This is an unofficial translation - please note that only the Danish version has legal validity.

Statutory Order on deliberate release into the environment of genetically modified organisms [1]

In pursuance of sections 9(2), 9a(1), (2) and (4), 13(1), 20(2), 25(1) and (2), and 27(1) of Act no. 356 of 6 June 1991 concerning the environment and genetic engineering, as amended by Act no. 921 of 25 November 1992 and by Act no. 384 of 6 June 2002, the following provisions are laid down:

Part 1

Scope and definitions

Article 1.-(1) This Statutory Order hereby implements Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. The Directive has been included in the Annexes to this Statutory Order.

(2) This Statutory Order concerns:

1) deliberate release of genetically modified organisms for any other purpose than for placing on the market (experimental release), (see section 9(2), no. 1 of the Act, and
2) deliberate release of genetically modified organisms as or in products for the purpose of placing on the market (see section 9(2), no. 2 of the Act).

Article 2.-(1) Genetically modified organisms shall mean plants, animals, microorganisms, cells in cultures or viruses in which the genetic material has been altered in a way that does not occur naturally (see Article 2 of the Directive).
(2) Deliberate release of genetically modified organisms shall mean any intentional introduction into the environment of such organisms for which no specific containment measures are used to limit their contact with, and to provide a high level of safety for the general population and the environment.
(3) Placing on the market shall mean/means making available to third parties. Cases where genetically modified organisms are made available to third parties solely for purposes other than placing on the market (experimental release) or are made available under conditions contained in section 7 and 8 of the Act shall not be regarded as placing on the market.

[1] This Act contains provisions implementing Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ 2001 L 106/1 of 17 April 2001.

Article 3. Experimental release or placing on the market of genetically modified organisms that transfer genes conferring resistance to antibiotics used in human or veterinary medicine shall not be granted approval.

Part 2

Experimental release

Article 4.-(1) Decisions on whether an experimental release may be granted approval or not shall be made by the Minister for the Environment (see section 9(1) of the Act).

(2) Applications for approval for experimental release shall be sent to the Danish Forest and Nature Agency. The application shall be considered in accordance with the procedure laid down in Article 6(5) of the Directive.

(3) After receipt of an application, the Danish Forest and Nature Agency shall carry out a public hearing (see Article 13 below).

Article 5.-(1) Applications for approval of experimental release shall contain the documented information necessary for the processing of the application (see Article 6(2)-(4) of the Directive).

(2) The guidance notes on environmental risk assessments referred to in Annex II to the Directive, and the forms to fill in the summary dossier required according to Article 6(2)(a)(vii) of the Directive, may be ordered from the Danish Forest and Nature Agency.

Article 6. An approval shall as minimum contain an explanation for and an assessment of information relating to the case, including:

1) applicant's name and address, description of the genetically modified organism(s), and the purpose and place for the release.

2) a summary dossier of assessments of the risks to the environment, nature and human health, answers from public hearings, and any statements from the relevant ethics authority (see section 9a(3) of the Act).

3) the Minister for the Environment's assessment of the case.

4) conditions for the carrying out of the experimental release (see section 16 of the Act), and conditions for reporting after the release has been carried out (see Article 10 of the Directive).

Article 7. If any new information has become available regarding the risks of genetically modified organisms to the environment, nature or human health, applicants shall notify the Danish Forest and Nature Agency thereof and take the measures referred to in Article 8(1) of the Directive.

Part 3

Placing on the market

Article 8.-(1) Decisions on whether approval for placing on the market may be granted shall be made by the competent authority of the EU Member State where the genetically modified organism is to be placed on the market for the first time. In Denmark, the decision shall be made by the Minister for the Environment.

(2) Applications for approval shall be submitted to the competent authority in the EU Member State where the genetically modified organism is to be placed on the market for the first time. In Denmark, applications shall be sent to the Danish Forest and Nature Agency.

(3) Applications shall be processed according to the procedure laid down in Articles 13(1), 14, and 15 of the Directive.

(4) The Danish Forest and Nature Agency shall carry out a public hearing according to the provisions in Article 13 below.

Article 9.-(1) Applications for approvals to place on the market shall contain the documented information, described in Article 13(2)-(4) of the Directive, necessary for the processing of the application.

(2) Guidance notes on environmental risk assessments, monitoring plans, and summary forms to fill in the summary dossier required according to Article 13(2)(h) of the Directive may be ordered from the Danish Forest and Nature Agency.

Article 10. Approvals for placing on the market shall contain the information referred to in Article 19 of the Directive.

Article 11. If any new information has become available regarding the risks of genetically modified organisms to the environment, nature or human health, applicants shall notify the competent authority thereof (see Article 8 of the Directive). In Denmark, the Danish Forest and Nature Agency shall be notified. Applicants shall at the same time take the necessary measures referred to in Articles 13(6) and 20 of the Directive.

Article 12.-(1) Applications for renewal of approvals for placing on the market shall be submitted no later than 9 months before expiry of the approval. The application shall be submitted to the competent authority which received the original application. In Denmark, application for renewal shall be submitted to the Danish Forest and Nature Agency.

(2) Applications for renewal shall contain the information referred to in Article 17(2) of the Directive, and shall be considered according to the procedure set out in Article 17(2)-(8) of the Directive.

(3) The Danish Forest and Nature Agency shall carry out a public hearing according to the rules set out in Article 13 below.

(4) Applicants may, until a final decision has been taken as to whether renewal of an approval may be granted, continue to use the original approval (see Article 17(9) of the Directive).

Part 4

Hearing and information

Article 13.-(1) A public hearing shall be carried out before a decision may be taken by the Minister for the Environment with regard to approval for experimental release or placing on the market of genetically modified organisms.

(2) The hearing shall be announced in national newspapers and on the Danish Forest and Nature Agency's website. As regard to experimental release, the hearing shall in addition be announced in local newspapers.

Article 14.-(1) A register of approvals for experimental release and placing on the market granted by the Minister for the Environment, and approvals for placing on the market granted by other EU Member States, shall be established on the Danish Forest and Nature Agency's website.

(2) The register of approvals granted for experimental release shall contain the information mentioned in Article 6 above.

(3) The register of approvals granted for placing on the market shall contain the information referred to in Article 19 of the Directive.

Article 15. The Danish Forest and Nature Agency shall make public on their website the following additional information:

1) Amendments and/or additions to an existing approval granted for experimental release (see Article 8(2) of the Directive).
2) The Minister's use of the safeguard clause in section 17(5) of the Act in cases where there are reasonable grounds for suspecting that an approval under section 9(2), no. 2 or section 9(5) of the Act will entail a risk to the environment, nature and human health (see Article 23 of the Directive).
3) Results of the monitoring of genetically modified organisms released for placing on the market pursuant to Article 20(4) of the Directive.
4) Violation of section 9(1) of the Act (see Article 4(5) of the Directive).

Part 5

Supervision

Article 16.-(1) The Danish Forest and Nature Agency shall carry out supervisory activities to ensure compliance with sections 9 and 14 of the Act and with any conditions required in approvals for placing on the market.

(2) The county council shall carry out supervisory activities to ensure compliance with conditions required in approvals for experimental release. In the City of Copenhagen supervision shall be carried out by Copenhagen City Council; in Frederiksberg Municipality by the city council; and in Bornholm Municipality by the regional council.

(3) The Minister for the Environment may in approvals for experimental release decide that supervision by a county council shall be carried out at specific stages during the experimental release period.

(4) County councils shall report immediately any irregularities to the Danish Forest and Nature Agency.

(5) The provisions of Parts 3 and 4 of the Act shall also apply to supervision and enforcement.

Part 6

Entry in to force and transitional provisions

Article 17.-(1) This Statutory Order shall enter into force on 17 October 2002.
(2) Statutory Order no 1098 of 11 December 1992 concerning the approval of experimental release and marketing of genetically modified organisms shall be repealed.

Article 18.-(1) Outstanding cases concerning approval for experimental release or placing on the market which have not been finally concluded on the day on which this Statutory Order enters into force shall be concluded in accordance with the provisions of this Statutory Order.

(2) Applicants with applications not finally concluded on 17 October 2002 shall add information to their application according to the requirements in Annex II to the Directive about environmental risk assessment, Annex IV about additional information, and Annex VII about monitoring plans, no later than 17 January 2003.

(3) Approvals for placing on the market granted before 17 October 2002 shall lapse on 17 October 2006 unless the holder of the approval has submitted an application for renewal before that date.

Ministry of the Environment, 3 October 2002

Hans Christian Schmidt