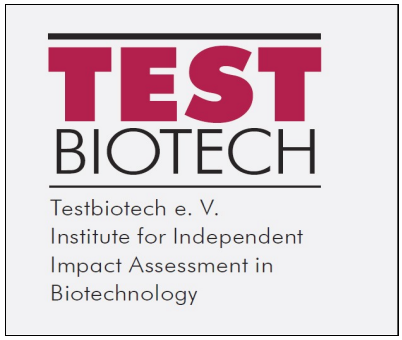
TESTBIOTECH Background 1-12-2010

European Food Safety Authority: A playing field for the biotech industry

Standards for risk assessment massively influenced by industry



Christoph Then and Andreas Bauer-Panskus

Table of Contents

Summary

Testbiotech investigations have revealed that conflicts of interest have a severe impact on the work of the G*MO Panel* at the Food Safety Authority (EFSA). The EFSA G*MO Panel* is responsible for the risk assessment of genetically engineered plants. Harry Kuiper, a leading scientist there since 2003, chairs the EFSA G*MO Panel*. Just before he joined the EFSA, he worked for a so-called *Task Force* established by the *International Life Sciences Institute* (ILSI). A Monsanto member of staff heads this *Task Force* and all other members are representatives from large biotech-corporations. Even after starting work at EFSA, Kuiper is still currently active within ILSI. There is also at least one other EFSA *GMO Panel* member who has worked for the *Task Force*.

The collaboration between ISLI and the *GMO Panel* experts has had a marked effect on EFSA. According to ILSI, the work of the *Task Force* has had an impact on the EFSA guidelines for the risk assessment of genetically engineered plants. *Comparative Assessment* was implemented as a starting point for risk assessment. So-called *Comparative Assessment* is based on the assumption that conventional breeding and genetic engineering can generally be seen as being equivalent. As a result, the risks of genetically engineered plants are less rigorously investigated than they would be if EFSA assumed that genetic engineering and conventional breeding are basically different –which is much more plausible from a scientific point of view.

Further problems arise from the fact that ILSI set up the databank used to compare the compounds of genetically manipulated plants with those of plants derived from conventional breeding. This constellation does not appear to provide adequate protection from targeted manipulation by industry.

Further evidence that the ILSI influences the EFSA *GMO Panel* has been found in the context of feeding trials. EFSA does not normally require feeding studies using genetically engineered to test for potential health impacts. The document published by EFSA to explain why feeding trials are not necessary, was partially plagiarized from an ILSI paper.

The Testbiotech investigation cannot give a fully comprehensive picture of the situation. More likely this is only the tip of the iceberg. The risk assessment of genetically engineered plants has been influenced by the relationship between the EFSA *GMO Panel* experts and biotech industry on several levels, and this is cause for concern.

Testbiotech recommends a far-reaching re-organisation of EFSA with significant participation of environmental and consumer organisations. As a first step, all members of staff, experts and members of the EFSA management board active in ILSI should step down from their positions at EFSA.

1. Introduction

The European Food Safety Agency (EFSA) was established in 2002. One of its tasks is the risk assessment of genetically engineered plants. This kind of risk assessment is based on EU regulations that foresee a high standard of safety for consumers and the environment, based on the precautionary principle (Directive 2001/18, Regulation 1829/2003). The EFSA is responsible for the practical application of these regulations in the context of market applications. A department for the risk assessment of genetically engineered plants (*GMO Unit*) was set up in 2003 to coordinate an expert panel, the so called *GMO Panel*. The *GMO Unit* was headed by Suzy Renckens. Harry Kuiper (originally from RIKILT Institute at the University of Wageningen) chaired the scientific work of the *GMO Panel*.

The *GMO Panel* published risk assessment guidelines in 2004. Since then several further documents have been published, dealing with various issues of risk assessment such as environmental risk assessment, animal feeding trials, allergenicity risk and monitoring. There has been a lot of criticism from various stakeholders that the work of EFSA is inadequate to fulfil EU requirements (see for example EU Commission, 2006[1]). Reports (so-called opinions) prepared by the EFSA *GMO Panel* have failed to gained necessary majorities in the EU Council voting.

The following overview shows that EFSA guidelines are influenced by industry. The most relevant drivers in this context are the *International Life Sciences Institute* (ILSI) and the chair of the EFSA *GMO Panel,* Harry Kuiper.

2. How the ILSI impacts the EFSA risk assessment of genetically engineered plants

ILSI has its headquarters in the US and maintains that it is not influenced by any vested interests from industry (ILSI 2004):

> *"The International Life Sciences Institute (ILSI) is a non-profit worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. ILSI also works to provide the science base for global harmonization in these areas. By bringing together scientists from academia, government, industry, and the public sector, ILSI seeks a balanced approach to solving problems of common concern for the well-being of the general public."*

The work of the ILSI has been greatly criticized for many years mainly because of its close cooperation with the tobacco industry to which WHO publicly objected. [2] More recently, ISLI made headline news because Diana Banati, a member of the EFSA management board, was also active within ILSI. Banati quit ILSI after media reports.[3] According to further research by the German media, ILSI also had an impact on the risk assessment of potentially hazardous chemical compounds such as Bisphenol A.[4]

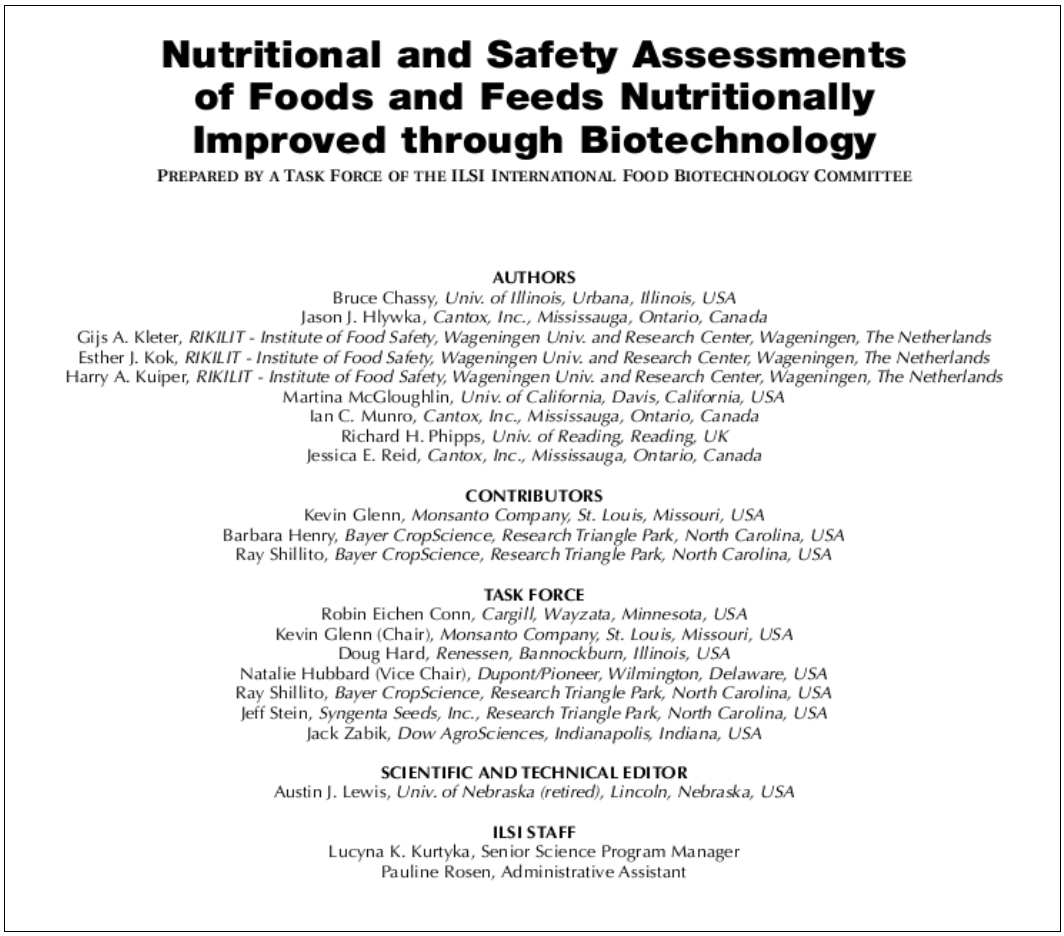
1 http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/498&format=HTML&aged=1&language=EN&guiLanguage=en
2 http://www.who.int/tobacco/media/en/ILSI.pdf
3 http://www.taz.de/1/politik/europa/artikel/1/aufseherin-gibt-industrie-job-auf/
4 http://www.spiegel.de/wissenschaft/mensch/0,1518,729902,00.html

2.1 The ILSI Task Force

Especially in the context of agri-biotechnology, there is no doubt that ILSI has a very close connection to industry. ILSI established a *Task Force* to deal with biotechnology, all of whose members belong to industry. The October 2010 ILSI homepage shows (see also Fig. 4 below), that the following companies are currently members of the *Task Force*: BASF, Bayer CropSciences, Dow AgroSciences, Monsanto, Pioneer HiBred/Dupont und Syngenta.[5]

ILSI has dealt with agri-biotechnology since at least1996, around the time that Monsanto first started to grow genetically engineered soy commercially. At that time agri-biotechnology faced the difficulty of opening up the European market for its new controversial products. In 1997, ILSI established a European work group to deal with Novel Food.[6] In Europe, the RIKILT team – Institute for Food Safety at the University of Wageningen and their experts Harry Kuiper, Gijs Kleter and Ester Kok were amongst those who cooperated with ILSI. Harry Kuiper had already worked with ILSI in 1998 (see ILSI, 1999).

From around the year 2001, Harry Kuiper, Gijs Kleter and Ester Kok were working together as authors for the ILSI *Task Force* (ILSI, 2004, picture 1). At that time, the members of the *Task Force* were from the following companies: Cargill, Monsanto, Renessen, Dupont/Pioneer, Bayer CropSciences, Syngenta, Dow AgroSciences. Kevin Glenn from Monsanto was head of the *Task Force* (ILSI, 2004, ILSI 2008).



Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology

PREPARED BY A TASK FORCE OF THE ILSI INTERNATIONAL FOOD BIOTECHNOLOGY COMMITTEE

AUTHORS

Bruce Chassy, *Univ. of Illinois, Urbana, Illinois, USA*
Jason J. Hlywka, *Cantox, Inc., Mississauga, Ontario, Canada*
Gijs A. Kleter, *RIKILIT - Institute of Food Safety, Wageningen Univ. and Research Center, Wageningen, The Netherlands*
Esther J. Kok, *RIKILIT - Institute of Food Safety, Wageningen Univ. and Research Center, Wageningen, The Netherlands*
Harry A. Kuiper, *RIKILIT - Institute of Food Safety, Wageningen Univ. and Research Center, Wageningen, The Netherlands*
Martina McGloughlin, *Univ. of California, Davis, California, USA*
Ian C. Munro, *Cantox, Inc., Mississauga, Ontario, Canada*
Richard H. Phipps, *Univ. of Reading, Reading, UK*
Jessica E. Reid, *Cantox, Inc., Mississauga, Ontario, Canada*

CONTRIBUTORS

Kevin Glenn, *Monsanto Company, St. Louis, Missouri, USA*
Barbara Henry, *Bayer CropScience, Research Triangle Park, North Carolina, USA*
Ray Shillito, *Bayer CropScience, Research Triangle Park, North Carolina, USA*

TASK FORCE

Robin Eichen Conn, *Cargill, Wayzata, Minnesota, USA*
Kevin Glenn (Chair), *Monsanto Company, St. Louis, Missouri, USA*
Doug Hard, *Renessen, Bannockburn, Illinois, USA*
Natalie Hubbard (Vice Chair), *Dupont/Pioneer, Wilmington, Delaware, USA*
Ray Shillito, *Bayer CropScience, Research Triangle Park, North Carolina, USA*
Jeff Stein, *Syngenta Seeds, Inc., Research Triangle Park, North Carolina, USA*
Jack Zabik, *Dow AgroSciences, Indianapolis, Indiana, USA*

SCIENTIFIC AND TECHNICAL EDITOR

Austin J. Lewis, *Univ. of Nebraska (retired), Lincoln, Nebraska, USA*

ILSI STAFF

Lucyna K. Kurtyka, Senior Science Program Manager
Pauline Rosen, Administrative Assistant

Fig. 1: ILSI, 2004, the Task Force and their authors

5 http://www.ilsi.org/FoodBioTech/Pages/NutritionalandSafetyAssessments.aspx
6 http://www.monsanto.com/newsviews/Documents/food_feed_safety.pdf

In parallel to his work at ILSI, Harry Kuiper was the chair of the EU project ENTRANSFOOD that was supported by the Commission and industry and was also dealing with the risk assessment of genetically engineered plants. Thus, in this context, Harry Kuiper was one of the most influential experts in Europe at a time when he was under contract to ILSI.

During the period that Kuiper, Kleter and Kok were working as experts for the ILSI *Task Force*, they published several papers on the risk assessment of genetically engineered plants in which there are references to ILSI concepts (Kuiper et al., 2001; Kok & Kuiper, 2003; Kuiper & Gijs, 2003). In this context one of the most important issues is the so-called *Comparative Assessment*, which is the actual basis and starting point for the risk assessment of genetically engineered plants of EFSA´s *GMO Panel*.

2.2 ILSI, EFSA and the Concept of Comparative Assessment

The concept of *Comparative Assessment* is based on a comparison between genetically engineered plants and conventionally bred plants. They are seen as being equivalent if no significant differences are identified in the comparison of the most important plant components:

> *"The underlying assumption of this comparative assessment approach for GM plants is that traditionally cultivated crops have gained a history of safe use for the normal consumer or animal and the environment. These crops can serve as a baseline for the environmental and food/feed safety assessment of GMOs." (EFSA 2004, page 12)*

In short, the concept of *Comparative Assessment* helps to simplify risk assessment. In consequence, it avoids a more comprehensive risk assessment of genetically engineered plants. An in depth investigation would be necessary if genetically engineered plants were considered as substantially different from conventional plants because of the methods used in their production. In this case, which is much more plausible from a scientific point of view , a much broader concept for risk assessment would be needed (for overview see Then & Pothoff, 2009). As EFSA (2004) says:

> *"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."*

The concept of *Comparative Assessment* is based on the previous concept of *Substantial Equivalence* developed by industry and the OECD in 1993 (OECD, 1993). The concept of *Substantial Equivalence* was criticised by various experts and stakeholders as inadequate. In 2003, Kok & Kuiper (2003), both of whom were working for the ILSI *Task Force*, said that the older concept of *Substantial Equivalence* should be renamed *Comparative Assessment* with no change to its core content. The concept could then serve as a starting point for testing genetically engineered organisms (Kok & Kuiper, 2003):

> *"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."*

The new concept of *Comparative Assessment* was first discussed in a joint working group of FAO and WHO (FAO/ WHO, 2000) chaired by Harry Kuiper. Between 2001 and 2003 the concept was shaped by Harry Kuiper and his colleagues to its present day form.

In 2004, ILSI published a report on its *Task Force* and referred to the publications of Kuiper et al (2001) and the joint workshop of FAO/WHO (2000). The concept of *Comparative Assessment* is described as follows:

> *"This comparative assessment process (also referred to as the concept of substantial equivalence) is a method of identifying similarities and differences between the newly developed food or feed crop and a conventional counterpart that has a history of safe use."*

Since 2003, Kuiper has headed the newly established EFSA *GMO Panel*, the group of experts responsible for the risk assessment of genetically engineered plants. Suzy Renckens, who was the head of EFSA's *GMO Unit* at this time, caused a public stir because she became a member of the agri-biotech corporation Syngenta immediately after leaving EFSA in 2008.[7]

The team around Harry Kuiper and Suzy Renckens worked on the basic EFSA *Guidance Document* for the risk assessment of food and feed derived from genetically engineered plants (EFSA 2004). *Comparative Assessment* became the most crucial element. Other co-authors of the guideline document (EFSA 2004) were the German experts Detlev Bartsch, Hans-Joerg Buhk and Joachim Schiemann whose particular closeness to the genetic engineering industry is described elsewhere (Lorch&Then, 2008).

Kuiper and his colleagues were active in several organizations (such as ILSI, EFSA, FAO/WHO and ENTRANSFOOD) and prepared several papers published in scientific magazines. This could give the impression that the concept of *Comparative Assessment* relies on a broad consensus of all kind of experts. On taking a closer look, however, it seems that to a large extent the concept was created just by the network around Harry Kuiper and his colleagues during the time he was active for the ILSI *Task Force* (see *table 1).*

Year	Events
1993	OECD publishes its concept of S*ubstantial 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

Table 1: Development of the concept of Comparative Assessment, chronological overview

7 http://www.testbiotech.org/en/node/312

ILSI claims the EFSA guidelines as a success of its *Task Force:* Kevin Glenn from Monsanto and chair of the ILSI *Task Force*, pointed out at a workshop 2006 in Athens, that the ILSI (2004) report had had a huge impact. Both the EFSA guidelines and the negotiations on the international standards contained in the *Codex Alimentarius* were influenced by the ILSI report (see FAO/WHO 2005, also *Fig. 3)*. The following explanation regarding a 2004 ILSI report is given in a 2008 ILSI report:

> *"In 2002, a task force of international scientific experts, convened by the ILSI Intl. Food Biotechnology Committee (IFBiC), addressed the topic of the safety and nutritional assessments of foods and feeds that are nutritionally improved through modern biotechnology. 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."*

Fig. 3: Presentation by Kevin Glenn, (Monsanto & ILSI) on the impacts of the ILSI Task Force[8]

8 http://www.ilsi.org/FoodBioTech/Pages/ViewEventDetail.aspx?ID=1

2.3. Further cooperation between ILSI and EFSA

The publication of the ILSI report (2004) and the elaboration of EFSA´s *Guidance Document* (2004) is not the only example of close cooperation between Harry Kuiper and Gijs Kleter and ILSI. Kuiper and Kleter are, in 2010, currently members of the EFSA *GMO Panel*. According to Harry Kuiper´s *annual declaration of interest* posted on the EFSA website, he is still, in 2010, working with ILSI.[9] Gijs Kleter was a member of the ILSI *Task Force* until 2007 (ILSI, 2008; also see Fig. 4).

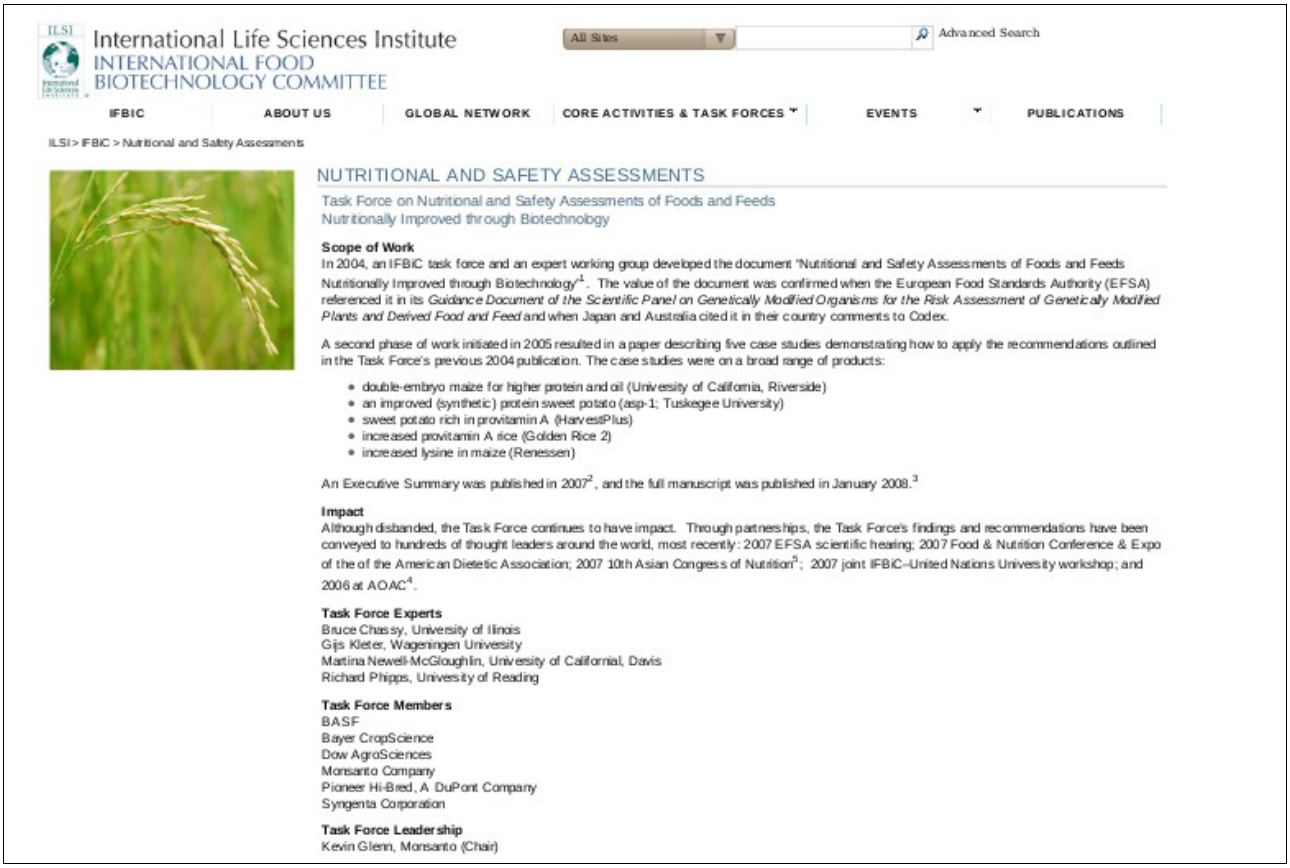


Fig. 4: ILSI website, 23.10.2010, Gijs Kleter is listed as a member of the ILSI Task Force[10]

The impact of ILSI on EFSA is not only limited to the *Guidance Document* of EFSA (2004). For example, striking indications for ILSI impact are evident in the EFSA position on animal feeding studies (EFSA, 2007). EFSA does not normally require feeding studies with genetically engineered plants to test them for potential health impacts (for overview see Then & Potthof, 2009). The document published by EFSA to explain why feeding trials are not necessary, was at least partially plagiarized from an ILSI paper. *Table 2* gives an overview of passages that have more or less the same wording in the EFSA (2007) and the ILSI (2004) reports. It is clearly the case that EFSA copied several passages from the ILSI report.

9 http://www.ilsi.org/FoodBioTech/Pages/NutritionalandSafetyAssessments.aspx
10 http://apjcn.nhri.org.tw/server/APJCN/Volume17/vol17suppl.1/229-232S13-1.pdf

ILSI, 2004	EFSA, 2007
In the case of GM crops with improved nutritional characteristics, livestock feeding studies with target species should be conducted on a case-by-case basis to establish the nutritional benefits that might be expected.	Livestock feeding studies with target animal species should be conducted on a case-by-case basis to establish the nutritional benefits that might be expected from GM plants with claimed nutritional/health benefits.
In addition, livestock feeding studies with target species are sometimes conducted to establish the effect of the new feed resource on animal performance with endpoint measurements such as feed intake, level of animal performance, feed conversion efficiency, animal health and welfare, efficacy, and acceptability of the new feed ingredient.	Livestock feeding studies with target species are sometimes conducted to establish the effect of a new feed material on animal performance with endpoint measurements such as feed intake, animal performance, feed conversion efficiency, animal health and welfare, efficacy, and acceptability of the new feed material.
In the case where nutritional components are to be deposited in the consumed tissue of the animal, specific tests for content should be conducted.	In cases where GM plants have been fed to livestock with the intention of modifying the nutritional components to be deposited in the consumed tissue of the animal, specific tests for content should be conducted.
The extent and type of livestock feeding studies conducted will depend on the type of feed resource developed, and their need should be determined on a case-by-case basis.	The extent and type of livestock feeding studies conducted will depend on the type of feed material developed, and their need should be determined on a case-by-case basis.
Sidhu and others (2000) and Ridley and others (2002) provide an excellent example of the compositional analyses conducted when comparing the grain and forage component of maize modified for an agronomic trait with its near isogenic counterpart and a number of commercially grown varieties.	The work conducted by Ridley et al. (2002) provides an excellent example of the extensive compositional analyses conducted when comparing the grain and forage component of HT maize (NK603) with its near isogenic counterpart and a number of commercially grown varieties.
Table 2-1: Examples of crops genetically modified with nutritionally improved traits intended to provide health benefits to consumers and domestic animals.	Table 1 Examples of GM plants with improved characteristics intended to provide nutritional or other health benefits to consumers and/or domestic animals
Once compositional equivalence, which is a cornerstone in nutritional assessment, has been demonstrated, work then focuses, if necessary, on livestock feeding studies to confirm nutritional equivalence (see Appendix 5-1) and on assessing the safety of any newly expressed components (proteins or nutrients).	Once compositional equivalence of the GM plant has been demonstrated, work may then be focused, where necessary, on livestock feeding studies to confirm nutritional equivalence, and to obtain further information on the safety.
Several crops with genetic modifications aimed at improving nutritional characteristics have been produced and are currently in trials (see Chapter 2).	A number of plants with genetic modifications aimed at improving nutritional characteristics have been developed (Table 1) and are currently in trials.
The exact experimental and statistical design will depend on a number of factors and will include animal species used in the study, the trait(s) being assessed, and the size of expected effect, which will in turn affect, for example, the number of animals per treatment group.	The exact experimental and statistical design of animal experiments to test the safety and nutritional value of GM plants with enhanced nutritional characteristics will depend on a number of factors and will include animal species, plant trait(s) and the size of the expected effect.

Table 2: Overview on paragraphs with similar wording that can be found both in EFSA (2007) and ILSI (2004) reports

ILSI is also important for the work of EFSA on another level. ILSI set up a databank with data from crop plants and it is this databank that is used to decide upon the outcome of *Comparative Assessment.*[11] The data from genetically engineered plants is compared with conventional plant data stored in the ISLA databank. The broader the range of ILSI data that is used in the comparison, the less a change in the components of genetically engineered plants will be judged as biologically relevant.

This procedure involving the comparison of data from industry (from genetically engineered plants) with the data from the ILSI databank does not appear to provide adequate protection from manipulation. It cannot be ruled out that data from industry is adapted to correspond with data from the ILSI databank.

This databank was used, for example, in the risk assessment of SmartStax, a genetically engineered maize with eight additional gene constructs.[12] The *Comparative Assessment* carried out with data from the ILSI databank[13] revealed nothing noteworthy and therefore EFSA concluded that it was not necessary to perform further risk assessment.

In 2010, EFSA published new guidelines on the environmental risk assessment of genetically engineered plants (EFSA, 2010). These guidelines are also based on the concept of *Comparative Assessment*.

3. Conclusions

As the Testbiotech report shows, there is some evidence that the work of the EFSA *GMO Panel* has, to an alarming degree, been impacted by the vested interests of industry. Based on current knowledge the following recommendations can be given:

- EFSA should be reorganised at management and *GMO Panel* levels
- Experts working for ILSI should step down from their positions at EFSA.
- A commission including representatives from the general public should be set up to investigate current EFSA standards and the extent to which EFSA has been undermined by industry. Under these circumstances, EFSA guidelines should not be adopted as EU regulations as currently planned by the EU Commission.[14]
- EFSA should establish an additional control body, integrating stakeholders from civil society such as environmental and consumer organisations.

11 ILSI 2006. International Life Sciences Institute Crop Composition Database Version 3.0. Available from: http://www.cropcomposition.org

12 http://www.efsa.europa.eu/en/scdocs/scdoc/1781.htm

13 ILSI 2006. International Life Sciences Institute Crop Composition Database Version 3.0. Available from: http://www.cropcomposition.org

14 http://www.testbiotech.org/en/node/334

Sources

EFSA, 2004, Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed, the EFSA Journal (2004) 99, 1–94

EFSA, 2007, Assessment of Genetically Modified Plants and Derived Food and Feed: The Role of Animal Feeding Trials – Report of the EFSA GMO Panel working group on animal feeding trials: Adopted by the Scientific panel on Genetically Modified Organisms on 12 September 2007. Food and Chemical Toxicology, Volume 46, Supplement 1, March 2008, http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902590265.htm

EFSA, 2010, Panel on Genetically Modified Organisms (GMO); Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879. [111 pp.]. doi:10.2903/j.efsa.2010.1879. Available online: www.efsa.europa.eu

FAO/WHO, 2000, Safety aspects of genetically modified foods of plant origin, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, World Health Organization, Headquarters, Geneva, Switzerland, 29 May – 2 June 2000

FAO/WHO, 2005, Joint FAO/WHO Food Standards Program Codex ad Hoc intergovernmental task force on foods derived from biotechnology, Fifth Session, Chiba, Japan, 19–23 September 2005, CX/FBT 05/5/4

ILSI, 1999, Detection methods for novel foods derived from genetically modified organisms, ILSI Europe Report Services, Summary of a workshop held in June 1998, Organised by the ILSI Europe Novel Food Task Force in collaboration with the ILSI International Food Biotechnology Committee.

ILSI, 2004, Nutritional and safety assessments of foods and feeds nutritionally improved through biotechnology. Prepared by a Task Force of the ILSI International Food Biotechnology Committee as published in IFT's Comprehensive Reviews in Food Science and Food Safety, 2004 Institute of Food Technologists (www.ift.org), http://www.ilsi.org/FoodBioTech/Publications/02_Nutritional%20_Safety%20Assessment%20of%20GM%20Foods_2004.pdf

ILSI, 2008, Assessments of Foods and Feeds Nutritionally Improved through Biotechnology: Case Studies Prepared by a Task Force of the ILSI International Food Biotechnology Committee, Comprehensive Reviews in Food Science and Food Safety, Vol. 7, 53–113, http://www.ilsi.org/FoodBioTech/Publications/10_ILSI2008_CaseStudies_CRFSFS.pdf

Kok, E.J., Kuiper, H.A., 2003, Comparative safety assessment for biotech crops. Trends in Biotechnology 21: 439–444.

Kuiper H.A., Kleter G.A., Noteborn H.P.J.M., Kok E.J, 2001, Assessment of the food safety issues related to genetically modified foods. Plant J 27:503–28.

Kuiper H.,A. & Kleter G.,A., 2003, The scientific basis for risk assessment and regulation of genetically modified foods, Trends in Food Science & Technology 14 (2003) 277–293

Lorch A. & Then C., 2008, Kontrolle oder Kollaboration? Bericht für die Grünen im Deutschen Bundestag,
http://www.ulrike-hoefken.de/cms/default/dok/232/232885.kontrolle_oder_kollaboration_agrogentech.html

OECD, 1993, Safety Considerations for Biotechnology: Scale-up of Crop Plants. OECD, 1993, http://www.oecd.org/dataoecd/26/26/1958527.pdf?channelId=34537&homeChannelId=33703&fileTitle=Safety+Considerations+for+Biotechnology+Scale-up+of+Crop+Plants

Then, C. & Potthof, C., 2009, Risk Reloaded – Risk analysis of genetically engineered plants within the European Union, Testbiotech report, www.testbiotech.org