Testbiotech Data Factsheet:
Bayer´s Basta Beans: Soybean A5547-127 (Bayer CropScience)

January 2012

Plant:
Soybean

Event name:
A5547-127

Applicant:
Bayer CropScience

Trait:
Herbicide tolerance

Herbicide:
Glufosinate (brand names such as Liberty or Basta)

Transformation method:
Particle bombardement

Scope of application:
Food and feed, import and processing

Impact on European market:
Millions of tons of genetically engineered soybeans are imported into the European market. Most of it is used in animal feed. But so far LibertyLink soybeans do not play a major role in the market.

Information on the transgenic plant:
Soybean A5547-127, “Bayer´s Basta Beans” is part of the so-called LibertyLink system which is mainly followed by Bayer CropScience. The plants are tolerant to herbicides with the active ingredient glufosinate (brand names Liberty or Basta). Soybean A5547-127 was first approved in the USA in 1998. In contrast to Monsanto's RoundupReady plants, the commercial success of the LibertyLink system is minor. Soybean A5547-127 was also approved for commercial cultivation in Brazil in 2010. It is likely that the reintroduction of this relatively old event is closely connected to the emergence of “superweeds” that are resistant to Monsanto's herbicide Roundup (active ingredient glyphosate). The LibertyLink system can be offered as an alternative in growing genetically engineered plants.

Glufosinate use in transgenic plants is problematic, the substance is regarded as potentially causing health effects. (EFSA 2005). According to the German Agricultural Ministry, glufosinate will be phased out in the EU in 2017 for reasons of reproductive toxicity (BMELV 2009). Plants contain residues from spraying with herbicide formulations and their metabolites. Furthermore, it could be shown that the metabolite of glufosinate (called NAG) produced by the transgenic plants can partially be reconverted into the pesticide itself by gut bacteria, leading to increased health risks for animals and consumers (Bremmer & Leist 1997). These risks were not assessed by EFSA in their opinion.

Compositional analysis and agronomic investigations showed several significant differences as compared to their conventional counterparts. There were no targeted investigations (such as a stress test under defined environmental conditions) to determine genetic stability and to explore if genetic stability is given under changing environmental conditions.

Despite all the known risks associated with these genetically engineered soybeans, no feeding studies with the whole plants were performed to investigate health effects related to toxicology, immunology and reproduction.

Specific risks and unintended effects

- Plants contain residues from spraying with herbicide formulations and their metabolites.
- The method used to insert the gene sequence has several technical deficiencies e.g. an interruption of a plant´s gene
- the gene construct is unintentionally divided into two parts, parts of the DNA show reverse orientation and deletions.
- Open reading frames were identified that can give rise to unintended gene products in the plants.
- In comparison with its conventional counterparts, many significant differences in compositional analysis were observed. Similar findings could only be found in some historical data unrelated to the actual field trials. Since it is not sufficiently clear under which specific conditions these additional historical data were generated, this kind of comparison inevitably contains major uncertainties.
- In agronomic parameters, several significant differences were identified in comparison to the control plants. The differences were not consistent over all field trials. The reason for this might be that these differences only emerge under particular environmental conditions. Several investigations show that genetically engineered plants can exhibit unexpected reactions under stress conditions (see for example: Matthews et al., 2005).
- Soybeans are known to cause severe allergic reactions. The newly introduced gene construct might for example enhance an immune response to these endogenous plant protein(s).
- Soy beans are known to produce compounds with hormonal activity. The content of these compounds might be changed by interference with the newly introduced gene constructs.
- These plants will be fed and might be eaten by mixing them with other genetically engineered plants. Tests have to be performed on potential accumulated effects such as combinatorial or accumulated effects.

Type of feeding trial conducted:

- An acute toxicity study was performed, feeding isolated enzyms that enable tolerance to glufosinate. These proteins were not isolated from the plants but produced by bacteria.
- A 42 days feeding study with poultry poultry to assess nutritional effects was conducted using maize kernels

Overview of some shortcomings of EFSA opinion:

- no assessment of risks stemming from residues from spraying with the pesticide formulations and their metabolites.
- no investigation under various defined environmental conditions was conducted to determine interactions between the genome and the environment.

- there was no detailed investigation of changes in composition and agronomic performance under various defined environmental conditions.
- functional stability of the transgene under various defined environmental conditions was not shown. Genetic stability was only considered in the context of the hereditary of the gene constructs to following generations.
- in comparison with its conventional counterparts, many significant differences in the compositional analysis were found but these were not investigated further. Instead references were made to unspecific and questionable 'historical' data from industry unrelated to the actual field trials, e.g. the ILSI database.
- significant differences in agronomic performances should have been investigated in relation to interactions between the genome and the environment under defined environmental conditions.
- there were no feeding studies conducted with the plants to investigate potential negative impact on human and animal health.
- there have been no feeding studies over the whole lifetime of animals and none including following generations.
- the protein used for acute toxicity tests was produced by bacteria. Toxicity maybe different if plant material is used.
- no empirical investigations were performed concerning allergies or other impacts on the immune system.
- no endocrinological studies were performed to investigate potential impacts on the reproductive system
- no investigations were conducted to assess the impact of a permanent ingestion of these plants on the intestinal microbial composition in human and animals.
- no investigation conducted for DNA traces in animal tissue after feeding.
- no assessment of combinatorial effects with other genetically engineered plants used in food and feed.

Surveillance – Monitoring

- No plan for surveillance was made available that would allow identification of particular health impacts that might be related to the use of these genetically engineered plants in food and feed.
- Monitoring of health effects has to include the risks associated with the spraying of glufosinate formulations and their residues in the plants.

Documents und publications:

BMELV, Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (2009) Neue Bewertungskriterien für Wirkstoffe in Pflanzenschutzmitteln. www.greenpeace.de/fileadmin/gpd/user_upload/themen/umweltgifte/BMELV-Homepage-Liste_der_18_Pestizide.pdf

Bremmer, J.N. and Leist, K.-H. (1997) Disodium-N-acetyl-L-glufosinate; AE F099730 - Hazard evaluation of Lglufosinate produced intestinally from N-acetyl-L-glufosinate. Hoechst Schering AgrEvo GmbH, Safety Evaluation Frankfurt. TOX97/014. A58659. Unpublished. (see FAO publication on www.fao.org/ag/agp/agpp/pesticid/jmpr/Download/98/glufosi3.pdf)

EFSA (2005) Conclusion regarding the peer review of the pesticide risk assessment of the active substance glufosinate. EFSA Scientific Report 27, 1-81. doi:10.2903/j.efsa.2005.27r.

http://www.efsa.europa.eu/en/efsajournal/doc/27r.pdf

EFSA (2011a) Scientific Opinion on application (EFSA-GMO-NL-2008-52) for the placing on the market of herbicide tolerant genetically modified soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. The EFSA Journal (2011); 9(5):2147, 1-28. [27 pp.] doi:10.2903/j.efsa.2011.2147. http://www.efsa.europa.eu/de/efsajournal/pub/2147.htm

EFSA (2011b) Application EFSA-GMO-NL-2008-52 (soybean A5547-127) Comments and opinions submitted by Member States during the three-month consultation period, accessed via http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO