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Testbiotech analysis of risk assessment strategies for genetically engineered plants used for food and feed in the EU

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Summary

Within the first ten years of its activities, the work of the GMO panel of the EFSA cannot be seen as being independent nor does it fulfil the requirements of EU regulations. In addition, the EU Commission fails to fulfil its task as risk manager, as it does not define sufficient risk assessment policies and neglects its duty to implement effective post marketing monitoring. The flaws of current risk assessment of the EFSA will be perpetuated by a new Implementation Regulation proposed by the EU Commission. The recommendations for future risk analysis strategies include to drop the concept of comparative risk assessment and to apply a comprehensive risk assessment to each application of genetically engineered organisms.

1. Overview of market authorisations in the EU

By August 2012, 46 events of genetically engineered plants had been authorised for usage in food and feed within European Union. Most of them are for import and processing, two events are authorised for cultivation: Monsanto's Maize MON810 and the BASF potato "Amflora".

The 46 events include the following species: 26 maize, 8 cotton, 7 soybeans, 3 rapeseed, 1 potato, 1 sugar beet. The events can be divided into four groups of technical traits (one of which overlaps with two other groups):

- 8 events producing insecticidal toxins,
- 15 events tolerant to herbicides,
- 22 events a combination of insecticidal and herbicide tolerant plants (stacked events)
- others: 1 potato producing starch for industrial use, 1 rapeseed producing infertile pollen.

2. General requirements for risk assessment of genetically engineered plants in the EU

According to the regulations of the European Union (Regulation 178/2002, Regulation 1829/2003 and Directive 2001/18), the overarching goal of EU policy is to ensure a high level of environmental and consumer protection. In case of uncertainties the precautionary principle shall prevail.

Some quotes from the 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." (Art. 6, 2).

>> Regulation 1829/2003, „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." (Recital 9).

>> Directive 2001/18, „deliberate release“: The directive requires the examination of the "direct and indirect, the immediate and delayed effects" of the genetically engineered plant on human health or the environment (Annex II), "in accordance with the precautionary principle." (Article 1)

3. Risk assessment and the comparative approach

Since 2003, the European Food Safety Authority, EFSA, is conducting risk assessment on the basis of its own Guidance. The EFSA Guidance is built on the 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 safety assessment 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.”

Consequently, current risk assessment is not comprehensive. For example, there are no requests for a detailed assessment of health risk in feeding trials and in long-term studies. The EFSA assumes that risks that cannot be compared to those of conventional breeding will only occur in rare cases, and only in such rare cases will a comprehensive risk assessment need to be carried out. However, so far this has never happened (EFSA, 2011):

“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.”

The EFSA Guidance for risk assessment of genetically engineered plants refers to international standards such as Codex Alimentarius and OECD, but, taking a closer look at those standards, it is evident that the comparative approach was mostly developed by industry. Here the International Life Sciences Institute (ILSI) plays a crucial role. The ILSI is funded by companies such as Monsanto, Dow AgroSciences, Bayer, DuPont and Bayer and it develops standards such as the comparative safety assessment on behalf of industry, and also plays an active role in introducing those standards to the Guidance of relevant state authorities.

In the case of the EFSA, Harry Kuiper who was the chair of the so-called GMO Panel from 2003-2012, not only played a decisive role in setting EFSA standards, but he was also a member of the ILSI task force which developed the concept of comparative safety assessment on behalf of the industry (ILSI, 2004; Then & Bauer-Panskus, 2010). The ILSI claims the introduction of the comparative assessment was a success:

“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)

What is the general problem with the comparative approach from a scientific point of view? Conventional breeding and genetic engineering can be seen as being fundamentally different from a technological point of view as well as from a biological perspective. Unlike conventional breeding, genetic engineering inserts technically derived DNA constructs to enforce specific biological functions in plants by disregarding the system of

gene regulation and the barriers between species. Choosing the comparative approach implies a high likelihood that risks attributed to the method of genetic engineering (such as disturbances of the gene regulation) are not identified.

In the Guidance of the EFSA, the comparative assessment is the starting point in the overall process of risk assessment. The first step in this process is the identification of potential hazards, which need to be assessed during the later stages of the risk assessment. This starting point impacts all following steps of the risk assessment, and thus only a limited 'check up' takes place rather than a comprehensive risk assessment. As will be shown in the following section, the comparative approach is associated with flaws during other steps of the risk assessment conducted by the EFSA (see also as example, Testbiotech, 2012). And these flaws are also perpetuated by the Implementation Regulation of the EU Commission (EU Commission, 2012).

4. The initiative of the EU Commission

In 2012 the EU Commission published a Commission Implementing Regulation (...) on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 (...) (EU Commission, 2012). As soon as this regulation is adopted, it will become the basis for the work of the EFSA. However, compared with the current Guidance of the EFSA this regulation is not a real improvement. The most relevant change would be a mandatory feeding study of 90 days with rats to examine health effects. However this would apply to stacked events, inheriting several additional DNA constructs, derived from crossings of genetically plants. And more relevant tests such as multi generational studies are still not required. In the following section, some points are listed to show some deficiencies of the current risk assessment as well as of the proposed new regulation.

- Comparative risk assessment is still seen as the standard procedure.
- The most relevant step in comparative risk assessment (the investigation of substantial equivalence) is still based on a concept that allows the introduction of flawed historical data.
- Interactions with the environment that may impact the composition of plants are not tested sufficiently.
- Testing for health risks is still not based on a stepwise concept that entails mandatory investigations such as toxicity tests on cell cultures, targeted investigation of relevant health risks and long term and multi-generational studies.
- There is no request to apply more recent technologies, such as metabolic profiling.
- The necessary interplay with pesticide regulation is missing.
- Bt toxins are not assessed according to pesticide regulation.
- The requirements for investigation of synergistic, additive and accumulated effects are not sufficiently defined.
- The need to establish fully evaluated methods to measure the expression of the newly introduced DNA constructs is not mentioned.
- The proposal of the Commission is missing sufficiently clear quality standards for investigations conducted by industry.
- Post-marketing monitoring to allow identification of negative health effects of the consumption of products derived is not required.

In conclusion, the current practice of post market monitoring does not meet the requirements of existing EU regulations.

5. Conclusions and recommendations

Within the first ten years of its activities the work of the GMO panel of the EFSA can not be seen as being independent nor does it fulfil the requirements of EU regulations. Further, the EU Commission fails to fulfil its task as risk manager. 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 included in the process of risk analysis.

Some recommendations for future risk analysis strategies:

- Drop the concept of comparative risk assessment; do not presume safety, equivalence, similarity or familiarity; use comparison as a tool and not as a concept;
- Always require a comprehensive risk assessment in the case of genetically engineered organisms;
- Establish clear cut-off criteria for rejection of applications;
- Reassess EU market authorisations;
- Promote independent risk research;
- Set higher standards for independency of the EFSA.

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