

## **GMO regulation in Denmark**

**Avosetta meeting, Siena September 2006 – by Peter Pagh**

### **Questions 1-2; National regulatory approach to GMO in the Member States; Executive competencies in the Member States**

The Danish legislation on Genetically Modified Organisms (GMOs) goes back to the 1986 Act on Environment and Genetic Engineering. The Act was adopted by the Parliament in attempt to establish an adequate regulatory response to the uncertainties and risks from the new technology. The 1986 Act was in 1991 replaced by Act no. 356 of 6 June 1991 on Environment and Genetic Engineering intended to implement Directive 90/219 and Directive 90/220. To implement the new Directive 2001/18 on deliberately release into the environment of genetically modified organisms and repealing Directive 90/220 the Danish 1991 Act was reversed by Act no. 384 on 6 June 2002 on amendments to the 1991 Act on Environment and Genetic Engineering.

The Danish Act on genetic engineering establishes the legal frame to control laboratory genetic engineering and any manufacturing, distribution and use of GMOs. The Act covers Directive 90/219 on contained use of genetic modified microorganisms as well as Directive 2001/18 on the deliberately release into the environment of genetic modified organisms. The Act is a framework legislation leaving a wide discretion for the Minister of the Environment regarding required information, procedures and criteria governing decision making.

Authorizations of deliberately release, manufacturing, import, transport and use of GMOs are issued by the Danish Minister of the Environment. The application for the authorization must be send to the National Forest and Nature Agency. Before the last revision in 2002 the authorization of manufacturing of GMOs was left to the regional councils but since 2002 the authorization power is in the Ministry.

The Act does not contain detailed procedures regarding manufacturing, transport and research but leaves it to the Minister of the Environment to decide detailed procedures. Regarding authorization of deliberately release of GMOs, the 1991 Act is more specific. As part of the decision making process, the agency must consult effected authorities and NGOs (business as well as green organizations) and before the final decision is made, the Parliamentary Committee on Environment and Physical Planning is notified on the draft decision. This prior notification of the Parliament is not required directly under the Act but has since the 1986 Act become an established procedure which have been followed in all cases. By the 2002 revision, prior public hearing was made mandatory under section 9a(2) of the Act.

Since the first Act in 1986, the Danish authorities until 2003 had made decisions in 40 applications for experimental release. Authorization for experimental release was granted regarding, genetic modified potatoes, corn, rape, sugar beet and fodder turnip. Regarding marketing of GMOs, the Danish EPA has only received one application for placing on the market of modified fodder beet. The application has been submitted to the EU Commission in accordance with Directive 90/220, but because of the stand-still moratorium final decision has not been made within the EC. Denmark has until now no experience on commercial farming with GMOs.

Regarding coexistence between GMO farmers and conventional and organic farmers, the Parliament adopted Act no. 436 of June 9 2004 on farming of GMO plants. The Act has two objectives: (1) to establish a legal framework to regulate the coexistence and (2) to establish a compensatory regime guarantee conventional farmers compensation from the State for damage caused by GMO crops.

### **Question 3 Implementation and enforcement of Directive 2001/18**

The Act on Environment and Genetic Engineering doesn't include any direct reference to the precautionary principle. The Act requires a permit from the Minister and permit for deliberately release can only be issued in accordance with Directive 2001/18. As a framework legislation, the Danish Act on Environment and Genetic Engineering leaves wide discretion for the Minister of the Environment in decision making. The Act doesn't include legal principles or substantial criteria which in particular concerns authorization of placing on the market of GMOs. The only guidance for the discretion of the authorities is found in section 1 of the Act on objectives, which says:

“[1] the purpose of this Act is to contribute to safeguarding nature and the environment, thus ensuring a sustainable social development in accordance with ethical values 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 health, importance shall be attached to the characteristics of the external environment and ecological conditions and to the risks of undesirable effects”<sup>1</sup>

Thus, the legal principles governing the decision making are rather unspecific. The overall object is to avoid *undesirable effects*. The term “undesirable effects” doesn't itself provide any guidance. However, the term replaced in the 1991 Act the earlier term “harmful” in the 1986 Act which indicates more discretion for the authorities. To fill out the meaning of the term in this context, there are four key word of importance in section 1 of the Act: (1) *sustainable development*, (2) *safeguard nature and the environment*, (3) *ethical values*, and (4) *risks*.

As legal principles governing the decision making, the keywords are weak. The legal implication of *sustainable development* is disputable, but at least the principle requires that the effect on future generations must be taken into account. “Safeguard nature and the environment” can be read as a reference to the *prevention principle*. The principle is reflected in the authorization scheme. According to section 1(2), the application of the principle in decision making requires to take into consideration the sensitiveness of nature.

The term “risks” is a vague indication of the application of *the precautionary principle*. The wording indicates only an option - not an obligation - for the Minister and the Danish EPA to apply the precautionary principle. However, according to papers presented before the

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<sup>1</sup> *Ethical values* was amended at the 2002 reverse of the Act. The limitation to *Danish environment* was withdrawn to ratify the Bio Safety Protocol to the Rio Convention on biodiversity and the consideration of *nutrition* also was withdrawn at the reverse. The translation is based on the official English translation of the Act made by the Environmental Protection Agency.

Parliament at the 2002 reverse of the Act, its mandatory for the authorities to apply the precautionary principle. According to these papers, the precautionary principle shall be interpreted as: where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reasoning for postponing measures to prevent environmental degradation. Authorization can be denied, if the knowledge on the effect on the environment of placing GMOs on the market is insufficient. The interpretation of the precautionary principle differs from the Rio Declaration principle 15 and the Communication of the EU Commission on the precautionary principle [Com(2000)1 final] because it disregards cost-effective aspect, but seems in all other aspects in accordance with the Communication of the Commission and how the principle is applied in the new Directive 2001/18 on deliberately release into the environment of GMOs.

### ***“Ethical values***

“*Ethical values*” was amended as a new consideration by the 2002 reverse of the Act based on the 9th considerations of the preamble to the new GMO Directive. What is meant by taken ethical considerations was explained more in detail before the Parliament and is based on a Parliamentary debate in year 2000 regarding ethical values and genetic engineering. According to the Minister of Environment, the ethical assessment must include: (1) *economic benefits as well as qualitative benefits* as life quality, public health benefits derived from the use of GMOs; (2) *autonomy, dignity, integrity and sensitivity*, which intends to reflect the right of selfdetermination of human beings and the integrity and vulnerability of animals and nature; (3) *a faire allocation of benefits and burdens*, meaning that the use of GMOs must not prevent a reasonable allocation and must take into account future generations as well as developing States and other States; (4) *codetermination and transparent*, meaning that decisions on use or not use and release GMOs must be open, transparent and based on a contradictory process based on mutual respect. How these general concepts will be integrated in future decision making is not clear. Although ethical values were emphasised during the Parliamentary debate, the statements and responses were all kept very abstract and seems not operational in a decision making process regarding a concrete authorization of a specific GMO. However, based on the discussion within the Parliament its expected the Minister of the Environment in accordance with section 9a(3) of the Act will establish a Committee on Ethical questions regarding GMOs and that this Committee will be consulted during the decision making process. So in practice, it will be up to this - not yet established - Committee to fill out the application of ethical values based on these general statements. Its not yet clear, whether consultation of this ethical Committee will be mandatory, restricted to certain types of authorization or optional for the Minister of the Environment. Anyhow, its for the Minister to decide, whether the consultation will be optional.

### ***Public participation***

When the Act on Environment and Genetic Engineering was reversed in 2002 a provision on public participation was adopted. According to section 9a(2) of the Act public hearing is mandatory prior to any permit and leaves for the Minister of the Environment to decide detailed rules for such public hearings. The provision is in accordance with the Directive 2001/18, article 9(1). The principle of information of the public required under the new

Directive 2001/18, article 9(2) has also been implemented in the Danish Act [section 9a(4) and (5)].

### ***Access to court***

Decisions regarding release of GMOs can be brought before and administrative appeal board – the Environmental Appeal Board by the parties and by some few NGOs.

### ***Penalties***

Violation of the Act on Environment and Genetic Engineering is subject to criminal sanctions which in case of serious offences include imprisonment up to two years and in extreme cases 4 years. The legal provisions on criminal sanction follow the same pattern as other Danish environmental legislation. – but is more theory than practice.

### ***Liability***

Denmark has not adopted any legislation on liability for marketing or use of GMOs – and how Denmark will implement the Environmental Liability Directive is not known.

### ***Administrative scheme***

Authorization of experimental release and other decisions on deliberately release of GMOs including placing on the market are governed by the Ministerial Ordinance no. 1098 of 11 of December 1992 on authorization of experimental release and marketing of GMOs as amended by Ministerial Ordinance no. 800 from 1994 and Ministerial Ordinance no. 630 from 1997. As the Directive 90/220, the Ministerial Ordinance on authorization of experimental release and marketing of GMOs, distinguish between experimental release and non-experimental release of GMOs. The Ministerial Ordinance does not contain provisions on principles governing when authorization are denied or can be granted but is restricted to procedural rules defining: [a] what information has to be provided in applications for authorization; [b] what has to be included in the authorization; [c] the obligation of the holder of the authorization to inform the Agency on new information on risks; [d] the supervision authorities. Regarding authorization to place a GMO on the market, the Ministerial Ordinance section 5(1)(2) requires the application includes a risk assessment of the potential impact on the environment, nature and human health. According to the Ministerial Ordinance section 9(2), the authorization of the Minister of the Environment must include an assessment of the information presented by the applicant including an assessment of the environmental and health risks related to marketing and release of the GMO. Thus, ***the principle of risk assessment*** can be deduced from the procedural rules of the Ministerial Ordinance as a governing principle for authorization of marketing of GMOs. As the Ministerial Ordinance is formulated, the risk assessment does not require the identified potential undesirable effects are placed on a scale (hazards, dangerous, medium). Regarding likelihood of the potential identified consequences, the Ministerial Ordinance requires information on the likelihood of unexpected or undesirable characteristic will develop in the released GMO as well as information on the likelihood of changes in the biological interaction with the released GMO. But except for these requirements on estimations of likelihood the Danish legislation does not include further provisions on likelihood or a scale of the likelihood of the potential identified consequences (likely, less likely, likely to zero). During the 2002 revision of the Danish Act

on Environment and Genetic Engineering, the principle of risk assessment under the new Directive 2001/18 and its implication were presented before the Parliament - not as part of the reversed Act, but as information on how the Minister of the Environment expected to implement the new Directive. The obligation to provide a risk assessment in accordance with the new Directive 2001/18 article 2(8) and Annex II, is expected to be integrated in a reversed Ministerial Ordinance on authorization for experimental release and marketing of GMOs.