the interaction of the factors referred to in Sub-paragraph 14.2 of this Regulation.

[*15 January 2013*]

**Informative Reference to European Union Directives**

[*26 February 2019*]

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) Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms.

Prime Minister I. Godmanis

Minister for Agriculture M. Roze