

GMO Management in Austria

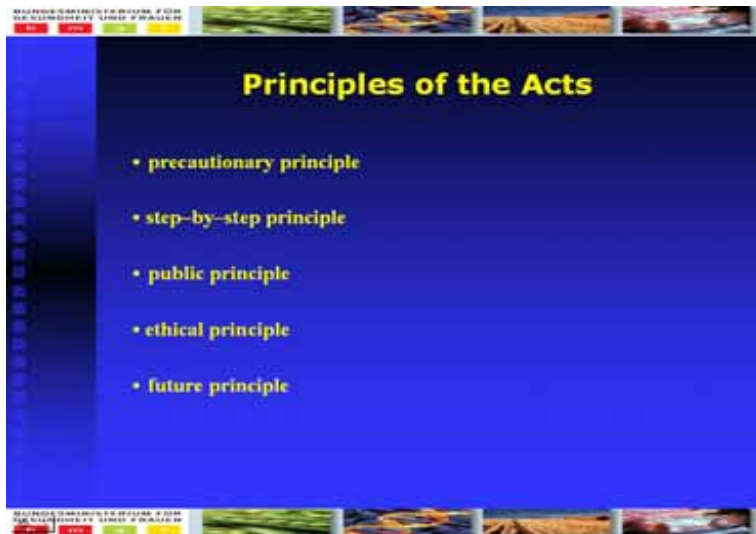


In this talk, the Gene Technology Act, as well as the required by-laws (e. g. ordinances, guidelines) of the Republic of Austria will be explained in detail.



The Austrian Gene Technology Act came into force in 1995. The act is based on the EU-Directive 90/219/EWG (contained use of genetically modified microorganisms), and on the EU-Directive 90/220/EWG (deliberate release of GMO in the environment). Since this time the act was amended twice. The first emendation was in the year 1998 because of the result of an referendum against genetically manipulated food, deliberate release and patents on life in 1997, which was signed by more than 1 million citizens. The emendation concerned about questions of liability. The second emendation in 2002 has to be done because of the emendation of the EU-directive 90/219/EWG with the directive 98/81/EG.

The Austrian act has two major aims. The first aim is to protect humans and the environment of adverse effects of genetically modified organisms and the second one is to encourage the applications of genetic engineering for the benefit of humans. Therefore it is laid down by the Austrian act, that research on biosafety issues has to be financed by the competent authority (CA).



Five principles are the basis for the Austrian act.

1.) The precautionary principle. This means that work with and deliberate release of GMO into the environment are only allowed if no adverse effects for safety are expected.

- 2.) Step-by-step principle. This means, that for an intended deliberate release of a GMO the stringency of the containment has to be eased stepwise, and the next step is only allowed if the assessment of this step fits with the precautionary principle.
- 3.) Public principle. The public has to be involved in the execution of the law and the public information and participation has to be encouraged. A good example of the public principle is the first emendation of the law as a result of the mentioned referendum in 1997.
- 4.) Ethical principle. This principle ensures, that when genetic testing or gene therapy is performed, human dignity has to be perpetuated. The responsibility of humans for animals, plants, and the environment has to be in mind.
- 5.) Future principle. This means, that, considering the safety, research on genetic engineering and the implementation of their results has not to be interfered.



The Austrian Gene Technology Act lays down the basic regulation for the following fields of genetic engineering and biotechnology. The contained use of GMO, deliberate release of GMO and placing on the market, the composition and the tasks of the advisory body as well as the liability for damages due to genetic engineering and the fines for violating the law. A unique feature of the Austrian law is, that genetic testing and gene therapy on humans is also regulated. Predictive genetic testing is only allowed in accredited facilities and the procedure for accreditation is very stringent.

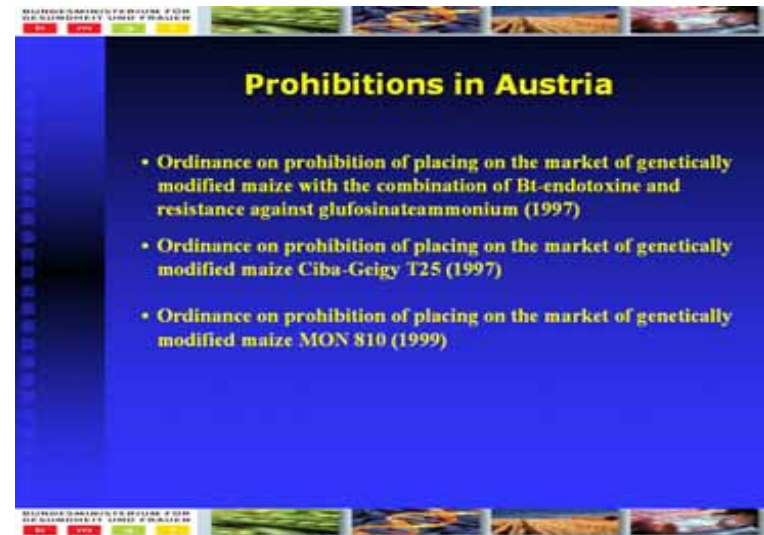


Since the Austrian act is only regulating the basics, accompanying regulations are essential. In Austria there are a lot of accompanying regulations, mainly as ordinances, which are laying down the rules for work with GMO in depth. The ordinance on work with GMO in the contained use came in force in 1996 and was amended in 2002 due to the implementation of the EU directive 98/81/EG. In this ordinance, the procedure for risk assessment, the levels of containment, the needed equipment and the needed safety precautions for work with GMO according to the four biosafety levels are explained.

The ordinance on deliberate release is the complement to the above mentioned ordinance for cases of release and placing on the market of GMO. It came into force in 1997

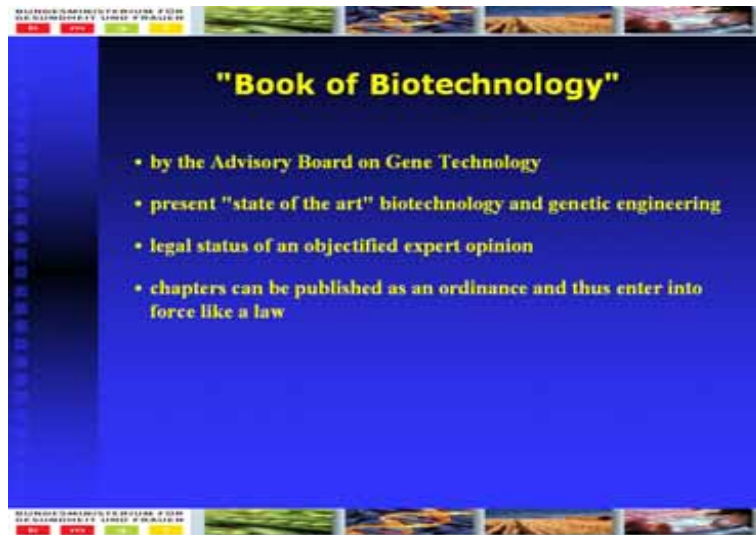
The ordinance on public hearings, which came into force in 1997 and was amended in 1998 based on the referendum, regulates the proceedings of a public hearing.

The ordinance to protect employees from adverse effects of biological agents, which came into force in 1998, is not a GMO specific regulation, but since GMO are also biological agents, this regulation has also to be executed, when working with GMO in the contained use. This regulation also contains a list of classification of biological agents into the four biosafety levels. Other regulations concerning the work with, or products made of or containing GMO are the ordinance on labeling of genetically modified seed (1999), the ordinance on labeling of products that contain GMO (1998) and the ordinance regulating the limitation for emissions in waste water resulting from work with GMO in the contained use (1997).



Three additional ordinances are in force in Austria. These ordinances dealing with the prohibitions for placing on the market of some GM maize in Austria.

It is prohibited to place on the market GM maize with an combination of Bt-endotoxine and resistance against glufosinateammonium (1997), the GM maize Ciba-Geigy T25 (1997) and the GM maize MON 810 (1999).



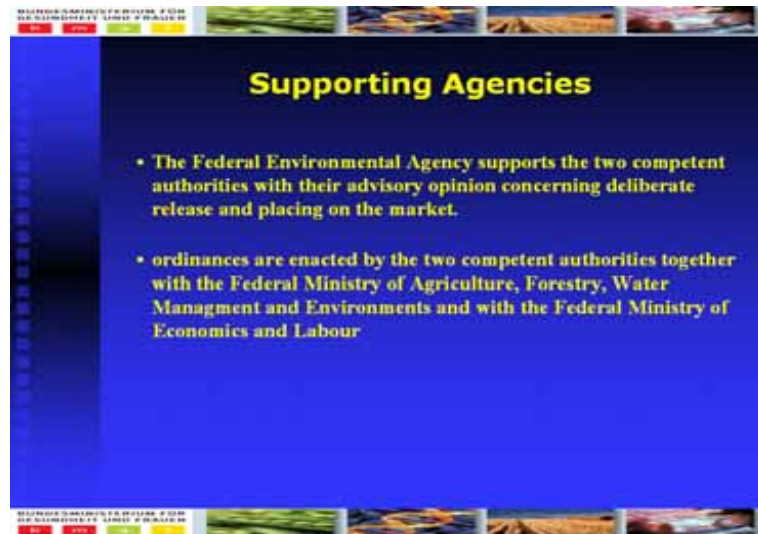
Due to the rapidly evolving nature of research a legislation on genetic engineering has to be able to react quickly on the newest results of research. Therefore the „Book of Biotechnology“ was established according to article 99 of the Austrian law. The chapters of this book, are the results of the scientific committees of the advisory board and present the „state of the art“ biotechnology and genetic engineering. Although this chapter are not an official law, the have the status of an objectified expert opinion and work as binding guidelines. In some cases in can be reasonable to publish chapters of this book as ordinances.



The Austrian GMO register, which is called „Register of Products containing GMO“ continuously lists up those products that have been approved under Directive 90/220/EC following the procedures of Article 13. This register has been made public on the ministries homepage.

There are two competent authorities in Austria. The main competent authority is the Federal Ministry of Health and Women. This CA is responsible for all applications from the private sector, inspections and for applications concerning genetic testing and gene therapy. Also all of the legislative work is done by this

ministry and it is the office of the advisory body. The second competent authority is the Federal Ministry for Education, Science and Culture. This CA is responsible for applications from universities, excluding genetic testing and gene therapy.



Additional to the CA the Federal Environmental Agency supports the two competent authorities with their advisory opinion concerning deliberate release and placing on the market. Ordinances are enacted by the two competent authorities together with the Federal Ministry of Agriculture, Forestry, Water

Management and Environment and with the Federal Ministry of Economics and Labor.



The advisory board on Gene technology consists of members from politics, science, philosophy, theology and NGO. The tasks of the advisory board are to give advice to the CA concerning genetic engineering and biotechnology, the approval of chapters of the „Book of Biotechnology“ etc.

Three scientific committees (contained use, deliberated release and placing on the market and genetic testing and gene therapy) are advise the CA at decision making.



Another system for executing the Austrian act in praxis is laid down by the law. It is the system of internal control. Therefore every facility, that works with GMO in the contained use, has to have an internal biosafety committee. This biosafety committee has to prove all the work that is done in the premises. Also a biological safety officer (BSO) is mandatory for each facility. The tasks of the BSO are laid down in the law. The BSO is the person responsible for the compliance of the work with the law.



Sometimes, when the law is violated, fines are needed. The fines are also laid down in the law. There are three categories. The first one is up to 7 260 € and can be given for work without notification or permit, when an company has no BSO, BSC or safety precautions.

The second category goes up to 21 800 € and can be given, when a company deliberate release GMO or place GMO on the market without permit.

The highest fines, up to 36 300 € can be given, when someone abuses data from human genetic testing.