Risk assessment of genetically engineered plants 'when no comparator is available'

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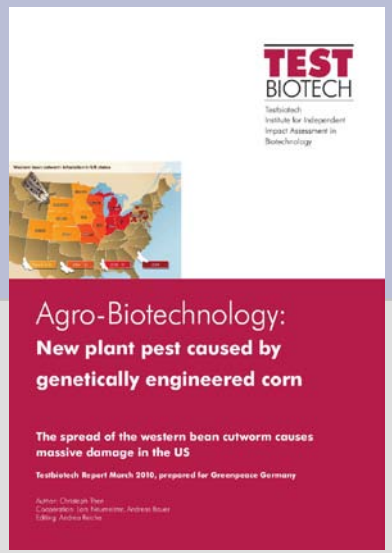
Risk Reloaded
Risk analysis of genetically engineered plants within the European Union
A report by Testbiotech e.V.
Institute for Independent Impact Assessment in Biotechnology
www.testbiotech.org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Agro-Biotechnology:
New plant pest caused by genetically engineered corn
The spread of the western bean cutworm causes massive damage in the US
Testbiotech Report March 2010, prepared for Greenpeace Germany


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Agro-Biotechnology:
Testbiotech opinion concerning the application for market approval of genetically modified maize 1507 (DAS-Ø15Ø7-1)


DOSSIER
International Federation of Organic Agriculture Movements EU Group
Economic impacts of labelling thresholds for the adventitious presence of genetically engineered organisms in conventional and organic seeds
SEED PURITY: COSTS, ADVANTAGES AND RISK MANAGEMENT FOR MARKETS AVOIDING GENETICALLY ENGINEERED PLANTS
Christoph Then - Matthias Stolze
IFOAM EU GROUP


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Agro-Biotechnology:
Cloned farm animals - a 'killing application'?
Risks and consequences of the introduction of cloned animals for food production
Authors: Christoph Then, Ruth Tippe
A Testbiotech Report prepared for Martin Häusling, MEP


TEST BIOTECH
Synthetische Biologie
Teil 1:
Synthetische Biologie und künstliches Leben – Eine kritische Analyse


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Agro-Biotechnology:
Testbiotech opinion on EFSA's draft guidance on the environmental risk assessment of genetically modified plants
A Testbiotech report for
The Greens/EFA in the European Parliament
THINK BIO DIVERSITY
July 2010
Author: Christoph Then


TEST BIOTECH
Synthetische Biologie und künstliches Leben – eine kritische Analyse
Teil 2:
Die Erzeugung und Nutzung von Biokraftstoffen der zweiten Generation („Synthi-Fuels")
grassroots foundation


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Gentechnisch veränderte Pappeln – eine ökologische Zeitbombe?
Ein Report von Testbiotech in Zusammenarbeit mit der Gesellschaft für ökologische Forschung
GEKKO

Some lessons learnt from tobacco industry ...

- Denial of specific risks
- Influencing scientific standards for risk assessment
- Close collaboration with scientists and international institutions

(Grüning T, Gilmore AB, McKee M: Tobaccoindustry influence on science and scientists in Germany. Am J Public Health 2006; 96: 20–32.)

...for example: Denial of specific risks

"The experiments were no more dangerous than feeding the children a small carrot since the levels of beta-carotene and related compounds in Golden Rice are similar."

(From the website of the Golden Rice Consortium http://www.goldenrice.org/)

....for example: Denial of specific risks

"For example, with GM oilseed rape with increased lauric acid content, a comparative food/feed risk assessment could be made using oils from coconut and palm kernel as comparators instead of conventional oilseed rape oil."

(From the draft Guidance on Selection of Comparators for the Risk Assessment of GM Plants)

… for example: Influencing scientific standards

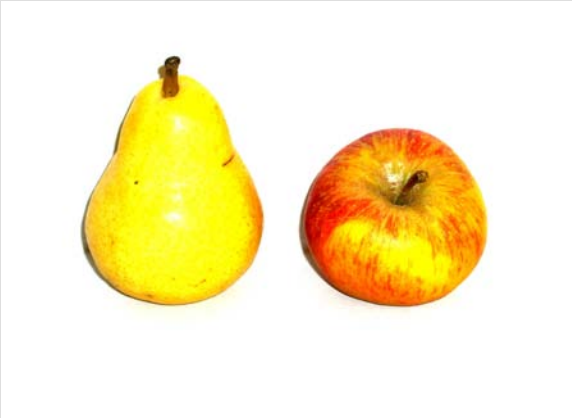
"In a study involving 94 articles selected through objective criteria, it was found that the existence of either financial or professional conflict of interest was associated to study outcomes that cast genetically modified products in a favorable light ($p = 0.005$). While financial conflict of interest alone did not correlate with research results ($p = 0.631$), a strong association was found between author affiliation to industry (professional conflict of interest) and study outcome ($p < 0.001$)."

Diels, J., Cunha, M., Manaia, C., Sabugosa-Madeira B., Silva M., (2011) Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products, Food Policy 36 (2011) 197–203

… for example: Influencing scientific standards

Comparative risk assessment:

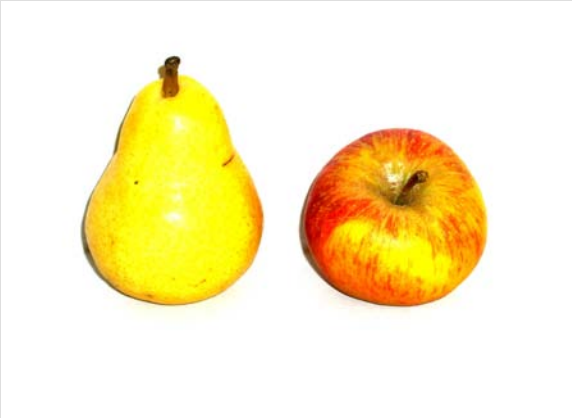
Based on a comparison of apples with pears



By genetic engineering the DNA is introduced by methods that are not based on the mechanisms of common gene regulation and heredity. The newly introduced gene constructs have a specific potential for escaping and/or disturbing the process of normal gene regulation that is unique for this particular technology.

Comparative risk assessment:

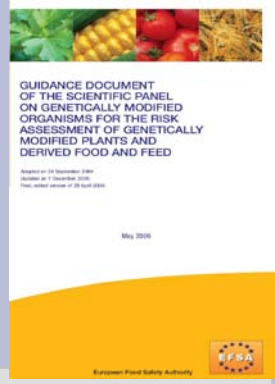
Hiding specific risks



The concept of comparative risk assessment allows to hide the specific risks of genetic engineering by comparing it with very general risks and non-relevant data.

Comparison can serve as a tool but not as a concept.

A better alternative: risk assessment 'per se'



"Where no appropriate comparator can be identified, a comparative safety assessment cannot be made and a comprehensive safety and nutritional assessment of the GM crop derived food/feed per se should be carried out."

EFSA Guidance, 2006/2008

Risk assessment 'per se' first step:

Generate a broad range of unbiased data

For example:

- molecular characterization – analysing the structure
- stress test (1): genetic stability and gene activity – analysing the dynamics
- stress test (2): compositional analysis - determining the range of variations

Risk assessment 'per se' first step:

Generate a broad range of unbiased data

For example:

- investigate toxicity (1): Impact of new proteins / whole plant preparations on biological systems in vitro (cell cultures, test organisms).

- investigate toxicity (2): combinatorial effects between plant compounds, residues from spraying, abiotic and biotic factors on target and non-target systems in vitro (cell cultures, test organisms).

Risk assessment 'per se': results from first step will allow to develop hypotheses

- derive first hypothesis about risks and potential hazards.
- apply cut off criteria such as genetic instability, persistence and/or invasiveness, signals of toxicity...
- in further risk assessment: expect the unexpected.

Risk assessment 'per se' next steps:

Require more mandatory testings

For example:

- multigenerational feeding studies on health effects including immunological and reproductive data.

- experimental release in all relevant climatic / bio-geographical zones over several years. Step by step from small scale to larger scale.

Some general requirements

- involve independent research institutions
- apply independent quality control
- publish results in peer review process
- give access to all raw data (including genomic data)
- give access to research material

Some last conclusions

- drop the concept of comparative risk assessment
- do not presume safety, equivalence, similarity or familiarity
- use comparison as a tool and not a concept
- do always apply a risk assessment >per se< in the case of genetically engineered organisms

.....thank you very much for your attention!