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Requirements for the content of the environmental monitoring report related to the marketing of genetically modified organisms and products and the procedure for submitting the report

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The regulation is established on the basis of subsection 1 of § 23 of the " Release of Genetically Modified Organisms into the Environment Act " (RT I 2004, 30, 209).

I. GENERAL PROVISIONS

§ 1. Scope of the Regulation

The regulation sets out the requirements for the content of the environmental monitoring report (hereinafter *report*) and the procedure for submitting the report related to the marketing of genetically modified organisms (hereinafter *GMOs*) and products containing or consisting of GMOs (hereinafter *product*) . The report is prepared on the environmental monitoring of GMOs established on the basis of the marketing authorisation.

II. REQUIREMENTS FOR THE CONTENT OF THE REPORT

§ 2. General requirements

(1) The report must comply with the requirements of the monitoring plan specified in the marketing authorisation.

(2) A separate report shall be prepared for each monitoring related to the marketing of a GMO or product.

(3) If necessary, illustrative material must be attached to the report.

(4) The report must include the following:
1) report number and date of submission;
2) marketing authorisation number and date;
3) name, signature, address and registry code of the person submitting the report;
4) status of the report (interim or final report).

§ 3. Information on the GMO marketed or the GMO used to obtain the product

(1) The following information shall be provided in the report on the GMO placed on the market or used to obtain the product:
1) the scientific name of the recipient;
2) the scientific name of the donor;
3) the names and biological functions of the transferred DNA sequences;
4) the integrity of the transferred DNA sequences and the number of copies in the GMO;
5) the unique code of the GMO, if possible.

(2) In addition to the information provided for in paragraph 1, a description of the GMO or product marketed shall be provided.

§ 4. Information to be provided regarding marketing

(1) The report must include information on whether the purpose of the marketing is:
1) import;
2) cultivation;
3) use in environmental protection;
4) use in industry;
5) other (specify).

(2) The following information shall be provided regarding the place, volume and time of marketing of the GMO or product:
1) the region or geographical location(s) of marketing;
2) the quantity of the GMO or product marketed;
3) the duration of marketing.

(3) When marketing a product, the report shall also include the labelling used on the product.

§ 5. Information to be provided regarding environmental monitoring

(1) Information on environmental monitoring must include data on the monitoring strategy, methods, volume, frequency and duration.

(2) The monitoring results report shall include data on the following circumstances:
1) general characteristics and functioning of the GMO;
2) monitoring of vertical gene transfer;
3) monitoring of horizontal gene transfer;
4) outcrossing with traditional crops and wild relatives;
5) possibility of self-sowing and its control;
6) invasiveness;
7) possible effects on target organisms and other organisms;
8) chemical and physical environmental studies;
9) identified direct and indirect, immediate and long-term effects on the environment and human health.

§ 6. Conclusions drawn from environmental monitoring, necessary measures and other information to be submitted

(1) The following information must be provided in the report based on environmental monitoring:
1) whether the monitoring can confirm or refute the assumptions regarding the occurrence and extent of the potential impact of the GMO or product identified during the environmental risk assessment;
2) whether the monitoring has revealed any potential new impact of the GMO or product on the environment or human health compared to the time of submission of the application, including whether the risk has increased, decreased or remained unchanged;
3) whether new information has become known during the marketing of the product regarding the potential impact of the GMO or product on the environment or human health, including whether the risk has increased, decreased or remained unchanged;
4) whether environmental monitoring is planned to be continued after marketing ends.

(2) If monitoring is continued, the monitoring methods, volume, and duration must be described.

(3) The report must also include other information that may be important for the future assessment of the impact of the marketed GMO or product, including any observed positive effects.

III. REPORTING PROCEDURE

§ 7. Procedure for submitting reports

(1) The report must be submitted to the extent and within the deadlines specified in the marketing authorisation.

(2) The report shall be submitted to the Ministry of Climate in writing or electronically.
[RT I, 13.07.2023, 1 - entry into force 16.07.2023]

(3) The Ministry of Climate, as the competent authority, shall organise the submission of the report to the Commission of the European Union.
[RT I, 13.07.2023, 1 - entry into force 16.07.2023]