



Testbiotech e.V. – Institut für unabhängige Folgenabschätzung in der Biotechnologie

„Quality of Science“

12. October 2011

Brussels

**EFSA Workshop on
Independence and Scientific
Decision-Making Processes**

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Problems discussed currently concerning 'Quality of Science' of EFSA

- Conflict of interest among panel experts
- Biased approach in risk assessment
- Missing scientific standards
- Major deficiencies in assessing specific applications

Example: ILSI infiltrating EFSA and influencing scientific standards



Funded by
Coca-Cola,
Monsanto,
Dow Chemical,
Nestle and others

AP-news, 2006: „U.S.-based research foundation is being barred by the World Health Organization from helping set global standards for protecting food and water supplies because of its funding sources.“

▼
•Management Board

▼
•ANS Panel (Food additives and nutrient sources added to food)

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• CEF Panel (Food contact materials, enzymes, flavourings and processing aids)

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•GMO Panel

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•PPR Panel (Pesticides)



Comparative risk assessment: A concept created by biotech industry



ILSI Task Force

Expert Working Group

Ian Munro & Jason Hlywka	Cantox, Inc./ U. of Toronto
Martina McGloughlin	U. of California, Davis
Bruce Chassy	U. of Illinois
Richard Phipps	U. of Reading
Harry Kuiper & Gijs Kleter	Wageningen University

ILSI Task Force Members

Bayer CropScience	Ray Shillito
Dow AgroSciences	Joseph Dybowski
DuPont/Pioneer	Matthias Liebergesell
Monsanto	Kevin Glenn
Renessen	David Russell
Syngenta Seed	Catherine Kramer



Example: missing scientific standards in case of SmartStax

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MSL0021061
Page 1 of 29

STUDY TITLE

Phenotypic Evaluation and Ecological Interactions of the Combined Trait (MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Grown Durin

This report reflects data developed and reported in Monsanto Study 07-

AUTHOR

Eric W. Rosenbaum

STUDY COMPLETION DATE

February 28, 2008

REPORT COMPLETION DATE

February 28, 2008

SPONSOR AND TESTING FACILITY

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STUDY DIRECTOR

Eric W. Rosenbaum

REPORT NUMBER

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Monsanto Company
Biotechnology Regulatory Sciences

QUALITY CONTROL STATEMENT

This report was reviewed to assure that it accurately reflects data collected and analyzed during the study conducted in Monsanto Study 07-01-52-05.

Reviewed by:

DeAnn Holder
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Unit

Study Director:

Eric W. Rosenbaum Date: 2/23/08

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During the process of data summarization and analysis, experienced scientists familiar with each experimental design and evaluation criteria were involved in all steps. This oversight ensured that the data were consistent with expectations based on experience with the crop. In addition, the overall dataset was evaluated for evidence of biologically relevant changes, and for possible evidence of an unexpected plant response. If cooperating scientists indicated any unexpected observations or issues in the course of the study, they are noted in this report. Data were then submitted to statistical analysis.

2/28/08
Date

Which scientific standards are applied?

- CEF-Panel/ Bisphenol A: Scientific standards are used to reject relevant findings from independent researchers ...
- GMO Panel: Papers from industry are accepted that would never have been passed a peer reviewed process
- Soft criteria such as 'biological relevance' or 'it is unlikely' are used to draw final conclusions, yet uncertainties are not indicated properly...
- International standards are referenced without securing that they meet the requirements stated in EU regulations...

Some recommendations to assure 'Quality of Science'

- Set strong rules and high standards for conflict of interests.
- Exclude 'industry' from the management board and instead involve a broader spectrum of stakeholders without vested economic interests.
- Establish new referee institutions dealing with scientific standards and controversial opinions.
- Organise heterogeneity of expertise among expert panels.

To be addressed by the risk manager: How to organise independent risk research?

„Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted. The necessary resources should be secured for such research by Member States and the Community in accordance with their budgetary procedures and independent researchers should be given access to all relevant material, while respecting intellectual property rights.“