USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network

Voluntary Report - public distribution

Date: 10/23/2003

GAIN Report Number: AU3014

Austria

Biotechnology

Status of Biotech Regulations

2003

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Report Highlights:
Austria's strong consumer-based biotech opposition influences government regulators to develop anti-biotechnology laws, rules and regulations. Science-based pro-biotech discussions with government regulators provide no change in consumer opinions and thus no change in Austrian laws, rules and regulations. To change Austrian anti-biotech laws, rules and regulations, consumer opinion must change. Austrian consumers perceive that America is forcing them to consume biotech products rather than their own organic products. One anti-biotech politician recently published an article for school children stating, "organic products not only are healthier for you, but as everyone knows, they also taste better."

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Vienna [AU1]
[AU]

Summary

Austria's current legislation prohibits the marketing of all products derived from agricultural biotechnology, although industry and agricultural businesses import significant quantities of soybean meal. EU biotech regulation in theory should supersede Austrian rules. However, only in July 2003 did the European Commission (EC) announce infringement proceedings against member states including Austria, for failing to adopt and notify national legislation implementing an EU law on the deliberate release of genetically modified organisms (GMOs) into the environment. It remains to be seen whether the EC will more vigorously enforce community-wide rules after new EU regulations on traceability and labeling (T&L) and food and feed (F&F) enter into force next year. Only rigorous EC enforcement of the regulations could make the Austrian legal environment for ag biotech more predictable. Austrian public attitudes toward biotech remain inimical. As a result, policy makers and other opinion leaders, even scientific experts, are loathe to challenge the anti-biotech consensus to provide sound and balanced information.

The following relevant EU regulations are applicable in Austria:

-- Directive 2001/18/EC on the deliberate release of genetically modified organisms (entered into force in October 2002, but will be amended by new "coexistence" language when T&L and F&F enter into force);

-- Regulation on Novel Foods and Novel Food Ingredients (258/97/EC, 1139/98/EC, 49/00/EC, 50/00/EC);

-- Directive on the contained use of genetically modified micro-organisms (90/219/EC);

-- Directive on the legal protection of biotechnological inventions (98/44/EC);

-- EU Directives on seeds and varieties;

-- Regulation on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (2092/91/EC).

Austria Not Yet In Favor Of Lifting The Moratorium

Austrian Members of the European Parliament played an influential role on drafting the final wording of the T&L and F&F regulations, which is likely to enter into force in April 2004. Austria is also among those EU member states that support a moratorium to temporarily ban the placing on the market of genetically modified maize and oilseed (rape) products. Even with T&L and F&F implementation, the GOA is unlikely to vote in favor of lifting the ban. It is among member states pushing the question of "coexistence" between biotech and conventional and organic crops (community rules instead of national legislation) as a reason to delay implementation. Moreover, Austrian provinces are defiantly proclaiming the introduction of "GMO-free zones" (although the EU Commission has declared a draft law in Upper Austria inconsistent with EU law), if coexistence cannot be guaranteed.

Austria has ratified the Cartagena Protocol on Biosafety that entered into force on September 11, 2003. EU Directive 2001/18/EC and the upcoming T&L and F&F regulations regulate the implementation and the Biotechnology Act (see below).

Austrian Biotechnology Act Applies "Precautionary Principle"

Within the EU, Austria introduced some of the strictest domestic policies and regulations with regard to agricultural biotechnology with the 1995 Biotechnology Act (Law Gazette No 510/1994, in force since January 1, 1995, as amended by version 94/2002). This law implements EU directives in this field but also goes further. It severely limits the contained use of genetically modified organisms (GMO's), the deliberate release of GMO's into the environment, and the placing on the market of products that contain GMO's. The precautionary principle applies. Each deliberate release or placing on the market of products that contain GMO's is subject to approval. In practice, the GOA has so far approved no/no product containing GMO's. Moreover, the law also regulates the application of biotechnology in human medicine.

Coexistence

Another draft to update the Biotechnology Act is already in the works in order to implement EU Directive 2001/18/EC (the EU Commission has already instituted action for infringement of the directive against Austria). The draft amendment may include some wording on "coexistence." The new law is not likely to enter into force before 2004. The draft should go to Parliament in October or November and may enter into force along with the T&L and F&F legislation.

Several ministerial ordinances based on the Biotechnology Act further regulate this field. The most important ones are:

-- the Ordinance on Deliberate Release of GMO's into the Environment (Law Gazette II, No 49/1997), which spells out the requirements for environmental release;

-- the Ordinances on Labeling of products that contain GMO's (Law Gazette II No 59/1998) and on Labeling of Genetically Modified Seeds (Law Gazette II No 74/1999), which prescribe mandatory labeling for products that contain GMO's or consist of mixtures of both modified and non-modified organisms;

-- the Ordinance on Contamination of Seeds by Genetically Modified Organisms (Law Gazette II No 478/2001), which sets a 0.1% threshold for adventitious GMO "contamination" in seeds. This ordinance is likely to be modified once the EU introduces new "contamination" legislation on Novel Seed with thresholds between 0.3 and 0.7%; and

-- the Ordinance on safety regulations when working with GMO's in closed systems (Law Gazette No II 431/2002).

Ban On Monsanto Seed Varieties

The GOA introduced three additional ordinances in 1997, 1999, and 2000 to ban imports of corn seed varieties developed by three companies (Ciba-Geigy, Monsanto, Novartis). The GOA

claimed it adopted these measures in accordance with Article 16 of the EU Directive 90/220/EEC (predecessor of 2001/18) on the deliberate release of GMO's. The EU Commission, however, had approved these varieties for placing on the market, and questioned the scientific justification of the ban.

Details On Deliberate Release And Market Placement

The authorities monitor/enforce by carrying out checks and inspections. The law requires removal or confiscation of any GMO released or placed on the market without approval. In most cases, the deliberate release and the placing on the market of products of agricultural biotechnology is an administrative offence that entails a fine of 21,800 Euro, according to Art. 109 of the Biotechnology Act.

With regard to deliberate release and placing on the market of agricultural biotech products the law applies relevant EU regulations (see para 2 and 3). In addition, the current Biotechnology Act stipulates the following procedures:

-- Deliberate release: the release has to follow a "step-by-step" approach (small-scale tests, then large tests). The applicant must provide information about the genetic and pathogen characteristics of the GMO, the preconditions of the release, the interaction between the GMO and the environment, surveillance measures, time frame and place of the test. The province and the municipality where the release is planned may also issue a statement in the procedure.

--Placing on the market: In order to get a product approved, the applicant must specify the item and the GMO it contains, describe the changes that the GMO causes, explain possible safety risks, and provide an inspection and emergency plan. In addition, the applicant should refer to special conditions for the use of the product, estimate the number of imports from and production in other EU/EEA countries, suggest packaging of the product in order to prevent unintentional multiplying of the GMO during storage, and make a proposal for labeling of the product. Appropriate packaging and labeling of the product is mandatory. The label must contain the marking of the product and its GMO, the name of the producer or importer, a statement on specific characteristics of the product that were caused by the GMO, a description of the use of the product, a statement on safety measures that will be taken in case of unintentional spread or misuse of the product, and instructions on storage and handling of the product.

Responsible Authorities

The department for Biotechnology in the Ministry for Health and Women has the principal responsibility to enforce and monitor biotech laws. The Department shares responsibilities with the Ministry of Agriculture, and Forestry, Environment and Water Management, which is in charge of negotiations on biotechnology measures at the EU level. The Federal Environment Agency releases expert opinion on deliberate release and environmental effects of GMO's in the name of this ministry. The Ministry of Social Security, Generations and Consumer Protection and the Ministry of Education, Research and Culture are involved on certain aspects as well.

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