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Information exchange and consultation with the European Commission on issues related to the release of genetically modified organisms into the environment and the marketing of products containing or consisting of genetically modified organisms¹

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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 word "Ministry of the Environment" has been replaced throughout the text with the word "Ministry of Climate" in the corresponding case.

The regulation is established on the basis of § 30 of the " Act on the Release of Genetically Modified Organisms into the Environment " (RT I 2004, 30, 209).

§ 1. General provisions

(1) The Ministry of Climate shall submit information to the European Commission regarding the release into the environment of genetically modified organisms (hereinafter *GMO*) or the marketing of a product containing or consisting of genetically modified organisms (hereinafter *product*) and, if necessary, shall consult the European Commission on issues related to the release into the environment of GMOs or the marketing of products.

(2) The regulation sets out the requirements for information that the Ministry of Climate is required to submit to the European Commission in addition to the information provided for in the "Act on the Release of Genetically Modified Organisms into the Environment", and the areas in which the Ministry of Climate may consult with the European Commission.

(3) In addition to the provisions of this Regulation, the rules and deadlines set out in 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) must be observed when submitting information to and consulting the European Commission.

§ 2. Submission of information to the European Commission regarding the release of a GMO into the environment or the granting of a marketing authorisation for a product

The Ministry of Climate shall submit to the European Commission:

- 1) information on the granting of a permit for the release of GMOs into the environment or the marketing of a product;
- 2) an overview of the permits granted during the year for the release of GMOs into the environment and the marketing of a product, including rejected applications, by 1 April of the following year;
- 3) applications for a permit for the release of GMOs into the environment and the marketing of a product and comments and reasoned objections made regarding the applications;
- 4) in the event of a refusal to grant a permit for the release of GMOs into the environment and the marketing of a product, the reasons for the refusal;
- 5) an opinion on the application for a permit for the release of GMOs into the environment or the marketing of a product submitted in a Member State of the European Union.

§ 3. Submission of information to the European Commission regarding applications for the release of GMOs into the environment or the extension of product marketing authorisation

The Ministry of Climate shall submit information to the European Commission regarding the receipt of an application for the release of a GMO into the environment or the extension of the marketing authorisation for a product, the comments made on the submitted application, the reasoned objections and the responses provided to them.

§ 4. Information that the Ministry of Climate shall submit to the European Commission after the release of a GMO into the environment or the commencement of marketing of the product

(1) After the start of the release of GMOs into the environment or the product on the market, the Ministry of Climate shall submit to the European Commission:

- 1) reports on environmental monitoring of the release of GMOs into the environment and the marketing of the product;
- 2) new information received from all sources on the impact of GMOs that pose a threat to human health or the environment or on the risk situation related to GMOs;
- 3) if the information referred to in point 2 has been received after the authorisation was granted, a new assessment report on the application for authorisation must be submitted to the European Commission within 60 days of the date of receipt of the new information, together with a position on whether the conditions of the authorisation should be amended or the authorisation revoked;
- 4) comments and reasoned objections made in the assessment reports on the application for marketing authorisation regarding the

continuation of the marketing of GMOs and proposals for amending the conditions of the authorisation within 60 days of the date of receipt of the reports by the Ministry of Climate;

5) a decision of the supervisory authority specified in the “Act on the Release of Genetically Modified Organisms into the Environment” to temporarily restrict the marketing of GMOs present as or in the composition of a product in the territory of its country if, after the granting of the marketing authorisation, proven data have been received that the GMO poses a risk to human health or the environment.

(2) When submitting the information referred to in point 5 of paragraph 1, the European Commission must also be informed of the measures taken.

§ 5. Notification of an infringement to the European Commission

The Ministry of Climate shall inform the European Commission of the illegal release of GMOs into the environment or the marketing of a product or of the violation of the requirements for the release of GMOs into the environment or the marketing of a product, and of the measures to be taken.

§ 6. Periodic reporting

The Ministry of Climate shall submit to the European Commission every three years a report on the measures taken to implement the provisions of Directive 2001/18/EC of the European Parliament and of the Council, including a report on the experience gained in marketing GMOs as or in products.

§ 7. Consultation with the European Commission

The Ministry of Climate shall consult the European Commission on all issues arising in the field of the release of GMOs into the environment and the placing on the market of products, in particular in relation to:

- 1) issues related to the granting or extension of a marketing authorisation for the release of GMOs into the environment or the placing on the market of products and the assessment report;
- 2) new data on the harmful effects of GMOs on human health or the environment become known.

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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).