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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 – 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 determine the characteristics of a genetically modified organism, which may cause potential adverse effects, taking into account the intended form of release and usage. 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 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 cumulative effects shall be acquired over a continuous period of time, 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;

5.7. 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;

5.10. 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]

### **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 Paragraph 8 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.

8. The following shall be included in information regarding a genetically modified organism:

8.1. detailed analysis regarding:

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

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

8.1.3. the structure of the genetically modified organism;

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

8.1.5. the potential receiving environment;

8.1.6. the interaction of the characteristics referred to in Sub-paragraph 8.1 of this Regulation;

8.2. analysis regarding the characteristics of the genetically modified organism, which could cause the potential adverse effects to human and animal health or the environment and the potential consequences caused. Adverse effects of the genetically modified organism are indicated in Chapter IV of this Regulation. The characteristics of the genetically modified organism which could cause potential adverse effects shall be determined as follows:

8.2.1. the characteristics of the genetically modified organism and the organism, which is not genetically modified and from which the genetically modified organism has been acquired, shall be compared, taking into account the conditions of release and use. Crops, which are propagated vegetatively, shall be compared with the parent species that is used for the creation of the genetically modified crop. For crops which propagate by means of sexual reproduction, comparative analysis shall be performed with the appropriate isogenic lines;

8.2.2. the genetic origin of the genetically modified organism or the structure thereof, which may cause the potential adverse effects, shall be described;

8.2.3. detailed analysis shall be performed regarding the genetic modification, altered genes and products thereof (for example, proteins) in order to evaluate the potential adverse effects;

8.2.4. the form of adverse effects of the genetically modified organism shall be assessed and indicated in accordance with the requirements referred to in Chapter IV of this Regulation. The type of release shall demonstrate how the genetically modified organism enters and spreads into the environment and how the potential adverse effect may occur (for example, by inhaling toxic micro-organisms or toxic proteins);

8.2.5. the release of the genetically modified organism shall be evaluated, by describing:

8.2.5.1. the biological appropriateness of the genetically modified organism (it shall be indicated whether the genetically modified organism has characteristics which ensure its competitiveness in the environment where release thereof is intended, and it shall be indicated whether the genetically modified organism is resistant towards the effects of natural selection, for example, abiotic factors);

8.2.5.2. the conditions for the release of the genetically modified organism (for example, the scale of release of the genetically modified organism) and indicating the amount (number) of the genetically modified organism to be released;

8.2.5.3. the form of release, as well as the form of the probability of accidental release, taking into account the form of the probability of release of the same genetically non-modified organisms;

8.2.5.4. the form of release of the viable material of the genetically modified organism (for example, seed, spore, pollen release methods with wind, water, animals);

8.2.5.5. the special environmental conditions for release (for example, the specific conditions of places or regions, favourable conditions which promote the crossing possibilities of genetically modified crops and related wild plants);

8.2.5.6. the life cycle of the genetically modified organism and the viability thereof in different habitats;

8.2.5.7. the forms of reproduction, survival and wintering of the genetically modified organism (for example, for plants – the viability of pollen, seeds and vegetative structure and for micro-organisms – the viability of spores or the ability of a micro-organisms to become viable);

8.2.5.8. specific environmental aspects. In order to assess each place or region individually, the data to be analysed shall be classified according to the areas of habitats, indicating botanical data regarding the incidence of the wild plants related to the genetically modified organism in different areas of agricultural production (conventional, genetically modified organism or biological agriculture) or within the boundaries of natural areas of habitats of European species;

8.2.6. the ability of the inserted genetic material to integrate into other organisms shall be assessed, indicating whether gene transfer has been performed to the genetically modified organism, which could cause adverse effects to human and animal health or the environment. Gene transfer to other species shall depend on the following:

8.2.6.1. the reproductive characteristics of the genetically modified organism, the inserted genetic material, the type of the genetically modified organism, the range of the receiving environment and recipients;

8.2.6.2. the release factors and special environmental factors (for example, climate and wind);

8.2.6.3. the reproductive differences of organisms. The highest possible gene transfer of plants and animals to related, distantly related and non-related species, as well as the possibility of horizontal gene transfer of micro-organisms shall also be evaluated. Upon evaluation it shall be taken into account that micro-organisms are able to grow and reproduce quickly and they may promote a high level of gene transfer;

8.2.6.4. agricultural practices. Gene transfer in largest areas of genetically modified crops will differ from small areas. The genetically modified organism may be invasive in the environment and outlive the existing species, if the viability of the genetically modified organism has been improved, using genetic modification. The implementation of adverse effects is proportionate to the method of release of the genetically modified organism;

8.2.6.5. the distribution of those organisms and recipients into the environment, with which the genetically modified organism may cross. Transgenic transfer in a specific period of time may cause the release of new genetic combinations into the environment, which in the long-term may cause significant adverse effects;

8.2.6.6. the promoters of pollination (for example, from insects or animals);

8.2.6.7. the presence of hosts of parasites;

8.2.7. the phenotypic and genetic instability of the genetically modified organism shall be evaluated and indicated. If the expression of the transgene is limited to a specific piece of the genetically modified organism, it shall be assumed that the instability of the regulation may result in the expression of the transgene throughout the organism. If an infertile genetically modified organism is acquired with specific infertility transgenes, it shall be assumed that there is a possibility that as a result of the instability of infertility transgenes the fertility of the genetically modified organism may be renewed and due to this reason transgenes will be able to spread without control. Upon evaluation it shall be taken into account that the transgenic stability has a significance not only in the newly created genetically modified organism, but also in the descendants in which changes might be observed as a result of long-term monitoring. The instability of the genetically modified organism shall be characterised by:

8.2.7.1. the line of the genetically modified plant, which contains more than one transgene. If division of these transgenes during subsequent separation processes may create plants in descendants in which there are less transgenes, a new organism phenotype is acquired;

8.2.7.2. attenuated mutants due to the instability thereof. Due to the specific structure of mutation virulence of the genetically modified organism may return;

8.2.7.3. the reproduction of transgenes which results in attenuation of genes;

8.2.7.4. the number of samples which is too high;

8.2.7.5. transferable elements. If transgenes are inactivated with an insertion of mobile genetic elements, new phenotypes occur during repeated insertion;

8.2.7.6. a significant level of expression of transgenes (for example, a very small expression of a toxic substance and instability of the regulating element may reinforce the expression of the transgenes);

8.2.7.7. the interaction with the environment during cultivation of the genetically modified organism, therefore the effect of environmental and agronomic factors on the expression of the transgene must be evaluated;

8.2.8. the interaction of the genetically modified organism with other organisms and the type of adverse effects thereof shall be evaluated and indicated in accordance with the requirements referred to in Chapter IV of this Regulation. The potential interaction with other organisms, as well as with other genetically modified organisms, shall be evaluated, taking into account the complexity of the multitrophic interaction. The direct adverse interaction of the genetically modified organism shall occur if the following is observed:

8.2.8.1. the effect on a human being (for example, persons who are in direct contact with genetically modified organisms);

8.2.8.2. the effect on animals;

8.2.8.3. the competition between the genetically modified and non-genetically modified organism for soil, growing area, water and light;

8.2.8.4. the outrivaling of the populations of other organisms;

8.2.8.5. the release of toxic substances;

8.2.8.6. a different growing system;

8.2.9. the environmental impact of the genetically modified organism shall be assessed, taking into account good agricultural practice:

8.2.9.1. the sowing or planting, cultivation, harvesting or transportation of crops and the periods thereof;

8.2.9.2. crop rotation (for example, cultivation of one plant species each year or every fourth year);

8.2.9.3. mechanisms for combating diseases or pests (for example, type and dosage of insecticide for plants or type and dosage of antibiotics for animals);

8.2.9.4. the management of resistance (for example, the type of herbicides and dosage to herbicide resistant plants or changes of the biological control with *Bacillus thuringiensis* proteins (hereinafter – Bt) or the effects of viruses);

8.2.9.5. the measures for isolation of agricultural production or aquacultural systems (for example, specification of the crop isolation distances or the quality of isolation in fish farms);

8.2.9.6. the forms of agricultural production (cultivation of genetically modified crops, conventional crops and biological crops);

8.2.9.7. the measures of risk management (for example, in relation to the control of isolation distances between natural habitats and areas of genetically modified crops);

8.3. assessment of the genetically modified organism and potential adverse effects and consequences of the use thereof, as well as the significance of the specific adverse effects in accordance with Chapter IV of this Regulation;

8.4. analysis regarding the possible occurrence of specific potential adverse effects of the genetically modified organism, taking into account the environmental base line data in which the release of the genetically modified organism is intended. Each characteristic of the genetically modified organism, which may cause the potential adverse effect on human and animal health or the environment, shall be described, indicating the possibility of occurrence of adverse effects and the significance of the consequences. In order to determine the probability of the adverse effect, the following information shall be indicated:

8.4.1. the size of the area where the release of genetically modified organisms is intended;

8.4.2. the receiving environment where the release of genetically modified organisms is intended;

4.4.3. [15 January 2013]

8.4.4. the climatic, geographic, soil and demographic conditions, as well as the type of the receiving environment of flora and fauna;

8.4.5. the viability of the genetically modified organism, without taking into account the intended measures of risk management. The approximate amount (number) of genetically modified organisms, which could survive in the environment where the release of the genetically modified organisms is intended, shall be assessed and described;

8.4.6. the probability of gene transfer from the genetically modified organism to other organisms. In such case the potential amount of gene transfer and the number of exposed organisms shall be indicated.

8.4.7. the organisms which in a specific receiving environment may affect the toxic characteristics of genetically modified organisms;

8.4.8. the probability of the occurrence of the adverse effect on other organisms. The possibility of the occurrence of adverse effects shall be characterised as significant, moderate, minor or minimal in accordance with Paragraph 13 of this Regulation;

8.5. analysis of each characteristic of the genetically modified organism, which may cause the potential adverse effect, taking into account the intended form of release of the genetically modified organism and usage thereof. The characteristics of the genetically modified organism shall be analysed, indicating the following information:

8.5.1. the significance of the consequences of the specific adverse effects – significant, moderate, minor or minimal in accordance with Paragraph 13 of this Regulation;

8.5.2. the probability of the occurrence of adverse effects – significant, moderate, minor or minimal in accordance with Paragraph 13 of this Regulation;

8.5.3. if any characteristic of the genetically modified organism has more than one adverse effect, the significance and probability of each adverse effect shall be evaluated individually;

8.5.4. inaccuracy of the methods used in the environmental risk assessment:

8.5.4.1. the conclusions and extrapolations made at different levels of the environmental risk assessment;

8.5.4.2. the different scientific assessments and opinions;

8.5.4.3. inaccuracies;

8.5.4.4. the potential derogations from certain restrictions;

8.5.4.5. the conclusions which are made on the basis of the existing data;

8.6. the quantitative and qualitative results of the methods of analysis used, the inaccuracy and measurement uncertainties thereof. Measurement uncertainties shall be determined by analysing the following:

8.6.1. the selected indicators;

8.6.2. the measurements performed;

8.6.3. the samples analysed;

8.6.4. the calculation models used;

8.6.5. the causal relationships used;

8.6.6. the contradictory data or the lack of the relevant data;

8.7. measures and strategy of the risk management according to the intended form of release of the genetically modified organism and usage thereof. If adverse effects of the genetically modified organism on human and animal health or the environment is specified in the environmental risk assessment, appropriate measures of risk management shall be applied to the intended activities and the following shall be re-evaluated:

8.7.1. the form of release and usage of the genetically modified organism;

8.7.2. the type of the genetically modified organism (for example, genetically modified micro-organisms, annual higher plants, perennial higher plants or animals, genetically modified organisms with one or more types of genetic modifications);

8.7.3. the general type of the habitat (for example, the biogeochemical condition, climate, possibility of crossing of the same species or interspecies, places of origin among different habitats);

8.7.4. the type of agricultural production (for example, agricultural, forestry, aquacultural, the field areas, the size of the territories, the number of different genetically modified organisms);

8.7.5. the form of the natural habitat (for example, the condition of the protected territory).

*[15 January 2013]*

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. the probability that the highest genetically modified plant in an area of agricultural production will become more persistent than recipient or parent plants or more invasive in natural habitats;

9.2.2. all selectively favourable or unfavourable factors, which the highest genetically modified plant has acquired;

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

9.2.3.1. to transfer genes to other species;

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

9.2.4. the potential immediate and delayed adverse effects which occur to the highest genetically modified plant upon direct or indirect interaction thereof with target organisms (for example, predators, parasites and pathogens);

9.2.5. the potential immediate and delayed adverse environmental impact, including the level of competitors, herbivores, symbionts, parasites and pathogens in the population, which occurs to the highest genetically modified plants upon direct or indirect interaction thereof with target and non-target organisms;

9.2.6. the potential immediate and delayed adverse effect on human health, which occurs to the highest genetically modified plants upon direct or indirect interaction thereof with persons who work with the highest genetically modified plants or are present in the place of release thereof;

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

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

9.2.9. the potential immediate and delayed direct and indirect adverse environmental impact, which is caused by the cultivation, risk management measures and harvesting techniques of the highest genetically modified plants if these differ from methods which are used in cultivation of the highest genetically modified plants.

10. In accordance with the laws and regulations regarding deliberate release of genetically modified organisms a person shall draw up a summary of 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;

12.5. 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]*

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 Directive**

This Regulation includes legal norms arising from 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.

Prime Minister

I. Godmanis

Minister for Agriculture

M. Roze