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

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EFSA´s Risk Assessment of Genetically Engineered Plants

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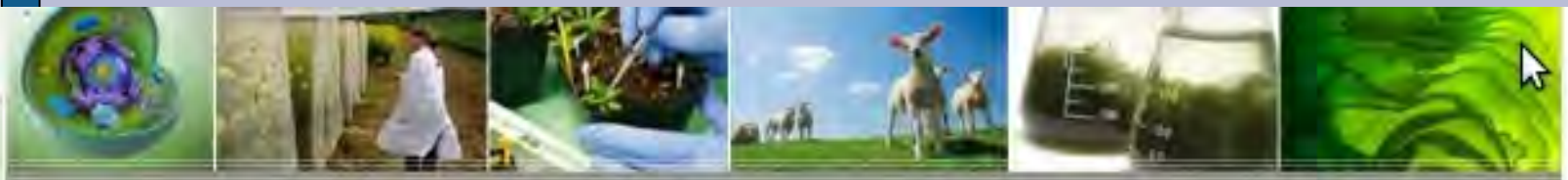
- promotes independent research
- examines ethical, social and economic issues and risks to health and the environment
- serves as a watchdog
- Initiates public debates



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English | Deutsch

PlantGeneRisk

Database on the authorisation of genetically engineered plants in the European Union

This database gives an overview of the authorisation of genetically engineered plants in the European Union. Special attention is given to the work of the European Food Safety Authority (EFSA). Each plant listed in the database is portrayed in a short summary, followed by a list that gives an overview of some specific known risks. These risks are contrasted with gaps in the EFSA risk assessment. High standards for the protection of consumers and the environment are set by EU regulations 178/2002, 1829/2003 and 2001/18. The purpose of this database is to enforce the implementation of those legal standards in the authorisation process of genetically engineered plants.

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Search

Event name

40-3-2
A5547-127
Bt11

Projekte

- EFSA GMO Watch
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What is authorised for EU markets?

46 events authorised for food and feed:

26 x maize

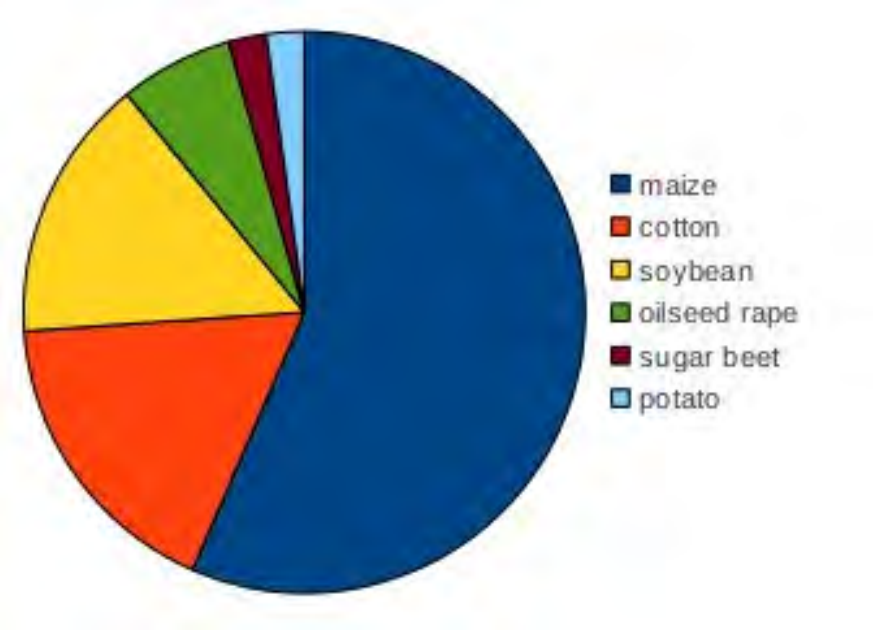
8 x cotton

7 x soy

3 x oilseed rape

1x sugar beet

1x potato (industrial usage)



What is authorised for EU markets?

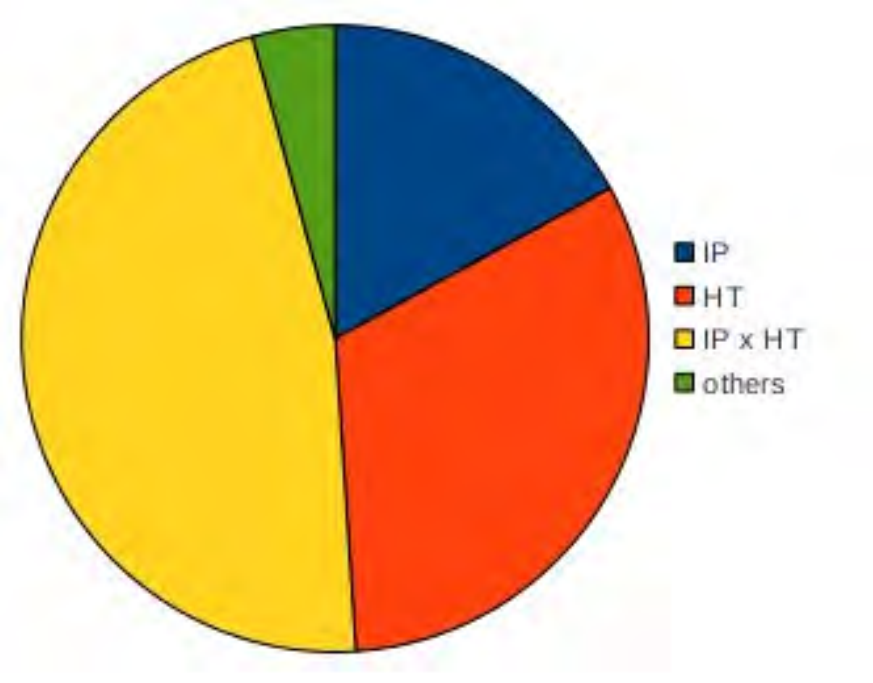
8 x insecticidal proteins (maize and cotton)

15 x tolerance against herbicides (soybean, oilseed rape, cotton, maize),

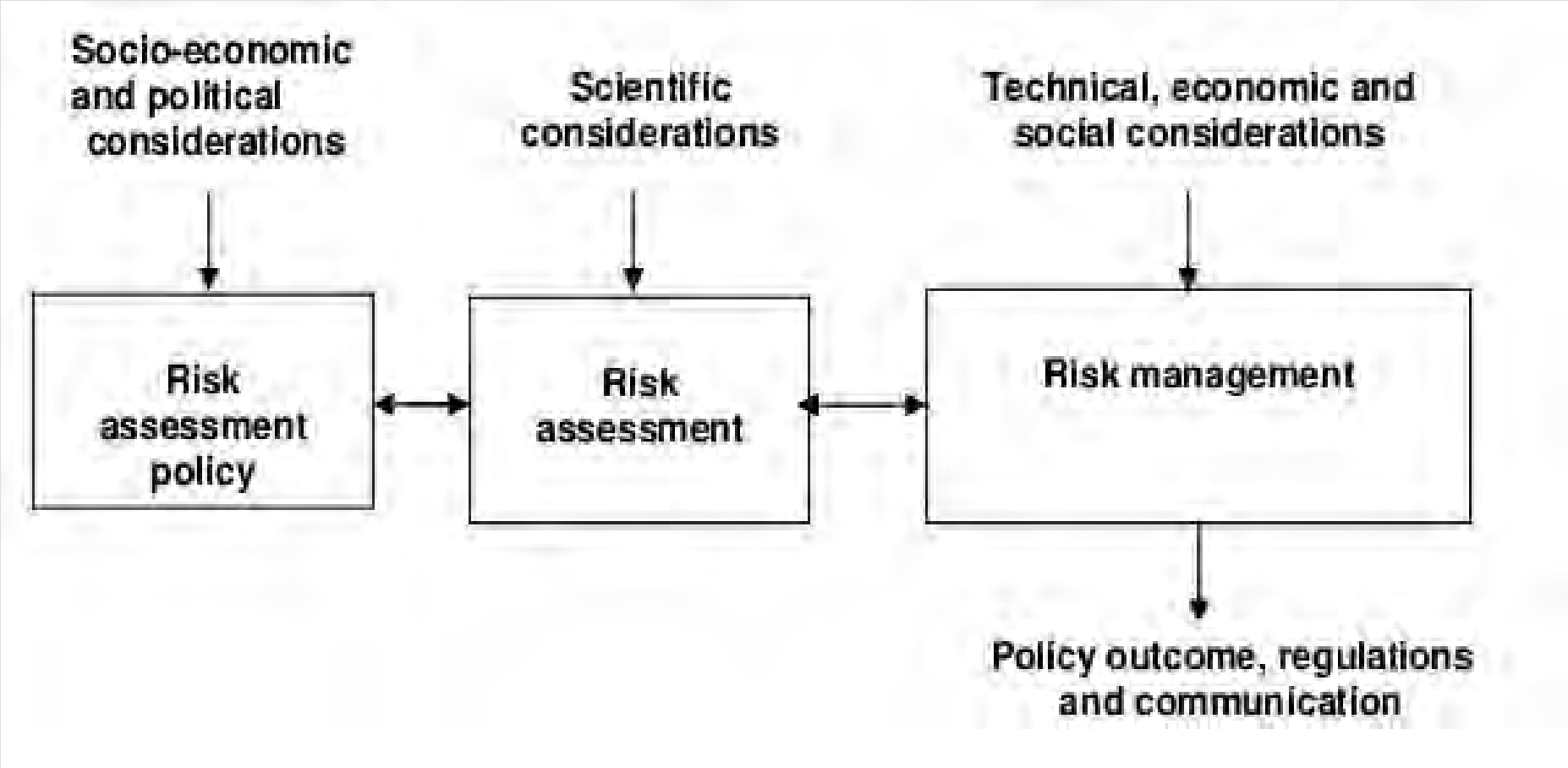
22 x “stacked events”

1 x starch (potato)

1 x male sterility (oliseed rape)



The EU system of risk analysis



Millstone, JRC, 2008

EFSA´s comparative risk assessment: not meant to be comprehensive.

„The underlying assumption of this **comparative approach** is that traditionally cultivated crops have a history of safe use for consumers and/or domesticated animals. These traditionally cultivated crops can thus serve as comparators when assessing the safety of GM plants and derived food and feed.“

EFSA, 2011

Comparing apples with pears

Conventional breeding and genetic engineering are fundamentally different from a technological point of view as well as from a biological perspective.

Contrary to conventional breeding, genetic manipulation is inserting technically derived gene constructs to enforce specific biological functions in the plants by disregarding the system of gene regulation and the barriers between species.

Comparing apples with pears

Comparative risk assessment starts with a wrong assumption which is impacting all following steps of risk assessment.

Instead of comprehensive risk assessment only a reduced 'check up' is conducted.

Comparative risk assessment: The concept of biotech industry

"In 2004, the task force's work culminated in the publication of a report that included a series of recommendations for the nutritional and safety assessments of such foods and feeds. This document has gained global recognition from organizations such as the European Food Safety Agency and has been cited by Japan and Australia in 2005 in their comments to Codex Alimentarius. The **substantial equivalence paradigm**, called the comparative safety assessment process in the 2004 ILSI publication, is a basic principle in the document."

(ILSI, 2008)

Comparative risk assessment: The concept of biotech industry

efsa
European Food Safety Authority
committed to ensuring that Europe's food is safe

Comparative risk assessment: The concept of biotech industry

Development of the concept of Comparative Assessment, chronological overview

Year	*Events*
1993	OECD publishes its concept of *Substantial Equivalence*
1999	Harry Kuiper writes his first report for ILSI
2000	Joint workshop of FAO & WHO chaired by Harry Kuiper discusses *Comparative Assessment*
around 2001	Harry Kuiper, Gijs Kleter and Ester Kok become authors for the ILSI *Task Force*
2001-2003	Harry Kuiper, Gijs Kleter and Ester Kok publish several papers on the risk assessment of genetically engineered plants and the concept of *Comparative Assessment* is given its current shape.
2003	Harry Kuiper, Gijs Kleter and Suzy Renckens become staff members of the EFSA GMO Panel
2004	The ILSI Task Force publishes its report particularly emphasising the concept of the *Comparative Assessment*.
2004	EFSA publishes its *Guidance Document* on the risk assessment of food and feed derived from genetically engineered plants. *Comparative Assessment* is hereby the most important starting point.
2005	"Mr. Kuiper´s contribution to ILSI´s scientific papers ended in June 2005." (EFSA, reply to Ombudsman, 2012)

Comparative risk assessment: The concept of biotech industry

„Although the Principle of Substantial Equivalence has received comments from all types of stakeholders (producers, regulators, consumers, evaluators, etc.), the basic idea behind the principle remains untouched. When evaluating a new or GM crop variety, comparison with available data on the nearest comparator, as well as with similar varieties on the market, should form the initial part of the assessment procedure.“

(Kok&Kuiper, 2003)

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/)

Monsanto about unintended effects

MONSANTO

"Nonetheless, the frequency of success of enhancing the transgenic plant is low due to a number of factors including the low predictability of the effects of a specific gene on the plant's growth, development and environmental response, the low frequency of maize transformation, the lack of highly predictable control of the gene once introduced into the genome, and other undesirable effects of the transformation event and tissue culture process."

Source: Patent application WO2004053055

A “comprehensive safety assessment” is mentioned but never applied by EFSA

„Where no comparator can be identified, a comparative risk assessment cannot be made and a **comprehensive** safety and nutritional assessment of the GM plant and derived food and feed itself should be carried out.“

EFSA, 2011

Some weaknesses in current RA of EFSA (1): Comparative approach

Comparative risk assessment is the standard procedure. Instead of a comprehensive risk assessment this is only a reduced 'check up' based on a assumption that risks from genetically engineered plants can be regarded as equivalent to those of plants derived from conventional breeding.

Some weaknesses in current RA of EFSA (2): Flawed reference data

The most relevant step in comparative risk assessment (the investigation of substantial equivalence) allows the introduction of flawed 'historical' data. Especially the data base of ILSI is used widely during risk assessment of EFSA.

Example: Flawed historical data as references

Joe Perry, current Chair of EFSA's GMO Panel:

"(…) at the present time we can't trust the ILSI database. There is not sufficient environmental information from where these trials were done and that's why we insist that the commercial reference variety should be planted simultaneously with the GM and the non-GM. Otherwise I think we are in an unsafe situation and I would worry that the limits would be too wide."

EFSA's consultative workshop on its draft guidance for the selection of Genetically Modified (GM) plant comparators, held in Brussels on 31 March 2011, http://www.efsa.europa.eu/en/events/event/gmo110331.htm

Some weaknesses in current RA of EFSA (3):

No investigations to defined stress conditions

Interactions with the environment (such as climate change or plant pests) that can impact the plants composition are not tested sufficiently. There is no investigation under defined conditions to assess the interaction of the gene construct with the plant´s genome.

There is no request to apply more recent technologies, such as metabolic profiling to study genomic reactions.

Example:
Stress test for genetically engineered maize

Reasoning: Several publications show genetically engineered plants react unexpectedly and unpredictably to environmental impacts. Ongoing climate change shows how important it is to have more data about these issues.

Some weaknesses in current RA of EFSA (4): No coherent testing for health effects

Testing for health risks does not entail mandatory investigations such as in vitro toxicity tests on cell cultures, targeted investigation of specific health risks (such as immune and reproductive toxicity) and mandatory long term and multi generational studies.

Feeding studies on health effects - not mandatory

Company/product	Trait	Duration, animal species	Issue in investigation
Bayer/LLRice62	Rice with herbicide tolerance	42 days, poultry 96 days, pigs	Feed conversion
Monsanto/MON863	Maize with Bt toxin	90 days, rats	Health risks
Monsanto/NK603	Maize with herbicide tolerance	90 days, rats	Health risks
Pioneer/1507	Maize with Bt toxin	90 days, rats	Health risks
Syngenta/ Bt11	Maize with Bt toxin	14 days, cows 14 days, poultry	Feed conversion

Some weaknesses in current RA of EFSA (5):

Residues from spraying not assessed

The necessary interplay with pesticide regulation is missing.

Residues from spraying with complementary herbicides are not taken into account.

Residues from spraying -

legal dossier of Professor Ludwig Kraemer

The objective of current EU legislation is to avoid *any* adverse effect on human health from genetically modified plants. Therefore, risk assessment must take the cumulative effect of herbicide residues on genetically modified plants into account.

www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf

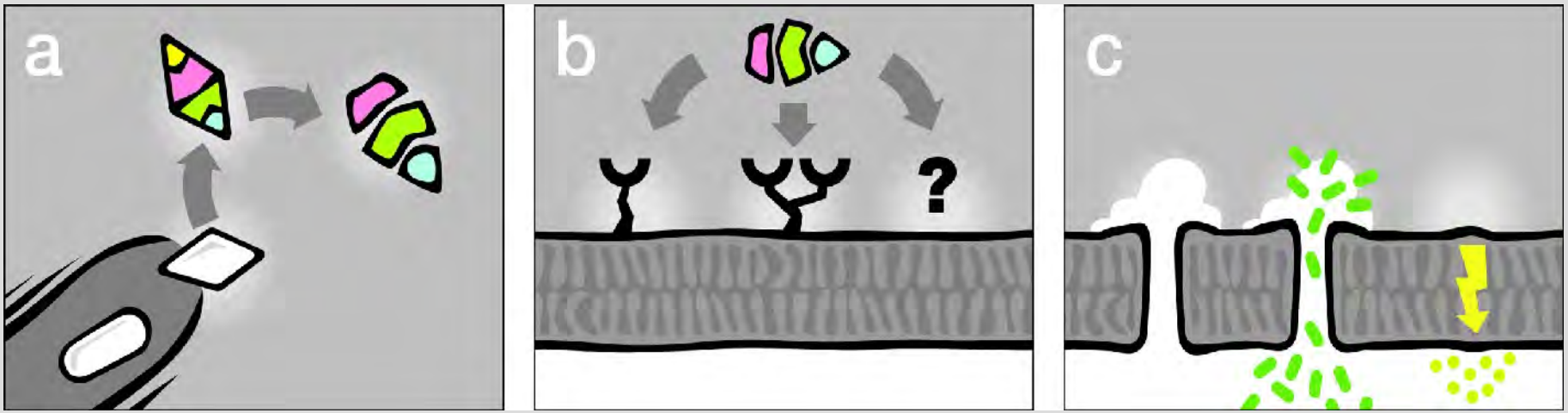
Some weaknesses in current RA of EFSA (6):

Mode of action of Bt toxins not fully understood

Risk assessment of Bt plants is based on a highly questionable assumption about their mode of action and their selectivity.

Bt toxins in the plants are modified and pre-activated – these toxins were never assessed according to pesticide regulation.

Example MON810, Cry1Ab:
mode of action is not known precisely



Example MON810, Cry1Ab: not neutral to human cells

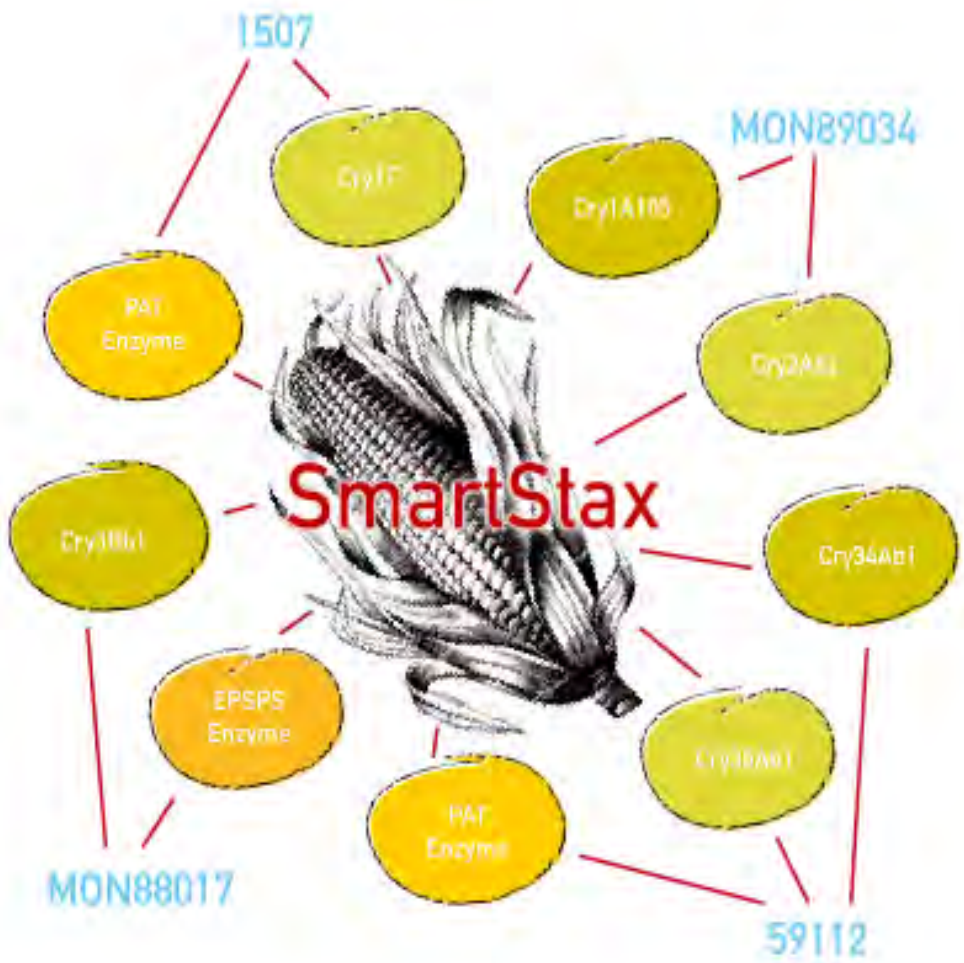
Mesnage R., Clair E., Gress S., Then C., Székács A., Séralini G.-E., 2012, Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide, Journal of Applied Toxicology.

Some weaknesses in current RA of EFSA (7): Combinatorial effects neglected

Stacked events are investigated less rigorously than single events.

The requirements for investigation of synergistic, additive and accumulated effects are not sufficiently defined.

Example: SmartStax



>> Ten artificial gene constructs, derived from more than seven species (or subspecies or specific strains)

>> Six modified bacterial toxins (one of them synthetic)

>> tolerance to two herbicides

...but synergistic effects in the food chain were not investigated.

Some weaknesses in current RA of EFSA (8):

Missing quality standards for data of industry

Quality standards for the investigations of industry are not defined.

Fully evaluated methods to measure the expression of the newly introduced gene constructs is not requested.

Example of SmartStax: Monsanto´s data on phenotype

STUDY TITLE

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

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
Monsanto Company
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St. Louis, Missouri 63167

STUDY DIRECTOR
Eric W. Rosenbaum

REPORT NUMBER
MSL0021061

Monsanto Company and Dow AgroScien

STATEMENT OF COMPLIANCE

This study does not meet the U.S. EPA Good Laboratory Practice requirements as specified in 40 CFR Part 160. Measures taken to ensure study quality have been included in the Quality Measures section of the report.

Study Director: Eric W Rosenbaum Date: 2/28/08

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Biotechnology Regulatory Affairs,
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3.5 Data Assessment

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.

Example:

how much toxin does GE maize actually produce?

Székács, A., Weiss G., Quist, D., Takács, E., Darvas, B., Meier, M., Swain T., Hilbeck A., (2011): Inter-laboratory comparison of Cry1Ab toxin quantification in MON 810 maize by ezyme-immunoassay, Food and Agricultural Immunology

Some weaknesses in current RA of EFSA (9):

No cut off criteria for persistent or invasive plants

It is not a requirement for industry to show that they can withdraw their product from the market if needed.

Example: Rape seed out of control

News

GM crop escapes into the American wild

Transgenic canola found growing freely in North Dakota.

Natasha Gilbert

A genetically modified (GM) crop has been found thriving in the wild for the first time in the United States. Transgenic canola is growing freely in parts of North Dakota, researchers told the Ecological Society of America conference in Pittsburgh, Pennsylvania, today.

The scientists behind the discovery say this highlights a lack of proper monitoring and control of GM crops in the United States.

US farmers have dramatically increased

If GM crops with herbicide resistance spread beyond farmland, they could become problematic weeds. *IStockphoto*

Source: Nature, 2010

Some weaknesses in current risk analysis (10):

Monitoring of health effects not requested

Post-marketing monitoring for identification of potential negative health effects is not requested.

Montoring of health effects - legal dossier of Professor Ludwig Kraemer

The present practice of not monitoring potential adverse effects on human health from genetically modified plants does not comply with existing EU legislation.

The objective of current EU legislation is to avoid *any* adverse effect on human health from genetically modified plants. Therefore, risk assessment must take the cumulative effect of herbicide residues on genetically modified plants into account.

www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf

Example: Post market monitoring of health effects of Roundup Ready soybeans

EFSA opinion (2010) in favour of further marketing Roundup ready soybeans after ten years without any post market monitoring:

“Although no post-market monitoring for food and feed safety of soybean 40-3-2 has formally been performed, there is no evidence of any adverse effects being associated with the consumption of soybean 40-3-2 as food or feed within the European community.”

What do we really know about any long-term effects?

"As regards food safety, even if some GM products have been found to be safe and approved on a large scale ... the lack of general surveillance and consequently of any exposure data and assessment means that there is no data whatsoever available on the consumption of these products – who has eaten what and when. … in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health."

Source: EU Commission, 2005

Some requirements from EU regulations

>> Regulation 178/2002 “the Food Safety Regulation”:
“Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.“

>> Regulation 1829/2003, „genetically modified food and feed“:
products derived from genetically engineered plants “should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard.”

>> Directive 2001/18, „release of genetically engineered organisms“:
requires the examination of the “direct and indirect, the immediate and delayed effects” of the genetically engineered plant “on human health or the environment”, “in accordance with the precautionary principle.”

EFSA standards: Just useful for industry?

MONSANTO

Monsanto´s fact sheet on stacked soy “Intacta” (MON87701 x MON89788), to be grown in Brasil:

“EFSA finalized the risk assessment and adopted its Scientific Opinion (...) concluding that 'the soybean MON 87701 x MON 89788 is as safe as its comparator with respect to potential effects on human and animal health or the environment in the context of its intended uses'.”

See complaint against 'stacked soy' Intacta, www.testbiotech.de/node/691

Some recommendations

- Drop the concept of comparative risk assessment; do not presume safety, equivalence, similarity or familiarity; use comparison as a tool and not a concept;
- Always apply a comprehensive risk assessment;
- Establish clear cut off criteria for rejection of applications;
- Promote independent risk research;
- Set higher standards for independency of EFSA;
- Reassess EU market authorisations;
- Do not adopt draft implementation regulation of the EU Commission.

EU Commission´s planned new regulation - not a real improvement

EUROPEAN COMMISSION

Brussels, XXX
SANCO/12462/2011 Rev. 1
(POOL/E1/2011/12462/12462R1-EN.doc)
[…](2012) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) No …/..

of XXX

on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations (EC) No 641/2004 and (EC) No 1981/2006

(Text with EEA relevance)

Some general conclusions

Within the first ten years, the work of the GMO panel of EFSA can not be seen as being independent nor is it fulfilling the requirements of EU regulations.

The EU Commission fails to fulfil its task as risk manager. It does not support independency of EFSA, it does not define sufficient risk assessment policies and it neglects its duty to implement effective post marketing monitoring. Ethical questions and socio-economic consequences are not integrated in the process of risk analysis.

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