

Unofficial translation of Danish**Bill on sharing benefits arising from the utilisation of genetic resources**

- 1.** The objective of this Act is to ensure the sharing of benefits from the utilisation of genetic resources with the provider of the genetic resources and with the parties in possession of the traditional knowledge significant to this utilisation.
- 2.** In this Act, genetic resources is understood to mean the functional inherited properties of the organism and naturally occurring biochemical substances which are a result of genetic expression or metabolism of the organisms.

(2) Utilisation is understood to mean to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology. Utilisation is also understood to mean development and marketing of products based on genetic resources.
- 3.** The utilisation of genetic resources is prohibited when these resources have been acquired in contravention of the legislation on access to genetic resources in the country from which they originate.
- 4.** The utilisation of genetic resources is prohibited when this use is based on the traditional knowledge of the indigenous peoples and this knowledge is acquired in contravention of legislation on access to traditional knowledge associated with genetic resources in the country from which the utilised resources or traditional knowledge originate.
- 5.** The Danish Minister for the Environment may make regulations on procedures and standards that must be followed to ensure compliance with the prohibitions in Sections 3 and 4, including regulation on digitisation of these.
- 6.** The Danish Minister for the Environment may make regulations on reporting the collection of genetic resources from wild organisms in Denmark, including information on the intended utilisation. The Danish Minister for the Environment may specify that this is done electronically.
- 7.** The Danish Minister for the Environment shall carry out supervision to ensure compliance with this Act and regulations issued in accordance with this Act.
- 8.** The Danish Minister for the Environment and persons authorised by the Minister shall, upon presentation of appropriate ID, have the right of access without court order to public and private properties and sites in order to exercise the powers provided by this Act or in regulations issued in accordance with this Act. Wherever possible, prior notification shall be given to the owner or user.

(2) Subsection 1 shall not apply to buildings or parts of buildings that are exclusively used as private residences.

(3) During inspections of commercial enterprises, the owner and employees shall provide the authorities with the necessary guidance and help when requested.

9. The Minister for the Environment may authorise an agency established as part of the Ministry or, after negotiation with the relevant ministers, other state authorities to exercise the powers conferred on the Minister by this Act.

(2) The Minister may make Regulations concerning the right to appeal decisions made on the basis of powers conferred in accordance with subsection 1, including that such decisions may not be appealed.

(3) The Minister may also make Regulations concerning the exercise of powers conferred on another state authority after discussion with the relevant minister pursuant to subsection 1.

10. The Government may conclude agreements with foreign States on common measures to comply with the objectives of the Act.

(2) The Minister for the Environment shall make regulations to comply with international agreements concluded in accordance with subsection 1.

(3) The Minister for the Environment may make the necessary regulations on the application in Denmark of the European Union Regulations concerning matters covered by this Act.

(4). The Minister for the Environment shall make regulations to comply with the European Union Directives and Decisions within the area of the Act.

11. Unless a higher penalty is applicable in accordance with other legislation, a fine shall be imposed on anyone who infringes Sections 3 and 4.

(2) The penalty may increase to imprisonment of up to two years if the infringement has been committed intentionally or due to gross negligence and, as a result of the infringement, an economic advantage has been obtained or is intended to be obtained for the party concerned or others.

(3) Regulations issued pursuant to the Act may specify that a fine shall be imposed on anyone who violates the provisions of these regulations.

(4) Companies etc. (legal entities) may be penalised in accordance with the rules in Chapter 5 of the Criminal Code.

(5) If the benefit achieved through the infringement is not confiscated, consideration shall be made of the size of the financial benefit achieved or strived towards when determining the fine, including a supplementary fine, cf. subsection 2.

(6) The statute of limitations for criminal liability is five years.

(7) In cases involving infringement of the Act and regulations issued in accordance with the Act, searches may be carried out in accordance with the regulations on this under the Danish Administration of Justice Act.

12. The Act will enter into effect as determined by an Order issued by the Minister of the Environment.

13. This Act shall not apply in the Faroe Islands and Greenland.

General notes

Background to the Bill

The Bill implements the requirements placed on parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. The Bill shall ensure that Denmark is able to ratify the protocol.

The Convention on Biological Diversity was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio Earth Summit), and it entered into force on 29 December 1993. The three main objectives of the Convention are the conservation of biological diversity, the sustainable use of the components of biological diversity and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

To further advance the implementation of the third objective, the World Summit on Sustainable Development (Johannesburg, September 2002) called for the negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of genetic resources. This regime should safeguard against “biopiracy”, where uncontrolled collection of genetic resources has taken place in countries with high biological diversity in contravention of the country’s right to decide on their biological resources, for use as medicines, cosmetics or other utilisation in developed countries, without the developing country from which they originate receiving a share of the benefit from the utilisation of the resource.

The Protocol significantly advances the Convention’s third objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. Specific obligations on compliance with domestic legislation or regulatory requirements of the party providing genetic resources and contractual obligations reflected in mutually agreed terms are a significant innovation of the Protocol. These compliance provisions as well as provisions establishing more predictable conditions for access to genetic resources will contribute to ensuring the sharing of benefits when genetic resources leave a party providing genetic resources. In addition, the protocol’s provisions on access to traditional knowledge held by

indigenous and local communities when it is associated with genetic resources will strengthen the ability of these communities to benefit from the utilisation of their knowledge, innovations and practices.

By promoting the use of genetic resources and associated traditional knowledge, and by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biodiversity, sustainably use its components and further enhance the contribution of biodiversity to sustainable development and human well-being.

The Protocol is based on the regulations in Article 15 of the Convention on Biological Diversity, which sets out the sovereign rights of states to demand that access to genetic resources takes place on the basis of prior informed consent and under mutually agreed terms. The countries are expected to legislate on these requirements if they request prior consent. Consent under public law and an agreement on terms for sharing benefits therefore form the basis for the utilisation of the genetic resources. The Protocol compels the parties to ensure that the utilisation of the genetic resources takes place in accordance with both the requirement for consent and the terms agreed for utilisation of the resources. The Bill contains the rules that shall ensure compliance with the requirement for consent, and that an agreement on terms is entered into, while compliance with the agreed terms will be brought before the courts as civil legal proceedings on breach of contract.

Main contents of the Bill

In its ratification of the Convention on Biological Diversity, Denmark declared that it would not request prior consent for collecting genetic resources in Denmark. There is no plan to change this, and there is therefore no reason to implement the provisions of the Protocol aimed at provider countries requiring prior consent. This concerns, among others, Articles 6-8. On the other hand, it has been suggested that a reporting system is introduced for the collection of genetic resources from wild species. This will provide the information on these resources which can identify them in further stages and will allow them to be tracked in the same way as genetic resources originating from countries requiring prior consent, and their legal status to be reported to the global "clearing house" set up under the Nagoya Protocol. For countries requiring prior consent, the Protocol stipulates that they enter information on consent in this "clearing house" in order for the resources to be tracked and their legal status documented in subsequent stages during utilisation of the resources.

In addition, the Bill includes the rules placed on the user country by the Protocol. The main content of these requirements is for the user countries to ensure that the genetic resources are not used in contravention of legislation in the countries from which they originate. Therefore, the Bill contains prohibitions which reflect the rules on access to genetic resources and to traditional knowledge associated with the genetic resources in the countries from which the resources originate.

The Protocol contains requirements for setting up at least one checkpoint in each country for collecting information on the legal status of genetic resources used for research, development or marketing of products based on genetic resources. In Danish patent legislation, the Order on

patent applications already contains a provision requiring the applicant to state the origin of genetic resources forming the basis of a patent application. This regulation will be expanded to ensure that the information required under the Protocol is reported to the global “clearing house”. In addition, the establishment of further checkpoints will be sought, where it can be ensured that the genetic resources used in Denmark were acquired in accordance with the legislation in the countries from which they originate.

The Bill does not place any new requirements on the institutions and businesses which use genetic resources, in that it simply introduces sanctions in Danish law which reflect the regulations institutions and businesses must already comply with in the countries providing the genetic resources they use.

The financial and administrative consequences for the government sector

The Government receives increased fees to report the information sent to the global register from checkpoints under the Protocol, as well as to follow up the referrals from providing countries which may have grounds to believe that Danish institutions or businesses have infringed their legislation. At the current time, it is estimated that these consequences, including the introduction of a reporting duty when collecting genetic resources in Denmark, will be a work load of approx. 0.6 years for one employee, corresponding to DKK 0.5 million. With the simultaneous introduction of the duty to report collection of genetic resources from wild organisms in Denmark, there will be a one-off cost for development of electronic reporting of DKK 0.3-1 million.

Financial and administrative consequences for the business sector

The Bill does not place any new obligations on the business sector, but contains a reflection of the requirements set out in legislation in the countries from which the genetic resources are collected. Therefore, the Bill has no financial or administrative consequences for the business sector.

Administrative consequences for citizens

The Bill has no administrative consequences for citizens.

Environmental consequences

The Bill has no environmental consequences.

Relationship to EU law

The EU Commission has commissioned an investigation of the potential need for EU legislation to comply with the Nagoya Protocol. The Bill does not anticipate the considerations on potential EU legal regulation in the area, as it only contains the regulations that can be implemented in national legislation to comply with the Nagoya Protocol. The Bill contains authorisation for the Minister to set rules which realise future EU legislation in the area. The Bill therefore has very limited aspects of EU law. As Denmark will not request prior consent for collecting genetic

resources in Denmark, implementing the Bill means it complies fully with the requirements in the protocol.

Relationship to other legislation

There is no other legislation aimed at genetic resources. Denmark has signed up to the UN FAO's International Treaty on Plant Genetic Resources for Food and Agriculture, but this has not led to a need for legislation. The Bill does not contain any provisions that affect the implementation of the FAO treaty.

Explanatory notes to the individual provisions of the Bill

To Section 1

The objective of the Bill, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, is to ensure that there is a fair and equitable sharing of the benefit arising from utilisation of the genetic resources with the countries from which the resources originate. This will contribute to a conservation of the resources and biological diversity and to a sustainable exploitation of nature.

To Section 2

The provision in subsection 1 covers the definition of genetic material contained in the Convention on Biological Diversity. This also covers the naturally occurring biochemical substances that are a result of the genetic expression or substance renewal in the biological resources.

The provision in subsection 2 corresponds to the Protocol's definition of utilisation. It is during this utilisation that a benefit of the genetic resources arises, and thus the need for sharing this benefit.

To Section 3

The provision implements the Nagoya Protocol's requirement for the parties to ensure compliance with the requirements in place in the countries from which the resources originate, which is essentially stated in Article 15 of the Protocol. By introducing a Danish prohibition against the utilisation of genetic resources acquired in contravention of the legislation in the country from which the resources originate, it is possible for Denmark to reflect the legal regime prevailing in the providing country. The Protocol requires the parties to introduce effective and proportional provisions to prevent infringement of the providing country's rules. The provision shall ensure that agreements are entered into on the utilisation of resources and on sharing the benefit their utilisation with the countries from which the resources originate. While infringement of the agreed terms does not mean an infringement of the prohibition, a complete failure to agree such terms could, depending on the legislation in the providing country, be an infringement of the prohibition.

To Section 4

The Nagoya Protocol contains provisions for the protection of the rights of the native population to the traditional knowledge associated with genetic resources. Similarly, the provision reflects the rules on the rights of the native population in the countries which are home to indigenous populations, as required under Article 16 of the Protocol. The provision shall ensure that agreements are entered into with this population on the utilisation of their knowledge and on sharing the benefit of using this knowledge. In the same way as for the prohibition in Section 3, complete omission of the requirement to enter into an agreement on the utilisation of traditional knowledge held by native populations could mean an infringement of the prohibition in Section 4.

To Section 5

The provision makes it possible to require institutions and businesses which use genetic resources to arrange fixed procedures, routines and standards that ensure the

resources used are acquired in accordance with the regulations in the country from which they originate. A duty of care can thus be stipulated, including the requirement that transactions of genetic resources shall be accompanied by a statement on the legal status of the resources. This type of regulation becomes an object of control in itself, regardless of whether or not the access regulations in the providing countries may be infringed. The provision is suggested in order to comply with anticipated EU legal requirements on such “due diligence” schemes.

To Section 6

In its ratification of the Convention on Biological Diversity, Denmark declared that it would not request prior consent for collecting genetic resources in Denmark. A requirement for prior consent has been introduced recently in Greenland, although the Bill does not plan for a corresponding requirement to be established in Denmark. The provision is expected to be used to place a requirement on the reporting of the collection of genetic resources in Denmark. This type of reporting would provide data which can ensure the traceability of these genetic resources and thus facilitate the implementation of the Nagoya Protocol’s objective of safeguarding the sharing of benefit arising from utilisation of genetic resources from the countries requiring prior consent.

A requirement for reporting collection will only apply to genetic resources from wild organisms and will therefore not affect the breeding and cultivation work using genetic resources in agricultural businesses and the fishing industry.

To Section 7

The Danish Minister for the Environment shall carry out supervision to ensure compliance with this Act and regulations issued in accordance with this Act. This supervision is expected to be allocated to the Danish Nature Agency. The supervision will be based on the information sent to the checkpoints in relation to the Act and referrals from providing countries which suspect infringement of their regulations on access to genetic resources and to traditional knowledge associated with genetic resources.

To Section 8

The provision contains the access rules necessary for an effective implementation of the supervision. Subsections 1 and 2 correspond to Section 50(1) and (2) of the Danish Hunting and Wildlife Management Act and Subsection 3 corresponds to Section 76 (3) of the Danish Nature Protection Act.

To Section 9

The provision is expected to be used to allocate administration of the Act to the Danish Nature Agency.

Subsections 2 and 3 correspond to provisions in other legislation by the Ministry. There are no provisions in the Act which give reason for decisions, but the issuing of Orders meaning decisions are made cannot be excluded. The provisions make it possible, if it becomes relevant, to decide that decisions cannot be appealed.

To Section 10

The provision makes it possible to enter into and comply with international agreements on shared data collection and exchange of data for use in the implementation of the Nagoya Protocol, for example. The Protocol creates a designated Clearing House under the secretariat for the Convention on Biological Diversity.

The provision also makes it possible to implement the regulations that could be issued in connection with the EU's adoption of the protocol.

To Section 11

The provision contains legal basis for sanctioning infringement of the prohibitions in Sections 3 and 4 with penalties. The provision corresponds to the criminal rules that are common to environment law legislation.

While an infringement of the provisions of the Act reflects an infringement of the provisions of the legislation of the providing country on prior consent for collecting genetic resources and for the utilisation of traditional knowledge associated with these resources, an infringement of the mutually agreed terms for utilisation of the genetic resources or the traditional knowledge shall be prosecuted via civil legal proceedings. Formal infringement of the providing country's legislation on entering into mutual agreement on utilisation, including sharing of benefit, will represent an infringement of the prohibition in Section 3 and 4.

To Section 12

The Act is implemented to ensure that Denmark is able to ratify the Nagoya Protocol such that Denmark can participate in the Protocol party meetings and take part in the decisions made at the first party meeting. A collective adoption of the Protocol across the EU would be appropriate, but a Danish ratification before the EU's adoption is possible if the Protocol enters into effect before the EU is ready for a collective adoption. It is therefore proposed that the Act can enter into effect according to the Minister of the Environment's Order.

To Section 13

This Act shall not apply in the Faroe Islands and Greenland.