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Information to be provided and disclosed regarding the risk that has become known when a genetically modified organism is released into the environment or when a product containing or consisting of genetically modified organisms is placed on the market¹

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Amended by the following acts

Reception	Publication	Entry into force
03.07.2023	RT I, 13.07.2023, 1	16.07.2023

The regulation is established on the basis of subsection 8 (4) and subsection 23 (2) of the " Act on the Release of Genetically Modified Organisms into the Environment " (RT I 2004, 30, 209).

§ 1. Scope of the Regulation

The regulation establishes the requirements for the content of the information to be submitted to the Ministry of Climate by an applicant for a permit for the release into the environment of genetically modified organisms (hereinafter *GMO*) (*hereinafter permit*) or a marketing permit for a product containing or consisting of genetically modified organisms (hereinafter *product*) (hereinafter product) if new information has become known about the risk of releasing GMOs into the environment or marketing the product. The regulation also establishes the requirements for the content of the information to be disclosed in the event of a risk becoming known.

[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

§ 2. Information to be submitted to the Ministry of Climate upon the emergence of a risk related to the release of GMOs into the environment before or after the granting of a permit for release into the environment

[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

If new information has become known about the risk of releasing a GMO or a combination of GMOs into the environment, the applicant or holder of the permit for the release of GMOs into the environment is required to submit the following information to the Ministry of Climate:

[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

- 1) the application for a permit for the release of GMOs into the environment and the registration number of the permit;
- 2) the name of the GMO causing the risk;
- 3) a description of the risk and possible consequences arising from the release of GMOs into the environment, including the routes of spread of the risk;
- 4) the sources that reported the occurrence of the risk;
- 5) information about the endangered location and the area of impact;
- 6) measures to prevent or avoid the spread of the risk (action plan);
- 7) information about whether GMOs have been released into the environment in a similar way before and to what extent;
- 8) the necessity of preventing access to the endangered area by unauthorized persons;
- 9) if necessary, the deadline for eliminating the expected risk and consequences;
- 10) the person submitting the information (name, contact details).

§ 3. Information to be disclosed in the event of a risk arising from the release of a GMO into the environment

Upon becoming aware of new data on the risk arising from the release of GMOs into the environment, the Ministry of Climate shall publish the following information in at least one newspaper with national circulation:

[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

- 1) the risk arising from the release of GMOs into the environment and its possible consequences;
- 2) the routes of spread of the risk;
- 3) information on whether GMOs related to the risk have already been released into the environment;
- 4) the endangered area and the place of release of the GMO into the environment;
- 5) the marking of the endangered area;
- 6) measures to be taken to protect human health and the environment;
- 7) the expected deadline for eliminating the risk, if necessary;
- 8) the contact person and their contact details.

§ 4. Information to be communicated in the event of a risk arising before or after the granting of a marketing authorisation for a product

Upon becoming aware of new information about a risk arising from the marketing of a product, the applicant for a marketing authorisation or the holder of a marketing authorisation must submit the following information to the Ministry of Climate:

[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

- 1) the application for a GMO marketing authorisation or the registration number of the marketing authorisation;
- 2) the GMO from which the risk arises;
- 3) the name of the product;
- 4) a description of the risk and possible consequences, including the routes of spread of the risk;
- 5) information on whether the GMO or product has actually been marketed, the quantities (volumes) of marketing and the possibility of withdrawing the product from the market;
- 6) the marketing area;
- 7) the health and environmental protection measures to be taken (action plan);
- 8) the necessity of withdrawing the product from the market;
- 9) the deadline for eliminating the risk and consequences, if necessary;
- 10) the sources of new data on the risk;
- 11) the person submitting the information (name, contact details).

§ 5. Information to be disclosed in the event of a risk arising from the marketing of a product

Upon becoming aware of new data on the risk arising from the marketing of a product, the Ministry of Climate shall publish the following information in at least one newspaper with national circulation:

[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

- 1) the risk and possible consequences that have emerged in connection with the marketing of GMOs;
- 2) the routes of spread of the risk;
- 3) the area of distribution of the product;
- 4) the name and description of the product causing the risk;
- 5) measures to be taken to protect human health and the environment;
- 6) the expected deadline for eliminating the risk;
- 7) the contact person and their contact details.

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Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (Official Journal of the European Union L 106 17/04/2001, pp. 1–38).