

Austria's View on GM Crop Varieties

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Jornades internacionals sobre els OGM

Arguments per una agricultura i una alimentació sense transgènics

Som lo que sembrem , Barcelona

6-7 March 2009

Content

- Socio-political context
- Biosafety research
- GMO legislation
- Views on risk assessment
- Views on post market monitoring
- National bans
- Coexistence policy
- Wrapping up
- Outlook

Socio-economic context

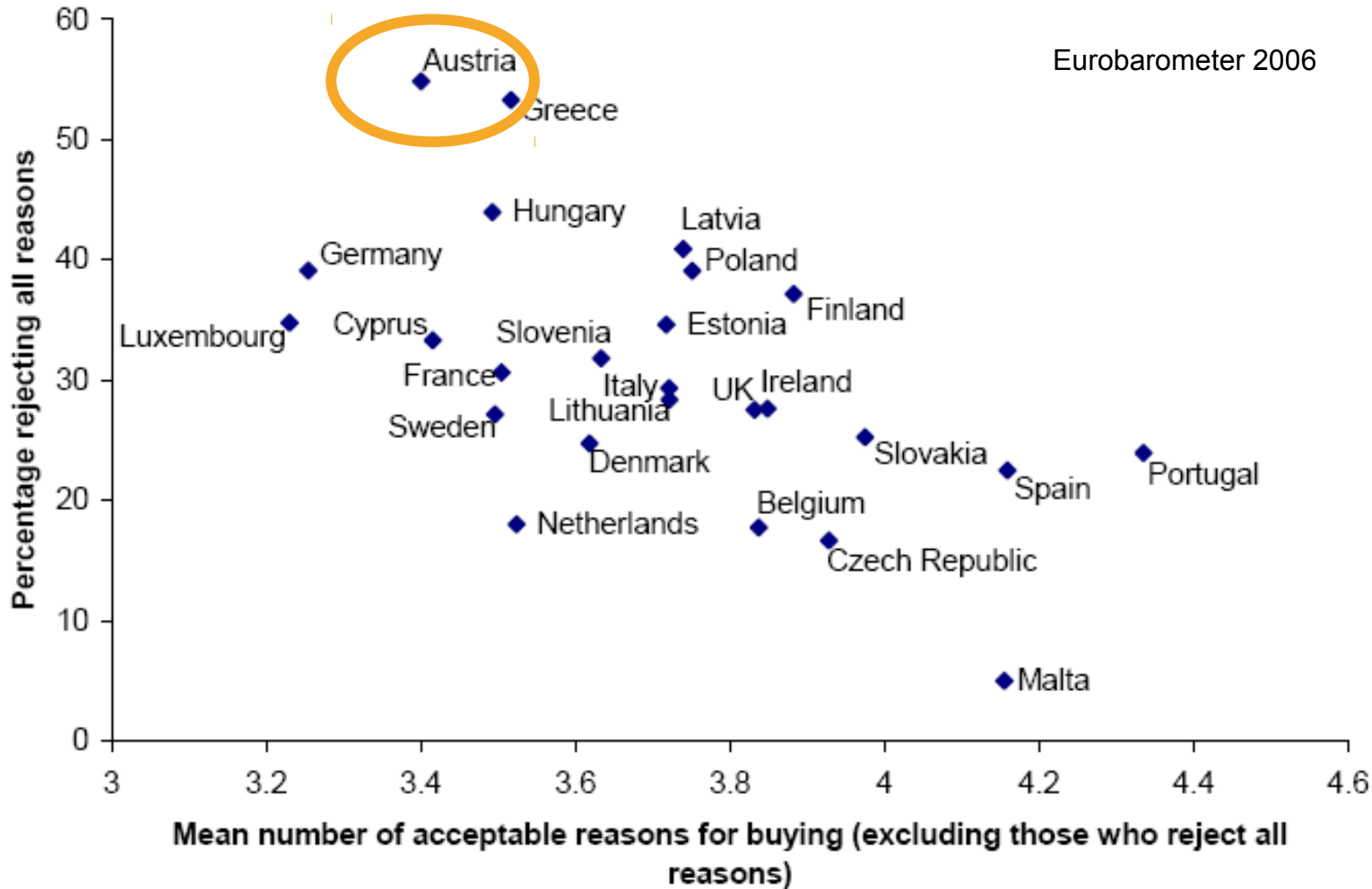
- Absence of agri-biotech companies
- Small-scale agriculture, partly mountain farming
- Agricultural policy and regional development highlighting sustainable (organic) farming, regional, fresh and high-quality/specialty products
 - especially since joining the EU in 1995

Public debate on GMOs in Austria

- Broad public debate on GMOs with environmental groups and media as key actors resulted in a
- Petition in 1997 supported by 1.2 mio citizens
 - No GM food, no GM crops in Austria, no patenting of life
- Strong public resistance to adopt GM crops and food
- Broad political consensus across all parties to maintain Austria's status of a GM-free country



Austrian publics on GMOs



Austrian publics on GMOs (cont.)

Table 1: Trends in optimism for biotechnology

	1991	1993	1996	1999	2002	2005
Spain	82	78	67	61	71	75
Sweden	-	-	42	-	61	73
Portugal	50	77	67	50	57	71
Italy	65	65	54	21	43	65
Denmark	26	28	17	-1	23	56
Luxembourg	47	37	30	25	29	55
Ireland	68	54	40	16	26	53
United Kingdom	53	47	26	5	17	50
France	56	45	46	25	39	49
Netherlands	38	20	29	39	39	47
Belgium	53	42	44	29	40	46
Finland	-	-	24	13	31	36
Germany	42	17	17	23	24	33
Austria	-	-	-11	2	25	22

Eurobarometer 2006

R&D/marketing of GM crops

- (Virtually) no field trials with GM crops
- No applications received for placing on the market
- Little academic research on/using GM crops in containment

National legislation

- Austrian Gene Technology Act: entered into force in January 1995 and has been amended in 1998, 2002, 2004 and 2005
 - Includes a provision to ban products from the market if they are socially unsustainable ('soziale Unverträglichkeit')
 - Never been applied
- Other provisions including
 - To label GM seed (threshold: 0,1%)
 - To protect areas of seed production
 - To allow for a GM-free label

National legislation (cont.)

- Ordinance on Deliberate Release of GMOs into the Environment (Freisetzungsverordnung 2005)
- Ordinance on Public Hearings (Anhörungsverordnung 1997,1998)
- Ordinance on GMO-Registers (Gentechnik-Registerverordnung 2006)
- GMO-Register
- Ordinance on Genetically Modified Seed (Saatgut-Gentechnik-Verordnung, 2001): prescribes a mandatory labelling for all GM seed varieties; sets thresholds for accidental contamination of conventional seed with GM
- Ordinance on Arable Land for the Production of Seed (Saatgut-Anbaugebiete-Verordnung 2005)

Labelling of GM food

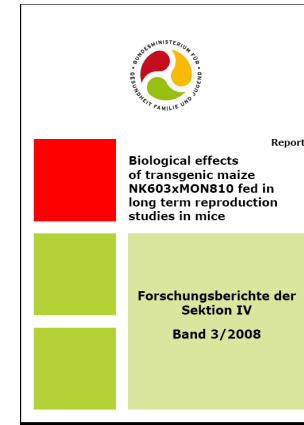
- A consistent labelling approach and to properly inform the consumer labelling of GM food should be extended to animal products produced with GM-feed (e.g. meat, milk or eggs)
- GM-free label also considering GM-feed or animal products as well as ingredients, additives and processing aids from GM microbes



Austrian GM-free label

Biosafety research ongoing

- Reviews and improvements of GMO risk assessment concepts and practice
- Studies on coexistence, biodiversity baseline data, monitoring, nature conservation aspects,
- Feeding studies: allergenicity and long-term toxicity
- Including field studies and recently also lab research
- More information at <http://www.bmgfj.gv.at/cms/site/thema.html?chan> and <http://www.umweltbundesamt.at/en/umweltschutz/gentechnik/>



Long-term feeding study

- Effects on reproduction detected
- Significance unclear pending a re-analysis



Report



**Biological effects
of transgenic maize
NK603xMON810 fed in
long term reproduction
studies in mice**



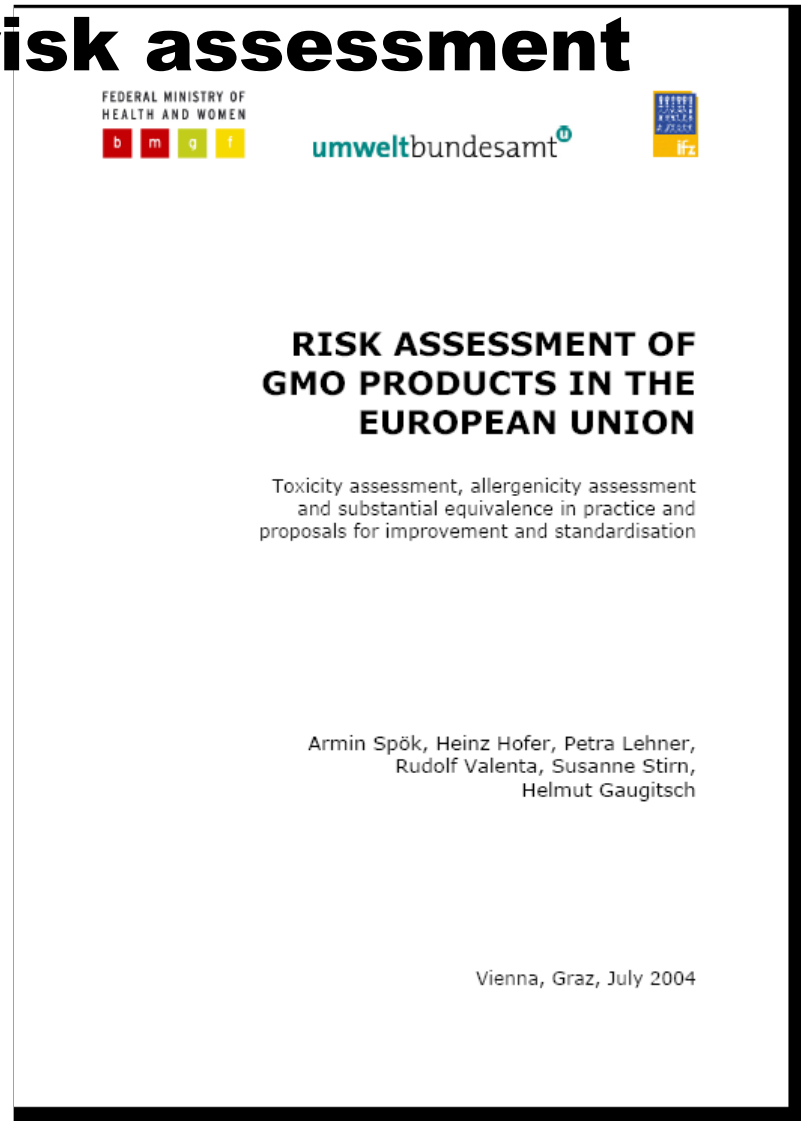
**Forschungsberichte der
Sektion IV**



Band 3/2008

Evaluating GMO risk assessment

- Evaluating GMO risk assessment practice in the EU
 - Approach
 - Methods
 - Conclusions



Antibiotic resistance marker genes



Report

**Risk Assessment of Antibiotic
Resistance Marker Genes in
Genetically Modified Organisms**

**Forschungsberichte der
Sektion IV**

Band 5/2007

Considering legal requirements from both environmental and nature protection



„Europe Legal protection obligations for protected habitats and species such as the Habitats Directive, as well as regional protection equipment remain largely ignored, if genetically modified organisms (GMOs) for EU-wide cultivation requested.

[...] The observance of the obligations nature of the individual Member States may be due to uncertainties in the risk assessment during the registration at EU level as well as by existing residual risks after the approval could be jeopardized.“

Source:

<http://umwelt.lebensministerium.at/filemanager/download/26891/>



GMO risks and risk assessment

- Austria persistently highlights
 - Shortcomings and inconsistencies in risk assessment approach and methodology
 - Particular lack of assessing long-term effects
 - Uncertainties, lack of knowledge, disagreements, needs for clarification and research (while broadening the basis of experts involved) on the scientific basis for risk assessment
- Numerous studies contributed to further development of guidance for and practice in GMO risk assessment

GMO risks and risk assessment (cont.)



- Austria persistently highlights
 - Impacts on local/regional environments
 - Precautionary approach (in risk assessment): favouring strong interpretation
 - Related: absence of comprehensive and mandatory EU-wide coexistence rules

GMO risks and risk assessment (cont.)



- Scope: safety, biodiversity, agronomic effects
- Baseline: sustainable (organic) agriculture
 - „As a sustainable cultivation method, organic farming is similarly important for environmental protection. Any restrictions imposed on organic farming by the cultivation of GM crops are thus, indirectly, also of environmental relevance.“
- Considering herbicide impacts on agricultural practice (particular difference under Directive 90/220/EC)
- Opposing the use of AR marker genes

Post Market Monitoring

- Two types of PMM
 - General surveillance: designed to pick up possible unexpected effects and is obligatory for all GM crops.
 - Case-specific monitoring: specified with certain GM crops to investigate correlations that were identified as a risk during the environmental risk assessment, like the occurrence of resistant pest insects following cultivation of insect resistant GM-Maize.
 - Missing
 - Appropriate concepts and methods for PMM
 - Feasibility studies

National Bans of GM Crops

- Article 23 of Directive 2001/18/EC measures (Article 16 of Directive 90/220/EEC)
 - **Maize T25**: ban on placing on the market partially lifted in May 2008 - except cultivation
 - **Maize MON 863**: ban of import and use up to 1 Oct. 2010
 - **Rape GT 73**: import ban valid until end of 2010
 - **Rape Ms8/Rf3 and Ms8xRf3**: import ban valid until 1st Oct. 2010
 - **Maize MON810**: ban on placing on the market partially lifted in May 2008 - except cultivation
 - **Maize Bt176**: ban lifted due to the phasing out of the GM line
- Bans are considered as precautionary measures triggered by insufficient risk assessment (data/knowledge)

Maize MON810 – weaknesses in comparative analysis

- Range of parameters do neither meet OECD (2002) nor industry requirements (EuropaBio 2001)
- Identified differences (glutamine, leucine, proline, C18:1, C18:2 fatty acids etc.) not further investigated
 - Points to a different interpretation of the concept of substantial equivalence
 - “indicator” function vs. endpoint in itself (biological relevance)
- No isogenic control line

Maize MON810 – weaknesses in toxicity assessment

- No toxicity of whole plants: important reassurance against pleiotropic effects
- Toxicity endpoints limited to acute oral toxicity (protein): not sufficient to detect sub-chronic/chronic effects (and to calculate a NOAEL)
- Test protein from bacterial sources: important reassurance if plant-produced protein differs in structure/properties

Maize MON810 – weaknesses in allergenicity assessment

- Based on indirect evidence
 - In-vitro digestibility studies
 - But: shortcomings in methodology and in-vivo relevance
 - Homology comparison of protein sequence
 - But: outdated (1990, 1995), not considering 3-dim epitopes
- No allergenicity assessment of whole plants
- Not suitable for detecting de-novo sensitizing properties

Maize MON810 – uncertainties about environmental effects

- Evidence of non-target effects, e.g.
 - Mortality of larvae of Chrysopidae (Hilbeck et al. (1998))
 - Mortality and reduced lifespan of larvae of Meteorus laeviventris (Hafez et al. 1997)
 - Insects living only on accompanying flora (Losey et al. 1999)
 - Particular risks because of constitutive expression in all parts of the plants including kernel and pollen (e.g. Losey et al. 1999, Armstrong et al. 1995)
- Range of test species in risk assessments too narrow and not related to the agricultural conditions for commercial production
- Experience on Bt spray products not necessarily relevant for plant expressed Bt (Hilbeck et al. (1998b))

Maize MON810 – weaknesses in resistance management



- Resistance management still controversial
 - E.g. resistance seems to be a dominantly inherited trait (Huang et al.1999)
- Information related to the resistance management plan missing
- Monitoring plan for cultivation missing

Justification for Banning – Maize MON863

- Shortcomings in experimental design and conduct
 - Nutritional equivalence
 - Whole-food toxicity studies
- Assessment of antibiotic resistance marker gene nptII based on flawed assumptions
 - Uneven background distribution of resistance across EU member states
 - Actual therapeutic use of kanamycin, neomycin and paromomycin
 - Low frequencies of ARM genes to microbes does not count as a safety argument
- Proposal for an environmental monitoring plan
 - does not adequately cover accidental spillage and
 - does not meet the objectives defined in Annex VII of Directive 2001/18/EC and the supplementing guidance notes (Council Decision 2002/811/EC).

Rape Gt73

- Accidental spillage
 - Evidence that rape can built-up persistent and self-sustaining populations in non-natural ecosystems including roadsides
- Toxicity assessment
- Allergenicity assessment

Rape MS8xRf3 (no cultivation)

- Impacts from gene flow into wild relatives of rape
 - Conventional rape
 - Biodiversity
- Feral GM rape “may”
 - have adverse long term effects
 - Affect conventional rape (link to coexistence)
- Accidental spillage
- Barnase/barstar: affecting reproductive characteristics – effects on environment not clear at present
- Allergenicity assessment
- Toxicity assessment (duration, relevance for feed safety)

Impacts of WTO Dispute Panel Report

- Requirement to lift the bans by Jan 2008
 - Under pressure from the EC Austria lifted one import ban for an event already phased out , upholds other and introduced new bans
- Austria did not conduct a proper risk assessment
 - Supplementary evidence was provided with respect to the bans on Maize T25 and MON810 in order to meet the presumed criteria of the SPS agreement and other internationally accepted guidance

Response from EFSA and the European Commission



- EFSA issued and updated several opinions
 - Generally that no *new information* was provided to consider that the authorised GM crops *constitute a risk to the environment*
- EC made several attempts to lift bans
 - Voting in Standing Committee
 - Votings in European Council
 - Most recently on 3 March 2009:
 - Against proposal of the EC justified on the basis that MON810 was approved under Dir 90/220/EC and has not yet undergone a procedure of re-assessment in accordance with Dir 2001/18/EC
 - 23 Member States voted against the proposal of the EC (except EE [Estonia], FI, NL, UK)

Legislation securing GM-free agriculture

- National
 - Ordinance on Genetically Modified Seed, 2001
 - Ordinance on Arable Land for the Production of Seed, 2005
 - Article 23 measures (Directive 2001/18/EC): safeguard bans
- Sub-national
 - Coexistence legislation

Attempts to ban GM crops by provincial governments

- Upper Austria and Salzburg: recourse to Article 95(5) of the EC Treaty: imposed a total ban on GM crops in those regions, thereby derogating from the harmonised rules laid down in Directive 2001/18/EC.
- Salzburg withdrew
- EC rejected the notification by Upper Austria, arguing that the conditions set out under Article 95(5) were not satisfied.
- Decision upheld in October 2005 by a ruling of the Court of First Instance.
- In December 2005, Upper Austria and the Republic of Austria appealed to the European Court of Justice against the ruling.

Coexistence link to nature conservation



- Nature conservation issues are considered relevant for environmental effects of GMO cultivation of GMOs but are not adequately taken into account by the EC

Coexistence legislation: “Gentechnik-Vorsorgegesetze”

- The Federal Länder (provinces) of Austria enacted special laws to ensure coexistence in their territory and the safety of fauna and flora (“Vorsorgegesetze”: “Genetic Engineering Precautionary Measures Acts” in literal translation)
 - Cultivation of GM crops is subject to an official (registration or authorisation) procedure
 - Authorities may impose conditions for, or prohibit, cultivation
 - Neighbouring farmers are parties to the procedure
 - Each authorised cultivation is registered
 - Presently under development: uniform Austria-wide guidelines to provincial authorities for co-existence management and under which conditions (e.g. minimum isolation distances) cultivation can be permitted

List of coexistence acts

- [Burgenländisches Gentechnik-Vorsorgegesetz](#) 19 May 2005
- Kärntner Gentechnik-Vorsorgegesetz 1 November 2004
- Niederösterreichisches Gentechnik-Vorsorgegesetz 30 June 2005
- Oberösterreichisches Gentechnik-Vorsorgegesetz 11 May 2006
- Salzburger Gentechnik-Vorsorgegesetz 1 August 2004
- Steiermärkisches Gentechnik-Vorsorgegesetz 1 Sept. 2006
- Tiroler Gentechnik-Vorsorgegesetz 1 July 2005
- Vorarlberger Gesetz über Naturschutz und Landschaftsentwicklung: existing legislation adopted
[Wiener Gentechnik-Vorsorgegesetz](#) 22 September 2005

Some general characteristics of Austrian GMO policy

- Remarkably persistent – hardly any changes over the last 15 years
- No strong coordination needed – rather a shared understanding of the problematique
- Resistance remains in the absence of campaigning NGOs and media
- GM-free has become a frequently highlighted issue of agricultural production and products, in regional development, public procurement and general food supply (including conventional products)
- Some politicians consider GM crops as threatening high-quality, fresh and healthy food products similar to food contaminants, pesticides etc.

Some cornerstones of Austria's views

- Based on a strong interpretation of the PP: asking for more robust risk assessments and monitoring
- Highlighting the need to consider differences in the ecology of the receiving environment
- Extending the scope of the assessment (agronomic effects, biodiversity)
- Pursuing a policy in favor of GM-free agriculture
- Highlighting consumer choice: extension of labelling

Outlook

- Pressure from EC (WTO) on Austria is increasing
- More and more support that MSs should decide on cultivation
 - *“... the Netherlands calls upon the Commission to put forward [...] a new balance in the assessment framework. What the Netherlands is seeking is a solution whereby the rules governing the internal market would apply to products imported in accordance with the current rules, whereas the Member States themselves should be able to decide in the case of domestic production.” (SCFAH meeting, 16 February 2009)*
- Unclear how this will work out
- No substantial policy change to be expected with new government

Further Information

- On Austrian Regulations
 - Federal Ministry of Health: www.gentechnik.gv.at
 - Austrian Biosafety Clearinghouse:
<http://www.umweltbundesamt.at/en/umweltschutz/gentechnik/abch/>
- On Austrian Biosafety Research and Coexistence
 - Federal Ministry of Health, Family and Youth: www.gentechnik.gv.at
 - Umweltbundesamt:
<http://www.umweltbundesamt.at/en/umweltschutz/gentechnik/>
 - AGES: <http://www.ages.at/ernaehrungssicherheit/gvo/projekte-und-studien/>
 - IFZ: http://www.ifz.tugraz.at/index_en.php/user/view/18

Thank you!