Regulations relating to impact assessment pursuant to the Gene Technology Act

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Laid down by Royal Decree of 16 December 2005 pursuant to section 11, cf section 8, of the Act of 2 April 1993 No. 38 relating to the production and use of genetically modified organisms, etc. Submitted by the Ministry of the Environment.

The translation is not official; it is provided for information purposes only. In the event of any inconsistency, the Norwegian version shall prevail.

Chapter 1. General provisions

§ 1. Scope

These regulations govern the content and processing of impact assessments required for deliberate release of genetically modified organisms that is subject to the duty to obtain approval pursuant to section 10, cf section 11, of the Gene Technology Act. They also govern the duty of applicants to carry out investigations during and after deliberate release in order to elucidate its effects, and to report to the authority responsible for granting approval (the competent authority) on the results of such investigations.

The regulations also apply if an impact assessment is required in connection with approval of contained use pursuant to section 8 of the Gene Technology Act.

§ 2. The purpose of impact assessment and the duty to carry out investigations and provide reports

Impact assessment pursuant to the Gene Technology Act is intended to provide a basis for assessing the risk of adverse effects on the environment or human or animal health and other consequences of projects for which approval is mandatory. An impact assessment is intended to ensure that an applicant takes any such effects into account before carrying out a project and that the competent authority has the best possible basis for determining whether and on what conditions to grant approval.
Investigations are intended to confirm that assumptions about the occurrence and magnitude of potential adverse effects of a genetically modified organism or its use are correct, and to identify any adverse effects that were not foreseen in the impact assessment.

Reporting is intended as a means of ensuring that approval for deliberate release and, if appropriate, the conditions on which approval is granted, are altered if new information so indicates.

§ 3. Competent authorities

The competent authority for deliberate release pursuant to section 10 of the Gene Technology Act is the Ministry of the Environment or the instance so authorised by the Ministry. The competent authority for approval for contained use pursuant to section 7, cf section 8, of the Gene Technology Act is the Ministry of Health and Care Services or the instance so authorised by the Ministry.

Chapter 2. Administrative procedures

§ 4. Impact assessment in connection with applications for deliberate release

An impact assessment for the project shall be submitted at the same time as an application for the approval of deliberate release pursuant to section 10, cf section 11, of the Gene Technology Act. The competent authority shall give the applicant written confirmation of the date on which the application and impact assessment were received.

§ 5. Impact assessment in connection with applications for contained use

If the competent authority decides to require impact assessment of any unintended release of genetically modified organisms in connection with contained use pursuant to section 8 of the Gene Technology Act, this requirement shall be laid down without any unnecessary delay after receipt of the application.

A decision to require impact assessment pursuant to section 8 of the Gene Technology Act may not be appealed.

§ 6. Duty of the applicant to provide information

After an impact assessment has been submitted to the competent authority and until a decision has been made regarding the application, the applicant has a duty to inform the said authority of any new information that may be of importance for its decision.

§ 7. Requirement to provide additional information

If the competent authority finds that the impact assessment does not provide an adequate basis for making a decision regarding an application, the applicant may be required to obtain further information and carry out further investigations, cf section 11, second paragraph, of the Gene Technology Act. Grounds shall be given for such a requirement.

§ 8. Time limit for processing applications for deliberate release pursuant to section 9, second paragraph, litrae a-e, and section 10 of the Gene Technology Act

The competent authority shall make a decision pursuant to section 10, first paragraph, cf section 10, second paragraph, of the Gene Technology Act, and Chapter 4 of these regulations, no later than 90 days after receipt of an application.

For the purpose of calculating the 90-day period referred to in the first paragraph, no account shall be taken of any period when the competent authority:

- is awaiting further information it has requested from the applicant,
- is holding a public consultation, cf section 13 of the Gene Technology Act. A public consultation shall not prolong the 90-day period referred to in the first paragraph by more than 30 days.

§ 9. Time limit for processing applications for deliberate release pursuant to section 9, second paragraph, litra f, and section 10 of the Gene Technology Act

The competent authority shall draw up an assessment report that is sent to the applicant no later than 90 days after receipt of the application. At the same time, the authority shall:

a. inform the applicant that the application for deliberate release has been sent to the other EEA states for comment together with a recommendation that it should be approved, or

b. inform the applicant that the application has been refused because the deliberate release does not satisfy the requirements of section 10, first and second paragraphs, of the Gene Technology Act, cf Chapter 4 of these regulations.

For the purpose of calculating the 90-day period referred to in the first paragraph, no account shall be taken of any period when the competent authority is awaiting further information it has requested from the applicant.

In cases such as are mentioned in the first paragraph, litra a, the applicant shall be informed about the decision no later than 30 days after processing of the application has been completed in accordance with the rules of the EEA Agreement, Annex XX, subsection 25, cf. Protocol 1 to the EEA Agreement.

§ 10. Time limit for processing applications for contained use pursuant to section 7, cf section 8, of the Gene Technology Act

The time limit for processing applications for contained use is set out in regulations laid down pursuant to section 7 of the Gene Technology Act.

§ 11. Referral to the Norwegian Biotechnology Advisory Board

The competent authority may refer an impact assessment to the Norwegian Biotechnology Advisory Board for evaluation and an opinion before making a decision, see section 26 of the Gene Technology Act.

Chapter 3. Form of impact assessments

§ 12. Requirements relating to the form of impact assessments

An impact assessment shall be submitted in the form of a single coordinated document.

To ensure that the impact assessment is suitable for consideration by the public authorities, scientific terms shall be defined or explained to the extent necessary, and the assessment shall include a readily understandable summary.

The impact assessment shall contain references to relevant background material, which shall be available to the competent authority.

Chapter 4. Content of impact assessments

§ 13. Impact assessment in the case of a first application for deliberate release for the purpose of placing on the market pursuant to section 9, second paragraph, litra f, and section 10 of the Gene Technology Act

To the extent necessary and practicable, an impact assessment shall give a description of the project in question and an account of the risk and magnitude of any adverse effects on the environment or human or animal health that may arise as a result of the project or any unintended release of genetically modified organisms from the project. The description shall include the information listed in Appendix 1 and an environmental risk assessment in accordance with Appendix 2.

An impact assessment shall specify which safeguard measures have been or will be taken to prevent the project from having adverse effects on the environment or human or animal health.