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Content of the assessment report for the application for marketing authorisation for a genetically modified organism and a product containing it

Adopted on 27.08.2004 No. 108

The regulation is established on the basis of subsection 2 of § 21 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 sets out the requirements for a written assessment report assessing whether a genetically modified organism or a product containing it may be authorised on the market and under what conditions, or whether authorisation to the market will be refused and for what reasons.

§ 2. Information to be provided in the assessment report

(1) When assessing an application for a marketing authorisation for a genetically modified organism (hereinafter *GMO*) or a product containing it, the potential harmful effects of the GMO or the product containing it on human health and the environment must be assessed in particular.

(2) The assessment report shall provide:
1) a description of the GMO or product containing it to be marketed and its use, including the purpose of marketing;
2) a description of the genetic modification;
3) a description of the risk that may arise from the release of the unmodified recipient organism into the environment;
4) an assessment of whether the genetic modification has been sufficiently characterised in the application for marketing authorisation to enable an assessment of the risk to human health and the environment;
5) a description of the risks to human health and the environment that may arise from the release of the GMO into the environment, compared to the release of the corresponding unmodified organism into the environment;
6) the risk management, monitoring plan and labelling planned for the marketing of the GMO or product containing it;
7) information on whether the position of other competent authorities and the European Commission on the environmental risk assessment of the GMO related to the application for marketing authorisation has been examined.

§ 3. Decision presented in the assessment report and its justifications

(1) The assessment report shall state the decision:
1) whether and under what conditions the GMO or a product containing it may be placed on the market;
2) whether the GMO or a product containing it should not be placed on the market.

(2) If, based on the assessment report, the GMO or a product containing it should not be placed on the market, such a decision must be justified.

**Minister of Agriculture
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Chancellor Sulev VARE