

The GMO Imperative

Dr. Eva Claudia Lang

Austrian Federal Ministry of Health, Dep. II/B/15

„Protecting an Promoting Real Food“-Conference
22 February 2013, Krakow

Overview

- History
- Risk assessment of GMOs
- Independent Risk Research activities
- National bans of GMOs
- New legislative acts – Art. 26b („opt-out“)
- New Austrian strategy – ecological sensitive areas
- GM-free food & feed production in Austria

History

- 1995 – Austria joined the EU, Austrian Gene-Technology Act was set into force, implementing relevant EU-Directives
- 1996 first deliberate release notifications in AT
- huge public awareness and protest against it
- 1997 referendum against GM-use in food & feed, signed by 1.2 million people in AT → amendment of Gene-Technology-Act!
- 1998 AT's first EU-Presidency, aiming at amending Directive 2001/18/EC! (uncertainty concept introduced!)

History

- 1997 first national ban on GM-maize Bt 176, 2008 product obsolete/withdrawn from the market
- 1999 national ban on GM-maize MON810, still valid!
- 1998 up to now: other bans on maize, potato, oilseed rape were set into force
- 2006 AT's second EU-Presidency: promoting the „precautionary principle“
- 2009 AT & NL-initiative on possibility for MS to restrict or prohibit cultivation of GMOs in their territory

Risk assessment of GMOs

- § 1 of national Gene-Technology Act: ...„protection of humans and environment“...
- AT uses efficient scientific network for risk assessment of GMOs consisting of experts covering all relevant disciplines for GMFF & ENV-aspects
 - Austrian Agency for Health and Food Safety (AGES)
 - Task Force GMO coordinates AT-position
 - Umweltbundesamt Wien GmbH
 - external experts (University)

Risk Research Activities

- § 102 of national Gene-Technology Act aims at promoting and financing risk research activities in the field of GMOs
- CA is obliged to finance RA-projects!
- Federal Ministry of Health financed from 1995 to 2012 around 60 scientific reports (in the past also sometimes in cooperation with Ministry of Agriculture (BMLFUW))
- Results of studies used in scientific statements of AT

Risk Research Activities

- Focus of risk research projects: Biodiversity, outcrossing, ecology, toxicology, allergenicity, socio-economy
- International activities of AT: 2009 initiation of SCAR-Collaborative Working Group „Risk Research on GMOs“ , supported by 20 MS (also Poland!)
- Aiming at:
 - Identification of EU-research priorities,
 - Identification of existing knowledge and research institutions
 - Promoting independent risk research
 - Initiation of international research cooperations

Risk Research Activities

- 2012 CWG finished
- EC started a call (KBBE.2013.3.3.5.-02) „GMO ERA-Net – preparatory action“: max. 1 Mio. €, Aim: Consolidation/strengthening of GMO-risk research activities in Europe
- Further Information on SCAR-CWG „GMO-Risk-Research“:

[http://www.bmg.gv.at/home/Schwerpunkte/Gentechnik/Fachinformation Allgemeines/SCAR Collaborative Working Group Risk Research on GMOs](http://www.bmg.gv.at/home/Schwerpunkte/Gentechnik/Fachinformation>Allgemeines/SCAR_Collaborative_Working_Group_Risk_Research_on_GMOs)

GMO - placing on the market

- Comprehensive risk assessment of GM-dossiers + results of risk research studies → basis for decisions of Federal Ministry of Health in regulatory committees and on national bans of products
- Since 2004 more than 111 new GM-dossiers, additional 20 „renewal“-dossiers
- Around 50 products got market approval

GMO - placing on the market

- EU Register of authorised GMOs:
http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
- AT GM-Register acc. to § 101 c Abs. 1 und 2 GTG
idgF:
http://www.bmg.gv.at/cms/home/attachments/8/4/8/CH1060/CMS1282037703208/gentechnikregister_07_2012.pdf

Legal basis of AT bans

Article 23 of Dir. 2001/18/EC - “Safeguard clause”:

Where a Member State, as a result of **new or additional information** made available since the date of the consent and affecting the environmental risk assessment **or reassessment of existing information on the basis of new or additional scientific knowledge**, has detailed grounds for considering **that a GMO** as or in a product which has been properly notified and has received written consent under this Directive **constitutes a risk to human health or the environment**, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

AT bans of GMOs

- In Austria currently 6 import- respectively cultivation-bans are in force:
 - maize MON 810 for cultivation since 1999
 - maize T 25 for cultivation since 2000
 - Amflora-potato for cultivation since 2010

 - GT 73 oilseed rape for import since 2006
 - maize MON 863 for import since 2008
 - Ms8xRf3 oilseed rape for import since 2008
- The bans also cover kernel/tubers, arising from crossing of the respective GM-line with other lines!

Future aspects of national bans of GMOs

- Now only two products for cultivation are in the pipeline acc. to Dir. 2001/18/EC: maize 1507 and Bt11-maize → Art. 23-bans of MS are possible to invoke!

- All the rest is notified acc. to Regulation (EC) No. 1829/2003!

→ only the possibility of Article 34 „Emergency measures“ :

Where **it is evident that products** authorised by or in accordance with this Regulation are likely to **constitute a serious risk to human health, animal health or the environment**, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.

„Opt-out-initiative“

- ENV-Council Conclusions 4th Dec. 2008
„POINTS OUT that in accordance with Community law, which includes the precautionary principle, regions with specific agronomical and environmental characteristics, including small isolated islands, may require particular case-specific management or restrictions measures, including prohibition measures for GMO cultivation.“
- 2009 AT & NL-initiative on possibility for MS to restrict or prohibit cultivation of GMOs in their territory
- 2010 EC presents „GMO-package“, including proposal on implementing a new Art. 26 b „opt out“ in Dir. 2001/18/EC

„Opt-out-initiative“

- Negotiations since 2010, outcome still open...
- Current mechanism:
- **phase 1:** during authorization procedure of a GMO a MS may request the notifier to adjust the geographical scope in a way, that parts or all of the territory of that MS is excluded from cultivation.
- **phase 2:** after a GMO/groups or all GMO got market-approval under Dir. 2001/18/EC and/or Reg. 1829/2003, MS has the opportunity – under the precondition that these measures taken are in conformity with Union law, are reasoned, proportional, non-discriminatory and does not conflict with environmental RA – to restrict or prohibit cultivation on its territory.

„Opt-out-initiative“

- reasonable grounds for justification of such measures:
 - Environmental policy objectives or other legitimate factors!
 - Regional and local dimensions of land use
 - Local agricultural structures
 - Protection or maintenance of habitats, ecosystems and landscape
 - Town and country planning
 - Socio-economic impacts
 - Coexistence

„Opt-out-initiative“

- Advantage of this model:
 - Phase 1: simple way of opt out by writing a letter requesting that the territory of the MS is excluded from geographical scope
 - Phase 2 offers the possibility to ban cultivation of all other GMOs that got already approval for placing on the market
 - Only a simplified notification procedure to EC, which plays the part of a consulter of the MS.
- Current state of play:
 - ENV-Council of 9th March 2012: 21 MS in favour of this proposal, **F,SP,UK,D,B,SK** against! → blocking minority (91 votes).
 - ENV-Council in June 2012: only progress report, no political agreement

Ecological sensitive areas

- New AT strategy: developing a scientifically justified definition of ecologically particularly sensitive areas in Austria regarding the cultivation of GM maize
- The bases for this approach can be found in the respective European legislation which allows **considering, on a case-by-case basis, ecologically particularly sensitive areas** when imposing certain measures, e. g. restrictions, on GMO cultivation.
- Legal basis: Article 6 (5) e) and Article 18 (5) e) of Regulation (EC) No. 1829/2003 stipulates that “conditions for the protection of particular ecosystems/environments and/or geographical areas” may be **included in the opinion of EFSA.**
- Another Reference is made in Directive 2001/18/EC in Article 19 (3) c)

Ecological sensitive areas

- These conditions can comprise restrictions and even prohibitions of cultivation as stated in conclusions of the Environment Council in 2008 (Council of the European Union 2008). The same Council Conclusions further mention particular ecosystems or geographical areas!
- In order to define, for the first time, ecologically particularly sensitive areas **a catalogue of criteria was developed** by the AT EPA (Umweltbundesamt) and **indicators defined**, which are to be used as a tool to make the selection clear and reproducible (Research projects of BMG & BMLFUW).

Ecological sensitive areas

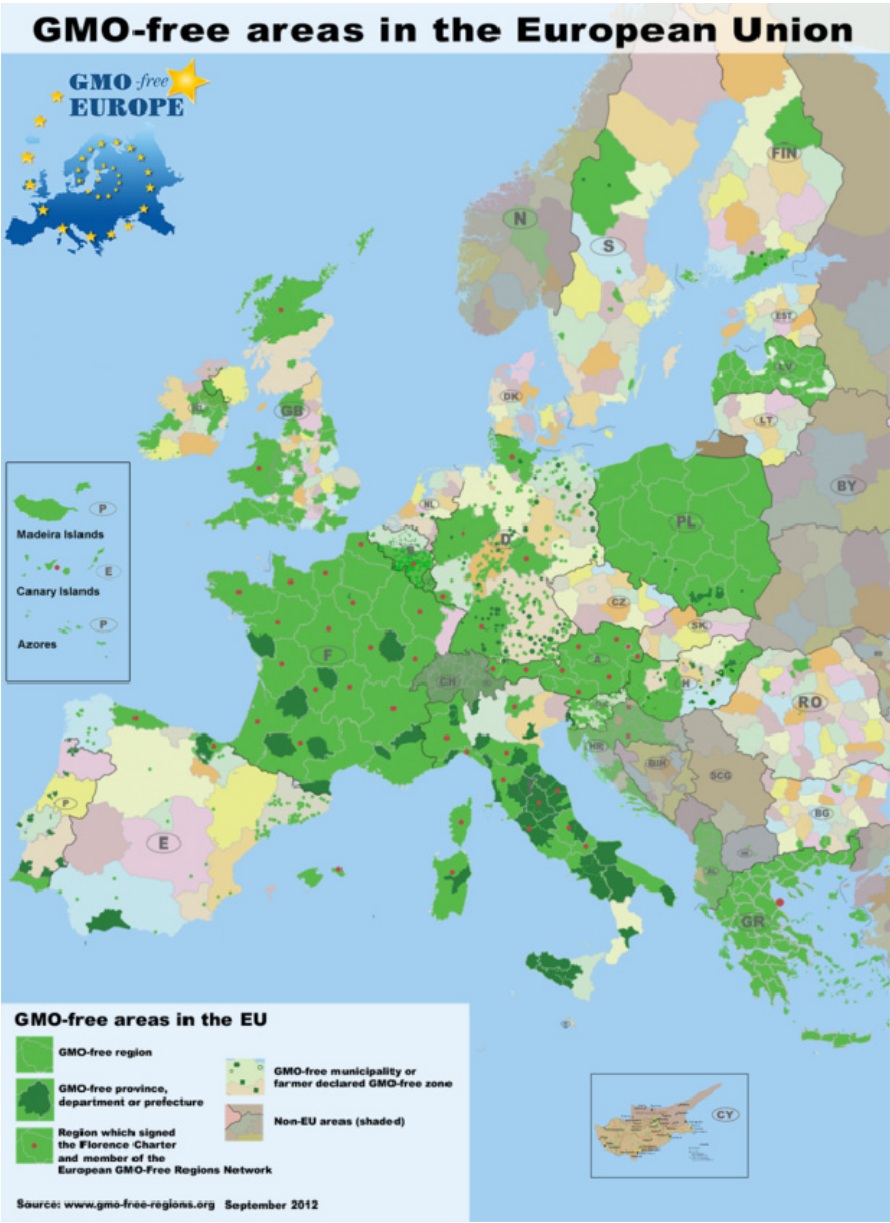
- Concrete case-study: MON89034xMON88017 (EFSA/GMO/BE/2009/71)
- Contains:
 - two insecticidal proteins Cry1A.105 and Cry2Ab2 that provide enhanced control of a wide spectrum of lepidopteran pests of maize (e. g. European corn borer, Mediterranean corn borer).
 - the Cry3Bb1 protein that provides protection against certain coleopteran insect pests belonging to the Crysomelidae family (i. e. corn rootworm complex).
 - the 5-enolpyruvyl shikimate-3-phosphate synthase (CP4 EPSPS) confers tolerance to glyphosate.

Ecological sensitive areas

Level	Criterion
Species	Endangered species and their habitats
	Endemic species and their habitats
	Protected species and their habitats
<hr/>	
Habitats & protected areas	Endangered biotope types
	Habitats of Community interest
	Protected areas if agricultural use is not prohibited
<hr/>	
Landscapes	Important areas for biodiversity
	Structurally diverse landscapes

Ecological sensitive areas

- The catalogue was developed along three different levels, and criteria which were defined for each of these levels.
- In addition indicator groups and single indicators were defined resulting in 419 endangered species, 21 endemic species, 28 protected species, 124 endangered biotope types, 32 habitats of Community interest and 7 diversity hot-spots.
- indicators were defined, based on species/protected habitats of Community interest!
- GIS-maps have been defined
- Case-study sent to EFSA & EC during evaluation timeframe of EFSA in order to be taken into consideration.



GM-free regions

- ENV-Council Conclusions 2008: “... GMO-free zones can be created on the basis of voluntary agreement which, in line with relevant national law,...”
- Total AT-Territory declared as GMO-free in cultivation, also based on many regional initiatives like “Bodensee-Akademie” , “Xundheitswelt“ in Lower-Austria, Alpe-Adria-Region
- GM-free Production in AT: since 1998 „soft-law“ Guideline acc. to Codex Alimentarius Austriacus in place.



GM-free food- & feed production

- Regulates strictly cultivation, production process and control standards
- So far around 2000 guaranteed GM-free food-products on AT market
- Milk-, egg-, most of poultry-production already GM-free
- Next aim: GM-free pork-production
- Possible limiting factor: protein-supply
- 2012 new initiative: Association „Donau-Soja“, aiming at providing GM-free soy in the danube region



Source: <http://www.gentechnikfrei.at/start.asp?ID=438>



Source: <http://www.donausoja.org/organisation>

Further information of the Federal Ministry of
Health on GMOs (also in English)

<http://www.gentechnik.gv.at>

Thanks a lot for your attention!