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A Playground of the Biotech Industry ?
Need for reform at the European Food Safety Authority

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The European Food Safety Authority (EFSA) is responsible for the risk assessment of food and feed in the European Union. In this capacity the EFSA deals with the issue of genetically modified organisms (GMO). However, recent research shows that the authority is neither sufficiently independent, nor does the risk assessment comply with EU regulatory framework.

In 2002, in the aftermath of the BSE crisis, the European Union created a new food agency called the European Food Safety Authority, EFSA. One of its tasks is to assess the risks of genetically modified plants. These assessments are based on EU regulations (such as Directive 2001/18, Regulation 1829/2003) which set high standards of safety for the environment and consumers, based on the precautionary principle. It is EFSA's task to implement these standards when assessing the market approval of genetically modified plants. The EU set the criteria very high, stating that

> *"(...) genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. (...)" (Recital 9 of Regulation 1829/2003).*

In 2003, a department for biotechnology including a *GMO Panel* was created at EFSA. Suzy Renckens took over the organisational guidance; Harry Kuiper (former RIKILT Institute at the University of Wageningen, Netherlands) became Chairman of the expert group. He held that position from 2003 until 2012. The first version of EFSA-Guidelines for the risk assessment of GMOs (EFSA 2004)was published under their guidance, with their main features still being in effect (EFSA 2011).

The case of Harry Kuiper, ILSI and...

Research conducted by Testbiotech in December 2010 revealed serious conflicts of interest at the EFSA department for biotechnology in which the *International Life Sciences Institute (ILSI)* played a central role. The work of ILSI has faced criticism for many years and the World Health Organisation (WHO) explicitly reprehended their work for the tobacco industry[1]. The ILSI is funded by companies such as Monsanto, Dow AgroSciences, Bayer, DuPont and Bayer and it develops standards for risk assessment in close cooperation with industry.

ILSI has concerned itself with agricultural biotechnology since 1996. It was then that Monsanto began the commercial cultivation of genetically modified soybeans. At the time, it was difficult for biotech companies to find an opening in the European market for new products made in the USA. In 1997, ILSI founded a European workgroup for *Novel Food* (such as that made from genetically modified plants)[2].

The long-time head of the expert group, Harry Kuiper, worked for an ILSI task force both before and after he took office at EFSA. This task force was led by an employee of Monsanto and was staffed with representatives from the big agricultural companies, such as BASF, Bayer CropScience, Dow AgroSciences, Monsanto, Pioneer HiBreed/Dupont and Syngenta. It worked on the examination requirements for risk assessment of genetically modified plants (ILSI, 2004; Then& Bauer-Panskus, 2010).

As said above, Kuiper had previously worked for ILSI. He is mentioned as early as 1998 as a project coordinator for the verification procedure of genetically modified organisms (ILSI, 1999). The institute backed much of his scientific career before he joined EFSA in 2003 – and afterwards as well. In 2010, Kuiper stated in his official declaration of interest for EFSA that he was still working for ILSI. When Testbiotech drew attention to this conflict of interest, the declaration was changed. His work for ILSI now officially ended in 2005 – at least two years after he had started working for EFSA.

Parallel to his work for ILSI, Harry Kuiper was also working as head of an ENTRANSFOOD project, which was supported by the EU-Commission and industry and was also concerned with the verification procedure of genetically modified plants. Additionally, he was a member of international WHO and FAO workgroups. As a result, Harry Kuiper became one of the most influential experts on risk assessment for genetically modified organisms in Europe.

While working for ILSI, Kuiper published several papers on the risk assessment of genetically modified plants in which he also refers to ILSI concepts. Integral in this regard is the concept of *Comparative Assessment*, which constitutes the foundation and origin of risk assessment of genetically modified plants.

… the EFSA Guidelines

The *GMO Panel* drew up their own guidelines on risk assessment for genetically modified organisms for the first time in 2004. Since then, they have been revised several times. But the basic conception of *Comparative Assessment* has not changed. The EFSA Guidance is built on the

1 http://www.who.int/tobacco/media/en/ILSI.pdf.
2 http://www.monsanto.com/newsviews/Documents/food_feed_safety.pdf

assumption that risks of genetically engineered plants are comparable to those of plants derived from conventional breeding. In consequence, a comprehensive risk assessment is not conducted and only a limited set of data is requested. The so-called comparative approach is explained in the current EFSA Guidance (EFSA, 2011):

> *"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)

In short, *Comparative Assessment*, simplifies risk assessment and avoids extensive assessment of genetically modified plants. Consequently, current risk assessment is not comprehensive. If genetically modified plants were to be considered as the new products they are and inherently different from conventionally bred plants this would consequently require a comprehensive rather than a comparative approach. EFSA (2011) describes the situation as follows:

> *"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."*

However, until now there has not been a *single case* where EFSA considered it necessary to use comprehensive risk assessment. Instead, all applications evaluated by EFSA received a positive evaluation – on grounds of mostly poor data[3].

The concept of *Comparative Assessment* was initially based on the concept of *Substantial Equivalence*, which was developed by the OECD (OECD 1993) and industry in 1993 and has been criticised by many experts as insufficient. As Kok and Kuiper, who also worked for the ILSI *Task Force*, stated in 2003, the concept of *Substantial Equivalence* should be renamed *Comparative Assessment* but no core changes made, and then be made the new starting point for the assessment of genetically modified 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."*

As Kuiper and his colleagues were members of different Institutions (e.g. ILSI, EFSA, FAO/WHO and ENTRANSFOOD) at the same time and published various scientific papers, it seemed as if the *Comparative Assessment* was based on a solid scientific consensus. Upon closer inspection, the concept and its usage can essentially be reduced to the network around Harry Kuiper, and was obviously developed during his time at the ILSI task force (see Kuiper et al., 2001; Kok&Kuiper, 2003; Kuiper&Kleter, 2003 and table).

3 Examples for deficiencies in risk assessment of EFSA see www.testbiotech.de/en/database

Tab 1: The development of *Comparative Assessment*

Year	Incidence
1993	OECD develops the concept of *Substantial Equivalence*
1999	Harry Kuiper creates a first report for ILSI
2000	Joint workshop of FAO and WHO on the concept of *Comparative Assessment* as a derivative of *Substantial Equivalence* under chairmanship of Harry Kuiper
around 2001	Harry Kuiper, Gijs Kleter und Ester Kok become authors for ILSI *Task Force*
2001-2003	Harry Kuiper, Gijs Kleter und Ester Kok publish various articles on the risk assessment of genetically modified organisms. Development of *Comparative Assessment* currently used
2003	Harry Kuiper, Gijs Kleter und Suzy Renckens become staff members of EFSA *GMO Panel*
2004	The Task Force of ILSI publish their report once more emphasising *Comparative Assessment*
2004	EFSA publishes their guidelines on risk assessment of food produced from genetically modified plants. This is in essence based on *Comparative Assessment*
2005	Kuiper officially ends his cooperation with ILSI

The collaboration of ILSI and the experts of EFSA's biotechnology division clearly left its mark. In retrospect, ILSI itself claims that the work of their Task Force influenced EFSA test guidelines on the risk assessment of genetically modified plants (ILSI 2008):

> *"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."*

One apparent indication of ILSI influence on the biotechnology division of EFSA can be seen in the requirements for feeding trials. EFSA does not generally require feeding trials with genetically modified plants to test for effects on health. The document published by EFSA justifying this position (EFSA 2007) was in parts literally borrowed from an ILSI paper (ILSI 2004). An assessment of the documents by Testbiotech revealed dozens of plagiarised paragraphs (Then & Bauer-Panskus. 2010).

Reactions to conflicts of interest

By the end of 2009, Testbiotech had already called attention to the fact that Suzy Renckens, former head of the biotechnology division at EFSA who coordinated the work of the experts, had moved directly from the agency to the biotech industry – without any restrictions. Renckens was head of the division from 2003 until 2008, while Harry Kuiper was the chairman of the expert panel. Her case is now seen as a striking example of revolving doors – the continuous movement of personnel from industry to the agency and back. Even the EU ombudsman and the European Parliament have criticised the behaviour of EFSA in this regard, whilst initially the EU Commission and EFSA refused to take any action.

In 2012, José Bové, a representative of the Greens in the European Parliament pointed to the fact that Diáná Bánáti, chairwoman of the administrative board of EFSA was at the same time working as a member of the administrative board of ILSI. After Ms. Bánáti resigned from her position at ILSI, she was re-elected as chairwoman of the administrative board at EFSA. By May 2012 she had moved back to ILSI again to become executive director and scientific director, resigning her position at EFSA.

The cases of Diána Bánáti and Suzy Renckens were important reasons for the European Parliament refusing to approve the EFSA budget for 2010[4]. The parliament followed a recommendation by the budget committee, which harshly criticised EFSA on conflicts of interest and "revolving doors". One of the central concerns was the ties between EFSA and ILSI.

The governments of EU Member States also reacted to the conflicts of interest at EFSA. In June 2012, they rejected a proposal by the EU-Commission to appoint Mella Frewen, a chief lobbyist for the European food industry and former employee of Monsanto, as new member of the EFSA administrative board[5]. Testbiotech and Corporate Europe Observatory had warned about the impending conflicts of interest with the nomination of Frewen. Since 2007, Frewen has been the chairperson of FoodDrinkEurope (former CIAA), an industry federation. Among other things, Frewen lobbied intensively for the toleration of food with genetically modified plants even if these plants have not been approved in the EU.

The case of Frewen shows that problems at EFSA are not always internal. It was the EU Commission, which recommended Frewen and then defended her against all criticism. The members of the administrative board are key to the independence of EFSA – they nominate the members of the expert panels. Strictly speaking, protecting the independence of this central board from all other influence should be one of the EU-Commission's greatest concerns. In contrast to the Parliament, the Commission still does not seem to have any interest in strengthening EFSA independence.

EFSA also reacted to the accusations, although only after criticism from the EU Parliament and the ombudsman. It did indeed tighten its internal guidelines on independence. Experts working for institutions such as ILSI were excluded from important boards[6]. However, this is far from a fundamental change. When the new members of the GMO-Panel were nominated in 2012, Gijes Kleter, amongst others, was still approved as new member. Like Kuiper, he worked for the ILSI for many years, but of late, not officially. He was even approved as assistant chairperson of the panel.

4 http://www.testbiotech.org/node/660
5 http://www.testbiotech.de/node/630
6 http://www.efsa.europa.eu/en/press/news/120516a.htm

EFSA still views work for the biotech industry or institutions such as the ILSI, although officially ended, as insufficient reason to assume conflicts of interest, even according to the new guidelines.

The above example of Diána Bánáti shows just how dubious this behaviour is. When it was made public that she worked for ILSI, Bánáti officially resigned from her duties at ILSI – but kept her assignment at EFSA and was even was re-elected as chairperson of the administrative board. Later on she moved back to ILSI for good. It must be assumed that she never severed her ties to industry. In this regard, it must be feared that the new EFSA guidelines independence will come to nothing – the case of Kleeter is a first precedence.

Consequences and Demands

- The result of the first ten years of EFSA is negative. It is neither independent of industry lobbyists nor does it fulfil EU standards. It does not sufficiently protect the environment or consumers.
- The concept of *Comparative Risk Assessment* is not scientifically qualified and ignores biological features of genetically modified organisms. Instead a *Comprehensive Risk Assessment* must be implemented.
- EFSA needs a fundamental reorganisation, involving environment and consumer organisations. For example, they should be allowed to nominate half of the members of the administrative board, while industry lobbyists should be kept out of EFSA.

References:

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. 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 (2011): European Food Safety Authority, Guidance on the Submission of Applications for Authorisation of genetically modified food and feed and genetically modified plants for food or feed under Regulation (EC) No 1829/20031 EFSA Journal 2011;9(7):2311 (doi:10.2903/Josefsaltar2011.2311 Laufvariable online: www.efsa.europa.eu/Journalismus).

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. & H.A. Kuiper (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.

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

Then, Chr. & A. Bauer-Panskus (2010): European Food Safety Authority: A playing field for the biotech industry Standards for risk assessment massively influenced by industry – a Testbiotech background (http://www.testbiotech.org/node/430).