

# Background of Austrian Mice Study Debate

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## 1. General View

For years, Austria's governmental and politically motivated GM crop safety claims have repeatedly been rejected by European Commission officials, by scientists with the European Food Safety Authority (EFSA), and by the judges of two European courts.

Government regulators and numerous safety scientists have rejected Austria's claims about GMOs as well as the country's attempts to retard EU policy and evade the requirements of European law and decisions.

Austrian ministries (as well as their counterparts in the French and Italian governments) have adopted novel tactics that were invented, suggested and endorsed by anti-GM activists.

As a result, the global media is regularly fed questionable claims based on reports which have not gone through the process of peer review, or – worse – which have passed a flawed peer-review process – examples given in (Miller et al., 2008). Some journals have accepted papers on the premise that because of the publicity given to studies in the media and on websites, the work should be published so that everyone has a chance to scrutinize the findings (Horton, 1999; Horton et al., 1999). And, unfortunately, it is also true that lower quality journals accept papers that would be found unacceptable by leading journals – here a few examples to illustrate the whole range of cases given above:

- Short letters to the editor, written by whistle blowers in good faith – or worse in many of the below cases – with a political agenda - on 'promiscuity of transgenic plants' (Bergelson et al., 1998) or the toxicity of Bt maize for non-target insects like the monarch butterflies (Losey, 1999; Saxena et al., 1999), but later devaluated as premature apprehensions.
- Critical scientists conducting experiments which do not respect the internationally agreed experimental procedures, so actually the results are questionable. But it has to be said that the authors were commenting their own results in a balanced way the possible negative effects by leaving open other causes than transgenesis (effects of transgenic soybeans on mice by (Malatesta et al., 2003; Malatesta et al., 2005; Vecchio et al., 2004)). Nevertheless, this work is often misinterpreted by opponents who make no mention of the researchers careful qualifications of their findings and certainly no mention of the questionable methodology.
- Publications by scientists who have a clearly negative view of GM crops that conduct research intended to reveal highly improbable negative effects. The research protocols and experimental conduct are flawed and the differences they make publicity about are usually not of biological significance or are not even statistically significant. (Serolini et al., 2007), critical comment see (Doull et al., 2007) (Ewen & Pusztai, 1999), contradiction see in the same Lancet volume: (Kuiper et al., 1999).
- Publications on topics related to epigenetics neglecting zero comparisons, although the findings per se are correctly commented, but in a balance not giving the whole picture. (Myhre et al., 2006), (Latham et al., 2005). for contradiction see [Jens Freitag in GMO Safety](#).
- Uncritical reviews by newcomers in the field of food safety (Dona & Arvanitoyannis, 2009), for contradiction see (Auer, 2008) and Sorghum (Botha & Viljoen, 2008) who do not understand some of the cited scientific publications seemingly supporting their negative cause of extensive gene flow and worse: ignore important scientific work as reviewers.
- Papers based on new methodological approaches, not following the internationally agreed protocols, which have to be interpreted with great caution and which need to be independently verified (Finamore et al., 2004; Finamore et al., 2008).
- Prematurely published reports propagated on numerous websites of the anti-gene-technology-community and in sensational newspaper articles, without having been scrutinized properly by peer-review (Ermakova, 2005a, b, 2007a, b; Marshall, 2007; Marshall et al., 2007). When Ermakova finally revealed her data, it was clear that

the research and data did not meet contemporary international standards of experimentation. The high observed mortality of rats in control groups was attributed to mistreatment of the animals.

See full details about Pusztai, Ermakova and Dona in the contributions of ASK-FORCE :

About the case of Pusztai:

<http://www.botanischergarten.ch/AF-2-Pusztai/Pusztai-Food-Safety-20090828-web.doc>

About the case of Ermakova:

<http://www.botanischergarten.ch/AF-4-Ermakova/AF-4-Ermakova-20090828-web.pdf>

About the Dona Review:

<http://www.botanischergarten.ch/AF-7-Dona-rebuttal/Ammann-et-al.-Rebuttal-Dona-AF-7-20090828-web.pdf>

## 2. The Transatlantic Rift

It was among others [Anne Marie Thro](#) (Thro, 2004) describing convincingly the transatlantic rift in risk perception of transgenic crops. GM crops are since many years the scapegoat of dissent on cultural and political aspects in agriculture, which have nothing to do with the ecological impact and the food safety of the new breeds per se. The bias is so strong, that it influences persistently the interpretation of scientific data even in peer reviewed papers (Miller et al., 2008), where often the editor in chief panders to the temptation to publish flawed experimental data for the sake of fostering a 'public debate' on highly questionable negative statements. Overall, it is amazing to see to what extent also biosafety research and resulting regulation is influenced by the transatlantic rift (Ramjoue, 2007).

In this light, we can see again a symptomatic example of premature and hasty interpretation of a feeding experiment with mice in Austria: Even before the report has been properly published and reviewed by peer experts, the political agencies and advocacy groups have prematurely trumpeted out the seemingly negative results. As will be shown in the following discussion, the cases of Ermakova and Zentek cannot be compared directly, since Dr. Ermakova is an [anti-gentech activist](#) (just have a look at her website, and despite her declaration in [Nature Biotechnology](#): p.1353 "I am not against GMOs ..."). Prof. Zentek as the principal scientist of the study most certainly is not an anti-GM activist (which cannot be said from the first author, A. Velimirova a clear-cut defender of organic farming). He still intends to publish a peer reviewed paper based on good scientific argumentation, and from what I gather in correspondence, he intends to take criticism into account and publish correct findings.

## 3. Austria's Position on GM-free zones

Another typical example of the transatlantic rift is the Austrian position on GMO-free zones, claiming new negative evidence against GM crops. The claim was rejected by EFSA in a detailed scientific argumentation, ([EFSA](#)) and ([Commission](#)): Margot Wallström, Environment Commissioner EU: "We have analysed the Austrian measures in great detail, and, legally speaking, this seems a clear-cut case. The treaty requirements

allowing for a derogation from EU legislation are not met". Far from giving up, the Austrian government went into a second round, [appealed](#) the decision but lost this time in 2007 in the [European court](#).

On December 4, 2007, the EFSA has once again rebuffed Austria's concern about transgenic maize: The request from the European Commission related to the safeguard clause invoked by Austria on maize MON810 and T25 according to Article 23 of Directive 2001/18/EC has been [answered](#):

*"Following investigation of the evidence presented in the Austrian submission, the Scientific Panel on Genetically Modified Organisms (GMO Panel) of EFSA concluded that there is no new scientific evidence that would invalidate the previous risk assessments of maize MON810 and T25. Therefore, no specific scientific evidence, in terms of risk to human and animal health and the environment, was provided that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC for the marketing of maize MON810 and T25, for its intended uses, in Austria:*

*On 10 June 1999 and on 8 May 2000, Austria invoked Article 16 of Directive 90/220/EEC (safeguard clause) to provisionally prohibit the placing on the market of the authorized genetically modified (GM) maize events MON810 and T25 on its territory. In February 2004 and November 2007, Austria provided additional information to support the national safeguard measure to be considered under Article 23 of Directive 2001/18/EC. To define whether the information submitted by Austria comprises new information that would affect the environmental risk assessment for the uses laid down in the corresponding consent, the European Commission requested in a letter, dated 18 April 2008, a scientific opinion from the European Food Safety Authority (EFSA)."*

Finally, EFSA also published, as part of their minutes from the 46<sup>th</sup> plenary meeting on December 4, 2008 a [statement](#), refuting the study, it is given in extenso under 13. Any other business:

**GMO Panel deliberations on the Austrian report "Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice"**

*"These deliberations have been adopted at the 46th plenary meeting (3-4 December 2008) and were published shortly afterwards as adopted part of the minutes. The present minutes of the 46th plenary meeting replace that publication, without changes to its content"*

*"On 11 November 2008 the Austrian Federal Ministry of Health, Family and Youth released a research report on studies in mice, conducted to assess the impact of genetically modified maize NK603 x MON 810 on reproduction (Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice, Dr. Alberta Velimirov, Dr. Claudia Binter, Univ. Prof. Dr. Jürgen Zentek).*

*The report includes three studies, a life-time study, a multigeneration study (MGS), and a reproductive assessment by continuous breeding study (RACB). According to the authors the life time study showed no statistically significant differences in survival between mice fed with kernels of maize NK603 x MON 810 and the controls. They also reported that, in the MGS study, no significant differences in reproductive traits were found between mice fed with kernels of maize NK603 x MON 810 and the controls. In the RACB study, the authors used a modified protocol of the original RACB study developed at the U.S. National Toxicology Program (NTP) for the testing of chemicals. Male and female mice were housed as breeding pairs for approximately 20 weeks and allowed to produce litters continuously throughout the cohabitation period. The authors identified differences in reproductive parameters between mice fed with the GM maize and the controls. They reported that there were statistically significantly fewer pups born in the GM group in the 3<sup>rd</sup> and 4<sup>th</sup> delivery and fewer pups weaned in the 4<sup>th</sup> litter compared with the control group.*

*EFSA/GMO/457 – Minutes 46<sup>th</sup> Plenary Meeting of the GMO Panel Page 10 of 11*

*The GMO Panel considered this report and came to the following conclusions. Regarding the RACB study, the summary Table 59 contains calculation errors and inconsistencies in the treatment of the data regarding the 3<sup>rd</sup> and 4<sup>th</sup> litters. In addition, it seems that the authors have calculated the number of pups at birth per pair and not per delivering pair, which is standard practice. Also, there appears to be methodological deficiencies in the statistical analysis that seriously compromise the interpretation of the data. For the reasons stated above, individual data are required for a proper assessment. In addition, more detailed information regarding the breeding scheme is needed. In particular, it should be clarified whether, in the 3<sup>rd</sup> and 4<sup>th</sup> pairing, the same or different pairs failed to reproduce.*

*Information regarding the normal variation of the parameters examined in this study for the mouse strain used (historical control data) is required before any conclusion may be drawn on possible alterations in reproductive performance. In addition, further*

information on the estrous cycle and histopathological parameters including spermatogenesis, follicle and oocyte counts is essential for assessing the claims of reduced fertility.

The GMO Panel also notes that information on the genetic identity and characteristics of the tested materials is not sufficient.

On the basis of the data presented the GMO Panel is of the opinion that no conclusions can be drawn from the report.

Further to its above deliberations on the Austrian report, the GMO Panel would like to draw the attention to the recently published EFSA report on the safety and nutritional assessment of GM plants and derived food and feed (Food and Chemical Toxicology 46 (2008) S2-S705) regarding the use of animal feeding trials for the evaluation of potential long term effects."

In a publication of (Bartsch, 2009) the latest situation is summarized:

**Bartsch, D. (2009)**

National safeguard clauses (Art. 23/ RL 2001/18) – The role of EFSA & National Biosafety Committees. Journal für Verbraucherschutz und Lebensmittelsicherheit, 3, 0, pp 63-63

<http://dx.doi.org/10.1007/s00003-009-0422-4>

*The whole published text including active links to the cited literature*

"Since 2003, EFSA has been requested by the European Commission, under Article 29(1) and in accordance with Article 22(2) and 22(5)© of Regulation (EC) No 178/2002, to assess the information submitted by Member States (MS) concerning the invoke of Article 16 of Directive (EEC) 90/220 or Article 23 of Directive (EC) No 2001/18 ('safeguard clauses'). The MS were Luxemburg for Bt176 maize; Germany for Bt176 and temporarily (in 2007) MON810 maize; Austria for Bt176, MON810 and T25 maize; France for Ms1xRf1, and Topas 19/2 oilseed rape, and MON810 maize; Hungary for MON810 maize, and Greece for Topas 19/2 oilseed rape and MON810 maize. The level of scientific information provided in the various safeguard clauses is very heterogeneous. In all cases the GMO Panel concluded, that, with respect to the specific questions raised, and on the basis of current scientific knowledge, there is no reason to believe that the continued placing on the market of Bt176, T25 & MON810 maize, and Ms1xRf1 & Topas 19/2 oilseed rape is likely to cause any adverse effects for human and animal health or the environment under the conditions of their respective consents (EFSA, 2004a,b, 2005, 2006a,b, 2008a,b). There is a discussion whether EFSA should request the opinion of the established Scientific Biosafety Committee of the applying EU Member State in order to clarify the scientific basis of future safeguard applications. With one exception (ZKBS, 2007), the author is not aware that such a national Biosafety Committee has published a scientific statement in relation to their specific Member State action. Another point of discussion might be on the novelty or additional scientific knowledge to base the safeguard clause on. In the safeguard clause issued in 2006 by Austria on GT73 oilseed rape for import, the argumentation had already been assessed (and dismissed) by the MS Authority (e. g. The Netherlands) under Directive 2001/18/EC who initially issued the consent. Despite that fact, in 2008, the same document was sent to EFSA again to justify a safeguard clause. A formal standardisation of the information required in support of a safeguard clause (e. g. novelty, additional scientific information, opinion of the national Biosafety Committee etc.) would be a way forward to streamline the regulatory requirement that the Member State shall immediately supply its review of the environmental risk assessment." (Bartsch, 2009)

In another very enlightening paper (Ely, 2005) come to the conclusion, that the Austrian government is "constructing ignorance" – and this as early as 2005. Today we have an extensive literature, proving that Bt maize is as safe – or even safer – as conventional maize, with view to food safety and environmental safety.

**Abstract:**

"This paper investigates Austria's precautionary responses to applications for the environmental release of two types of transgenic insect-resistant Bt maize in the late 1990s. In contrast to the 'deficit model' analysis implied by the title, the paper examines different concepts of 'ignorance' drawn from studies of decision-making under uncertainty. The utility of these concepts in understanding Austrian policy is tested by dissecting the scientific arguments put forward by the Austrian government in support of Article 16 bans of Bt maize under EC Directive 1990/220. The study shows that, although they were not originally formulated for this purpose, concepts of 'ignorance' have a useful, although limited, role in comparative studies of risk assessment."

And more specifically in the conclusions on the 2005 state of ignorance of scientific biosafety literature:

"Although epistemological ignorance is only possible to identify post hoc, might it be possible to judge if it is more or less likely to emerge? This would be the equivalent of navigating between the top-left and bottom-right corners of figures 1 and 2. According to (Andrew Stirling, 1999; Stirling, 2007) 'no matter how well informed, judgments concerning the extent to which 'we don't know what we don't know' are intrinsically subjective and value laden'. In the case in hand these judgments have translated into differences over what evidence and assumptions regulatory institutions accepted as valid. According to the Austrian government's reasons for banning Bt176, 'the qualitative and quantitative differences of the use of genetically modified plants expressing 'B.t. toxins' in comparison with

*the conventional use of microbial 'B.t. substances' were not considered sufficiently in the application'. Through questioning the assumption of equivalence between these types of Bt, the evidence provided in the regulatory dossier's eco-toxicological studies and the experience of decades of use of Bt sprays were declined as unacceptable. In the Mon810 case, Austrian authorities also drew into question the specificity of Bt toxins. 'Recent findings indicate possible differences and problems in specificity with Bt plants. Exact arguments therefore are still unknown and need further investigations'. **Rejecting or questioning the acceptability of these studies, principles and assumptions left Austria with no valid scientific basis on which the non-target risks of Bt maize could be assessed.** Just as other competent authorities had constructed a state of knowledge characterized by 'risk' through accepting the assumptions and evidence put forward or implicit in the regulatory dossiers, **Austria's arguments constructed a state of uncertainty and ignorance.** In terms of figures 1 and 2, Austria has placed itself at the bottom (especially in the lower right-hand corner) of the diagrams, and responded accordingly."*

It seems that the Austrian government has exhausted all legal avenues, and therefore the ministry of health has decided to take the same scientifically dubious route as Irina Ermakova: avoid the peer-review process, announce study results at a well organized conference, hide the data from scientists, and let the activists run amok with the help of some uncritical the media. But there is hope: it is remarkable to see the lukewarm reaction of major media: The time seems to be over when important newspapers just follow every craze of activists regarding GM crops, it is hard to find a major documentation in a reputed newspaper or magazine in Europe at present time related to the latest case. In contrast to the press, there are several regulatory agencies in Germany and France and other European countries, and also the commissioner for environment of the EU Dimas, which have a political interest to use such reports and cherish their contents by neglecting quality science.

Deplorably, by adopting Ermakova's tactics, Austria is inviting the same outcome for the Velimirov mice study.

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