

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

## **CONSOLIDATED ENVIRONMENT AND GENETIC ENGINEERING ACT ACT NO.**

This is to promulgate Act no. 356 of 6 June 1991 on the environment and genetic engineering as amended by section 2 of Act no. 921 of 25 November 1992, section 81(2), no. 10 of Act no. 471 of 1 July 1998 (see Statutory Order no. 928 of 13 December 1999), section 41 of Act no. 145 of 25 March 2002, and Act no. 384 of 6 June 2002 amending the Act on the environment and genetic engineering<sup>1</sup>.

### **PART 1**

#### Objectives and Scope

1.-(1) The purpose of this Act is to contribute to safeguarding nature and the environment, thus ensuring sustainable social development in accordance with ethical values and in respect of human conditions of life and for the protection of flora and fauna. The Act shall also seek to protect human health in connection with genetic engineering.

(2) In determining the extent and nature of measures designed to prevent and counteract undesirable effects on the environment, nature and human health, importance shall be attached to the characteristics of the external environment and ecological conditions and to the risks of undesirable effects.

2.-(1) This Act shall apply to the production or use of genetically modified organisms.

(2) Genetically modified organisms shall mean plants, animals, microorganisms, cell cultures and viruses in which the genetic material has been restructured in a way that does not occur naturally.

(3) Genetically modified organisms produced by conventional breeding methods are not covered by this Act.

(4) The Minister for the Environment may lay down rules that specific genetically modified organisms and certain applications involving their use shall be exempt from this Act.

(5) The Minister may lay down rules required for implementation in Denmark of EC regulations on matters covered by this Act.

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<sup>1</sup> This Act contains provisions implementing and authorising the implementation of 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, OJ 2001 L 106/1 of 17 April 2001.

3. This Act shall also apply to the territorial waters and the fishery territory as specified under the Territorial Fisheries of the Kingdom of Denmark Act.

4.-(1) The rules on sale in this Act shall also apply to offering for sale, storage for commercial purposes, tenders and any assignment whether or not against payment.

(2) The rules on production in this Act shall also apply to manufacture, storage, bottling, packaging, repackaging and waste management.

5.-(1) Section 10 below shall not apply to genetically modified organisms intended for export outside the European Communities.

(2) Section 10 below shall not apply to drugs and animal feed.

## **PART 2**

### Approval etc.

6. Genetically modified organisms shall only be manufactured, used, imported, transported, released, sold or placed on the market in the instances provided for in sections 7-10 below, cf., however, section 5 above.

7.-(1) Research involving the production or use of genetically modified organisms shall be conducted only in laboratories or on laboratory premises approved for that purpose pursuant to rules laid down under the Working Environment Act.

(2) Large-scale research involving the use of genetically modified organisms shall be conducted only in plants approved for that purpose pursuant to rules laid down under the Working Environment Act.

(3) The Minister for the Environment shall lay down rules or decide on discharge or transfer of genetically modified organisms from the laboratories, laboratory premises and plants for large-scale research referred to in subsections (1) and (2) hereof, and rules prohibiting discharge or transfer of genetically modified organisms to the environment, and on measures to prevent discharge of transfer.

(4) The Minister for the Environment may lay down rules or decide that exhibitions or other provision of information etc. and specified tests for educational purposes involving genetically modified organisms may be conducted outside the laboratories and laboratory premises specified in subsection (1) hereof.

8.-(1) Production involving genetically modified organisms shall not be commenced without the approval of the Minister for the Environment.

(2) The Minister for the Environment may lay down rules on notification schemes applicable to certain types of genetically modified organisms.

9.-(1) Genetically modified organisms shall not be released without the approval of the Minister for the Environment, cf., however, subsections (3)-(5) hereof.

(2) Approval may be granted for

- 1) deliberate release of genetically modified organisms for any other purpose than for placing on the market, or
- 2) deliberate release of genetically modified organisms as or in products for the purpose of placing on the market.

(3) Medical substances or preparations for human use, which consist of or contain genetically modified organisms, and which are released for the purposes mentioned in subsection (2), no. 1, hereof, shall not require approval under this that if the release has been approved under other Community legislation fulfilling the approval requirements laid down in Article 5 of Directive 2001/18/EC of 12 March 2001.

(4) Placing on the market of genetically modified organisms as or in products, which has been approved under other Community legislation, shall however not require approval under subsection (2), no. 2, above, if the approval fulfils the requirements laid down in Article 12 of Directive 2001/18/EC of 12 March 2001.

(5) Placing on the market of genetically modified organisms as or in products, which has been approved by a country within the European Communities in accordance with the provisions set out in Directive 2001/18/EC of 12 March 2001, shall however not require approval under subsection (2), no. 2 above.

(6) 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.

(7) Placing on the market shall mean 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 or are made available under conditions contained in sections 7 and 8 above shall not be regarded as placing on the market.

9a.-(1) The Minister for the Environment shall consult relevant authorities and organisations regarding approvals for release of genetically modified organisms.

(2) The Minister shall consult the public before a decision in pursuance of section 9 above. The Minister shall lay down more specific rules in this regard.

(3) The Minister may establish an authority which, at the Minister's request, shall give its statement in ethical matters of relevance to this Act.

(4) The Minister shall inform the public about approvals granted under section 9 above, approvals granted under section 17(5) below, and in cases where new information in accordance with section 15(2) below leads to changes in the approval granted under section 9 above. The Minister shall lay down the necessary rules here fore, including rules on the establishment of a register of releases of genetically modified organisms.

10.-(1) Genetically modified organisms, substances and products, containing or consisting of genetically modified organisms, which are not granted approval under section 9(2), no. 2, above, shall not be imported, transported or sold without the approval of the Minister for the Environment.

(2) The Minister may lay down rules that approval under subsection (1) hereof is not required when specified conditions are fulfilled.

11. Repealed.

12. Repealed.

13.-(1) The Minister for the Environment may lay down detailed rules on the approval schemes set out in Part 2 of this Act.

(2) The Minister may lay down rules on transport, storage and waste management etc. of genetically modified organisms.

(3) The Minister of Food, Agriculture and Fisheries shall lay down rules within the framework of Community legislation that severely minimise the risk of genetically modified organisms spreading into other fields, including organic fields.

14.-(1) Where genetically modified organisms are placed on the market in Denmark under section 9(5) above, the holder of the approval or the importer shall notify the Minister for the Environment accordingly, if the approval to place on the market was granted in another Member State of the European Communities.

(2) The Minister may lay down rules on information to be included in the notification and on the form of the notification..

15.-(1) The applicant for approval shall if so directed by the approval authority, supply all relevant information and carry out or commission appropriate investigations, including investigations based on specific guidelines and carried out at specified laboratories. Where the approval authority itself carries out investigations, the applicant may be directed to defray the costs thereof.

(2) Any person to whom an approval was granted shall notify the approval authority beforehand of modifications or additions to the information already submitted. The authority shall then decide whether such modifications or additions require a new approval.

16.-(1) The approval shall lay down conditions on the design, operation, and discharge of the undertaking, conditions restricting transfer of genetically modified organisms to the environment, and conditions governing measures to prevent and counteract undesirable impacts on the environment, nature and human health. Conditions shall also be laid down on own control, monitoring, restrictions of use, and submission of information to the supervisory authority.

(2) The validity of a first-time approval for placing on the market may not exceed 10 years. Other approvals may be granted according to a time limit. This applies both to the approval in its entirety and to individual provisions thereof.

(3) The approval may stipulate a deadline specifying the dates before and after which the approval shall not apply.

17.-(1) The approval authority may change the approval conditions or issue appropriate directives, if justified in the interest of the environment, nature or human health, or in the event of development of cleaner technology, less polluting production methods or improved purification procedures.

(2) For up to four years after an approval was granted, the approval authority may issue orders or prohibitions only if

- 1) new information has come to light on the harmful effects of genetically modified organisms
- 2) the genetically modified organisms have undesirable effects on the environment, nature or human health which could not be foreseen when the approval was granted, or
- 3) other effects on the environment, nature or human health exceed the scope or the provisions forming the basis for the approval.

(3) The approval authority may impose an immediate prohibition if the genetically modified organisms present an imminent danger to the environment, nature or human health.

(4) The approval authority may revise the conditions governing the approval or licensing of an undertaking with a view to improving the undertaking's control of its own discharge or transfer (own control) or to ensuring more appropriate supervision. The provisions of the order may be similarly revised.

(5) The approval authority may temporarily restrict or prohibit the use and sale of genetically modified organisms approved under the rules laid down in section 9(2), no. 2, and section 9(5), above, if there are grounds for supposing that the genetically modified organisms present a risk to the environment, nature or human health.

18.-(1) Any person responsible for undertakings likely to be involved in discharge or transfer of genetically modified organisms to the environment shall at the request of the local council, regional council or the Minister for the Environment supply all information – including economic and accounting details – that is relevant to the administration of this Act.

(2) The local council, regional council or the Minister may order the responsible party at his own expense to:

- 1) take samples and carry out analyses and measurements of the genetically modified organisms discharged or transferred to the environment,
- 2) take samples and carry out analyses of materials and products used or processed, and possible waste substances,
- 3) explain the reasons for or effects of a previous instance where genetically modified organisms were discharged or transferred to the environment,
- 4) explain the remedial or preventive measures to be taken to counteract the effects of such discharge or transfer.

19. The Minister for the Environment may lay down scales of fees to cover in whole or in part expenses incurred by the authorities in matters relating to approval, investigations supervision and control.

### **PART 3**

#### Supervision

20.-(1) The supervisory authority shall supervise the observance of:

- 1) this Act and rules laid down under this Act,
- 2) orders and prohibitions,
- 3) conditions laid down in connection with approvals and conditions laid down in connection with approvals under section 9(5) above.

(2) The Minister for the Environment may lay down rules that supervision shall be carried out by the regional council, the local council or by other authorities.

21. The supervisory authority shall take steps to rectify illegal matters, unless they are of minor significance only.

22. In the cases described in section 21 above the supervisory authority shall serve notice on the party responsible for the existing state of affairs that the illegal matters shall be rectified. To this end the supervisory authority may:

- 1) prohibit the activity,
- 2) order the party responsible to restore, as far as possible, the original situation,
- 3) have the requisite measures taken at the expense of the responsible party, after expiry of the specified time limit.

23.-(1) In case of imminent and serious danger to human health, and where immediate intervention is otherwise required, the supervisory authority shall take the measures required without prior notice and at the account of the responsible party.

(2) Distress can be levied on expenses incurred by the authorities and recoverable under section 22, no. 3, above and section 23(1) hereof.

24.-(1) Any person responsible for activities or arrangements under sections 7-10 and section 13 above shall forthwith notify the supervisory authority and public health officer of any interruption or accident in operations likely to result in discharge or transfer of genetically modified organisms which are potentially harmful to or present a risk to the environment, nature or human health.

(2) Notification under subsection (1) hereof shall not reduce the obligation of the responsible party to prevent or counteract the consequences of interruption of operation, and does not exempt him from the obligation to restore the original situation as far as possible.

25.-(1) The Minister for the Environment may lay down rules on the conduct of supervision by the supervisory authority.

(2) The Minister may lay down rules requiring the local councils and the regional councils to submit reports on their supervision activities, including results of measurement and investigations, and may lay down rules on the form of such reports.

## **PART 4**

### Administrative provisions

26.-(1) Decisions under this Act shall be communicated in writing to the party responsible for the state of affairs in question.

(2) Decisions shall at the same time be communicated in writing to:

- 1) persons, institutions, organisations and authorities entitled to lodge complaints, cf. section 30 below, and
- 2) other authorities involved.

(3) Notification to the private individuals referred to in subsection (2) no. 1 hereof may take the form of a public announcement.

27.-(1) The Minister for the Environment may authorise an agency under the Ministry or similar institution to exercise the powers vested upon the Minister under this Act.

(2) The Minister may lay down rules on the title to complain against decisions taken under the authorisation provided for in subsection (1) hereof, and decide that the decisions cannot be brought before the Minister.

(3) After negotiations with the Minister involved, the Minister for the Environment may lay down rules on collaboration by other authorities or institutions in the undertaking of functions under this Act. Subsections (1) and (2) hereof shall apply correspondingly.

(4) In the City of Copenhagen and Frederiksberg municipalities the local council shall discharge the functions assigned to the regional council under this Act, or under rules laid down under the provisions of this Act.

28.-(1) In specific cases of wider-ranging importance the Minister for the Environment may decide that decisions under this Act shall be made by the Minister rather than by the regional council.

(2) The Minister may direct the regional councils and the local councils to take up matters, including concrete cases, under this Act for consideration and decision.

(3) Acting on his own initiative the Minister for the Environment may refer any decision taken by a local or a regional council for closer examination and subsequent ruling.

29.-(1) Environment authorities and persons authorised by them have, where deemed necessary, at any time and upon proof of identity without a court order, access to public and private properties and localities to discharge the functions assigned to them under this Act or under rules laid down under the provisions of this Act.

(2) The police shall assist in such matters. The Minister for Justice may after negotiations with the Minister for the Environment lay down rules on such assistance.

(3) The authorities may take samples with a view to subjecting the genetically modified organisms to closer examination. Such samples shall be taken without remuneration, and any parties possessing genetically modified organisms shall, if so requested and without remuneration extract, package and submit samples for examination, as specifically directed by the supervisory authority.

(4) In connection with the activities specified in subsections (1) and (3) hereof, the responsible parties involved and the persons working in the undertaking shall afford the environment authorities all necessary guidance and assistance.

## **PART 5**

### Complaints

30.-(1) Complaints against decisions taken under this Act or under rules laid down under the provisions of this Act may be lodged by:

- 1) the party to whom the decision is directed,
- 2) any party having an individual, significant interest in the outcome of the case, and
- 3) the regional councils and local councils involved.

(2) The public health officer, the Danish Society for Nature Preservation, the Danish Angling Society, the Danish Fisheries Association and the Danish Sea Fisheries Association may appeal against decisions taken under section 8 above, under section 17 above as regards undertakings covered by section 8 above, and decisions under section 32 below.

(3) The Danish Consumer Advisory Council and the Economic Council of the Danish Labour Movement may appeal against decisions taken under sections 8, 10, and 17(1)-(4) above, and section 32 below.

31.-(1) The limit for lodging complaints is four weeks from the day the decision was notified to the party concerned. Where notification was made by public announcement the time limit shall be calculated from the day the decision was announced, cf. section 26(3) above, irrespective of the date of individual notification, where such was given. If the time limit expires on a Saturday or a public holiday, the limit shall expire on the following workday.

(2) Approval granted under section 10 above shall not be used before the expiry of the time limit for complaints.

(3) A complaint against approvals notified under section 10 above shall have suspensive effect until the decision of the appeal authority is taken or until otherwise decided by the appeal authority.

(4) In approval cases under section 8 above the approval authority may decide that the approval shall not be used before the expiry of the time limit for complaint, and that, if complaints are lodged within this time limit, the approval shall not be used pending a ruling by the appeal authority.

(5) The Minister for the Environment may lay down rules on suspensive effects under subsection (4) above, and rules that complaints against the decision of the approval authority may not be lodged with other administrative authorities.

(6) Complaints against orders or prohibitions shall have suspensive effect, pending the decision of the appeal authority or until such time as otherwise directed by the appeal authority.

(7) The authority responsible for taking the decision on issuing an order or prohibition may, however, where specific grounds exist, at the same time direct that the order or prohibition be complied with, irrespective of complaints. Irrespective of complaints against this decision, the order or prohibition shall be complied with until such time as the appeal authority directs otherwise.

(8) Complaints shall be lodged with the authority making the decision, and by that authority be transmitted to the appeal authority together with the material on which review of the case was based, cf., however, section 34(3) below.

32. Complaints against the decisions of the local councils under this Act or under rules laid down under the provisions of this Act may be lodged with the Minister for the Environment, cf., however, section 33 below and section 27(2) and (3) above.

33.-(1) Complaints against the decisions of the approval authority under section 15(2) above may not be lodged with other administrative authorities. The same shall apply to decisions taken pursuant to section 17 above with respect to decisions relating to approvals granted under section 9(2), no. 2 and 9(5) above.



(2) Complaints against the decisions of the supervisory authority under section 22 above may not be lodged with other administrative authorities.

34.-(1) The Environmental Appeal Board set up in pursuance of the Environmental Protection Act is the authority of complaints against administrative decisions under this Act to the extent specified in subsection (2) below. The rules stipulated in the Environmental Protection Act for the activities of the Environmental Appeal Board apply correspondingly to the amendments laid down under the rules of this Part.

(2) Complaints may be made to the Environmental Appeal Board against:

- 1) decisions under sections 8 and 32 above made by the Minister for the Environment or by Agencies empowered to this effect, and
- 2) decisions under section 28(1) and ( 3) above made by the Minister for the Environment or by Agencies empowered to the effect.

(3) Complaints may be lodged directly with the Environmental Appeal Board.

35.-(1) The review of complaints shall be carried out by expert members appointed by the Minister for the Environment for terms of up to four years. The number of members appointed shall be fixed by the Minister for the Environment. The members shall be appointed by the Minister upon the recommendation of:

- 1) The Confederation of Danish Industries, the Economic Council of the Danish Labour Movement, the Federation of Smaller Industries, the Agricultural Council, the Federation of Danish Agricultural Societies, the Federation of Danish Smallholders' Societies jointly,
- 2) the Danish Environmental Protection Agency in cooperation with the Danish Forest and Nature Agency, the Danish Environmental Research Institute and the Danish Veterinary and Food Administration.

(2) Decisions in each individual case shall be made by the Chairman or a deputy and two or four appointed members. The appointed members shall be designated by the Chairman with equal representation of the two groups specified in subsection (1) hereof. Decisions shall be by majority vote.

(3) The Minister may lay down rules on the composition and activities of the Board with respect to the review of cases under this Act.

## **PART 6**

### Penalties Entry into Force and Transitional Provisions

36.-(1) Unless more severe penalty is due under other legislation, non-compliance with the following provisions shall be liable to a fine:

- 1) violation of sections 6, 7 or 31(2) above,
- 2) commencement or conduct, without prior approval, of activities covered by sections 8-10 above,
- 3) disregard of conditions governing an approval under this Act, or disregard of conditions governing an approval under section 9(5) above.
- 4) failure to comply with a prohibition or order under this Act, including orders to rectify illegal matters,

- 5) failure to provide samples in accordance with section 29(3) above or to submit information under sections 15 and 18 above,
- 6) failure to give notification under sections 14, 15(2) and 24 above,
- 7) obstruction of self-help measures pursuant to section 22(1) no. 3, and section 23 or obstruction of the law under section 29 above,
- 8) causing damage to or endangering the environment, nature or human health by irresponsible handling of genetically modified organisms.

(2) The penalty may be increased to imprisonment for up to two years if the offender acted deliberately or by gross negligence or if the infringement resulted in:

- 1) damage to the environment, nature or human health, or risk of damage, or
- 2) achieved or intended economic advantages, including savings, for the offender or for others.

(3) For violation of sections 6, 7(1) and (2), 8, 9(1) and (5), and 10(1) above, fines may be imposed on a manufacturer, importer or the owner or operator of an undertaking, even if the violation cannot be attributed to deliberate intent or gross negligence. Where fines are imposed, no provision shall be made for alternative sentences.

(4) In rules laid down under sections 2(5), 7(3) and (4), 8(2), 10(2), 13(2) and 14(2) above, fines may be imposed. In addition it may be decided to increase the penalty to imprisonment for terms of up to 2 years under circumstances similar to those mentioned in subsection (2) hereof.

(5) Companies etc. (legal persons) may be held criminally liable under the rules set out in Part 5 of the Danish Criminal Code.

(6) The period of limitation of criminal liability is 5 years for violations etc. specified in subsection (1) no. 1 and no. 3 hereof.

37. Violations shall be subject to police prosecution. The remedies contained in Part 73 of the Administration of Justice Act may be applied as in actions brought by the public prosecutor.

38.-(1) This Act shall enter into force on 23 October, 1991. As from the same date Act no. 288 of 4 June, 1986 on Environment and Genetic Engineering shall be repealed.

(2) Rules laid down under the old Act shall remain valid until they are replaced by new rules under this Act. Violations of the rules shall be punished pursuant to the rules applying before the entry into force of this Act.

(3) Decisions made pursuant to the rules currently in force shall remain valid until new decisions are made under this Act or under rules issued under this Act. Violations of such decisions shall be punished pursuant to the rules applying before the entry into force of this Act.

(4) The Minister for the Environment may lay down transitory provisions.

39.-(1) This Act shall not apply to the Faroe Islands and to Greenland

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Act no. 921 of 25 November 1992 amending a number of environmental Acts (The Home Rule of Greenland's authority regarding the marine environment etc.), which amends section 39 above, contains the following provisions regarding entry into force:

3. This Act shall enter into force on 1 January 1993.

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Under the provisions of section 81 of Act no. 471 of 1 July 1998 on food, the Minister for Food, Agriculture and Fisheries is granted authority to repeal sections 11 and 12 above. This amendment entered into force 1 January 2000 under the provisions of Statutory Order no. 928 of 13 December 1999.

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Act no. 145 of 25 March 2002 amending a number of Acts following the merging of Bornholm's municipalities, which amends section 27 above, contains the following provisions regarding entry into force:

78.-(1) This Act shall enter into force on 1 January 2003 (see however section 79(1) of this Act)  
(2) (Omitted).

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Act no. 384 of 6 June 2002 amending the Act on the environment and genetic engineering, which amends sections 1, 5, 6, 8, 10, 13, 14, 16, 17, 20, 24, 33, 34, 35, and 36 above, and inserts the new sections 9 and 9a above, contains the following provisions regarding entry into force:

2.-(1) This Act shall enter into force on 17 October 2002.

(2) Rules laid down under the old Act shall remain valid until they are repealed or replaced by new rules under this Act

(3) Outstanding applications for approval under the old section 9(2), which have not been concluded by 17 October 2002, shall be processed according to the rules in this Act or the rules laid down in pursuance hereof.

*Ministry of the Environment*

Hans Christian Schmidt