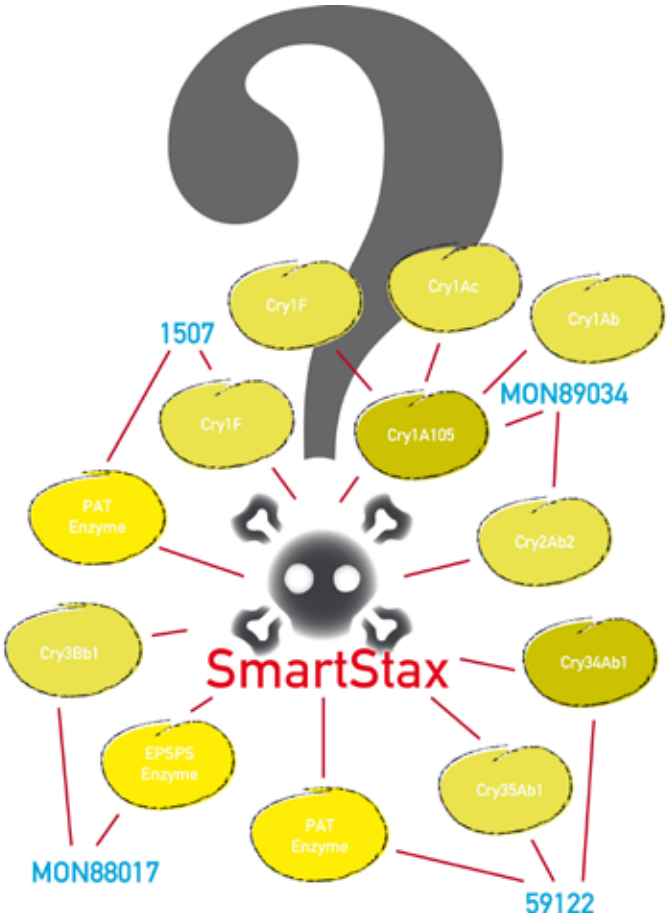

TEST BIOTECH

Testbiotech e. V.
Institute for Independent Impact Assessment in Biotechnology

„... ensured that the data were consistent with expectations..."

How industry and EFSA have been systematically undermining the risk assessment of 'SmartStax'

Testbiotech Report by
Christoph Then and Andreas Bauer-Panskus

June 2011

grassroots foundation

"...ensured that the data were consistent with expectations..."

How industry and EFSA have been systematically undermining the risk assessment of ‚SmartStax'

Testbiotech Report by Christoph Then and Andreas Bauer-Panskus

Sponsored by the grassroots foundation

June 2011

Editorial office: Maren Borgerding

Layout: Claudia Radig-Willy

Impint

Testbiotech e.V.
Frohschammerstr. 14
80807 München

Tel.: +49 (0) 89 358 992 76

Fax: +49 (0) 89 359 66 22

info@testbiotech.org
www.testbiotech.org

Geschäftsführer: Dr. Christoph Then

Eingetragen als gemeinnützig beim
Finanzamt München 2008

Content

Summary

In this report some confidential dossiers from company of Monsanto and Dow AgroSciences are made available to the public. The material is concerned with SmartStax maize. SmartStax is the brand name of a genetically engineered type of maize inheriting a a unique combination of six different insecticidal toxins and tolerance to two herbicides.

The documents were passed to Testbiotech, there was no legal infringement on the part of Testbiotech. This material has been made public to help to prevent any risks, possibly major, to the health of humans or animals, which may be caused because risks were not assessed as foreseen by European legislation. In this context, the material might be of relevance for further legal steps in order to prevent market authorisation of the controversial product.

The dossiers as discussed herein concern some key issues in risk assessment:

- the content of insecticidal proteins in the genetically engineered maize plants
- risks associated with the insecticidal toxins,
- interaction of the plants and the environment
- feeding studies with the grains from the maize.

In SmartStax maize, six insecticidal toxins (so-called Bt toxins) from soil bacteria (*Bacillus thuringiensis*) are combined in a new way. For production in the plants, the insecticides are changed in their structure in comparison to naturally occurring toxins. One of them was even artifically synthesised. As a result, the toxins and toxin combinations in the plant have new characteristics, and the risks that they might pose cannot be assessed by comparing them with toxins that occur naturally.

The risk assessment of SmartStax is a complex matter:

- Synergies and interaction between the toxins and other compounds must be included in risk assessment as their effects could impact on the health of humans and animals.
- Changes in the composition of the microorganisms in the intestines of humans and animals caused by the ingredients of the genetically engineered maize and their interactivity could also have an impact on health.
- Further, some of the Bt-proteins produced in the plants are known to impact the immune system.
- Finally, the residues from routinely sprayed herbicides are under suspect to inherit hormone disruptive properties.

Despite all these known risks, there have been no feeding studies or other in-depth investigations to explore potential health hazards in human and animals. Possible synergies of the toxins in this combination were only performed on pest insects. Feeding trials were conducted to test nutritional quality but not to examine health impacts.

During cultivation, the plants showed a high range of variation in the expression of the foreign proteins. Their toxic burden on the food chain is significantly higher than the one caused by genetically engineered plants already on the market. No reliable protocols to enable independent control of the toxin load in the plants were provided, nor were there any investigations into the life cycle of the proteins or environmental exposure.

The industry dossiers not only have major defects in study design, they also lack independent quality controls. There are even some indications of systematic fraud. Indeed, one dossier states "... oversight ensured that the data were consistent with expectations ...". It is impossible to decide if, and to which extent, the dossiers were manipulated because no independent institutions carried out quality controls.

Major deficiencies in risk assessment also render it impossible to carry out effective post-market monitoring of the genetically engineered plants as required by European regulation.

1. Introduction

SmartStax is the brand name of a genetically engineered maize that produces six different insecticidal toxins and is resistant to two herbicides. Monsanto and Dow AgroSciences have applied for market authorisation in Europe. The maize itself was produced by crossing the following genetically engineered parental lines: MON89034, DAS1507, MON88017 and DAS59122. In September 2010, EFSA released a positive opinion on the use of SmartStax for food and feed (EFSA, 2010).

Testbiotech strongly criticised the EFSA opinion as early as November 2010.[1] Meanwhile, the European Commission has also requested further examination by EFSA. The Testbiotech analyses in this report show that market authorisation for SmartStax is unacceptable on the basis of the existing data.

At the beginning of 2011, some confidential documents related to the risk assessment of genetically engineered maize SmartStax were leaked to Testbiotech. These documents were originally forwarded to EFSA and EU Member States by Monsanto and Dow AgroSciences for risk assessment as foreseen by European legislation. In a follow up, Testbiotech approached EFSA in Mai 2011 to obtain official access to the documents in order to compare the data they contained with those leaked to Testbiotech.

EFSA granted restricted access to the documents, publication of the documents was not allowed. After careful consideration, Testbiotech decided to publish the documents that had been leaked to them, together with a detailed analysis. From the point of view of the general public, it is completely unacceptable that important documents relating to health risks can only be accessed via the EFSA databank, because this material is subject to major restrictions. On the other hand, this limited access is a valuable instrument in gaining at least some transparency, and as such should not be jeopardised by activities that contravene current access regulations. Therefore, Testbiotech will not publish any material that was accessed via EFSA, but only those documents that were leaked via other sources.

Testbiotech believes that the dossiers leaked to their organisation show the need for more transparency and unrestricted access to data. The documents show alarming deficiencies in risk assessment as performed by industry and EFSA, these deficiencies should not be hidden behind confidentiality issues. In fact, the documents exemplify how risk assessment is being systematically undermined by industry and the unquestioning acceptance of the European Food Safety Authority (EFSA). The documents might be necessary to initiate necessary legal steps against market the authorisation of the controversial products.

1 http://www.testbiotech.org/en/node/423

On that account, Testbiotech will make these documents available to the broader public, without any restrictions. There is no infringement by Testbiotech of obligations concerning data confidentiality, as the leaked dossiers were made available to Testbiotech without any restrictions.

The documents in this report bear upon the following issues:

- Expression rates of the insecticidal proteins (Stilwell & Silvanovich, 2007; Phillips, 2008)
- Interaction between the insecticidal toxins (Levine et al., 2008; MacRae 2008)
- Interaction between the plants and the environment (Rosenbaum, 2008)
- Nutritional feeding study (D., 2008[2])

This reports contains an overview of the industry's dossiers and a detailed analysis by Testbiotech. Four appendices are attached with further detailed analyses and a list of further sources.

2 Name of the author is known to Testbiotech, but EFSA considers this information to be confidential.

2. Overview: technical background

In 2008, Monsanto and Dow AgroSciences filed an application for market authorisation of a genetically engineered maize to be sold under the brand name SmartStax. The maize has already been approved in USA and Canada for cultivation, food and feed.

Smartstax produces six different Bt toxins. This combination of toxins does not occur in nature:

- The Bt toxins are derived from at least four different subspecies of *Bacillus thuringiensis*.
- The Bt toxins produced in the plants display modified DNA and changes in the structure of their proteins. They are, therefore, fundamentally different from naturally occurring toxins.
- The Bt toxins in the plants are produced in an activated form. They are solubilized and shortened and are not produced in their natural inactive and crystallized form.
- One of the Bt toxins in SmartStax (Cry1A.105) is a synthetic protein that did not previously exist in nature.

Furthermore, SmartStax contains two gene constructs that confer herbicide tolerance to glufosinate (brand names such as Liberty or Basta) and one gene construct that confers herbicide tolerance to glyphosate (brand names such as Roundup). All in all, SmartStax produces nine foreign proteins on the basis of gene constructs that are derived from seven species or subspecies or specific strains. Since the gene constructs themselves contain further elements such as promotors, the net result is that even more species are involved than listed in Table 1.

Table 1: Overview of foreign proteins produced in SmartStax and the source of their original DNA

Foreign proteins produced in SmartStax	Source of the original DNA
Cry1A.105 toxin	*Bacillus thuringiensis, synthetic protein showing analogies with three Bt toxins (Cry1Ac, Cry1Ab, Cry1F) from two different strains (kurstaki and aizawai).*
Cry1F toxin	*Bacillus thuringiensis,* subspezies *aizawai*
Cry2Ab2 toxin	*Bacillus thuringiensis,* subspezies *kurstaki*
Cry3Bb1 Toxin	*Bacillus thuringiensis,* subspezies *kumamotoensis*
Cry34Ab1 and Cry35Ab1 toxins	*Bacillus thuringiensis,* strain PS149B1
EPSPS enzyme	*Agrobacterium* sp. strain CP4
PAT enzyme (2x)	*Streptomyces viridochromogenes*

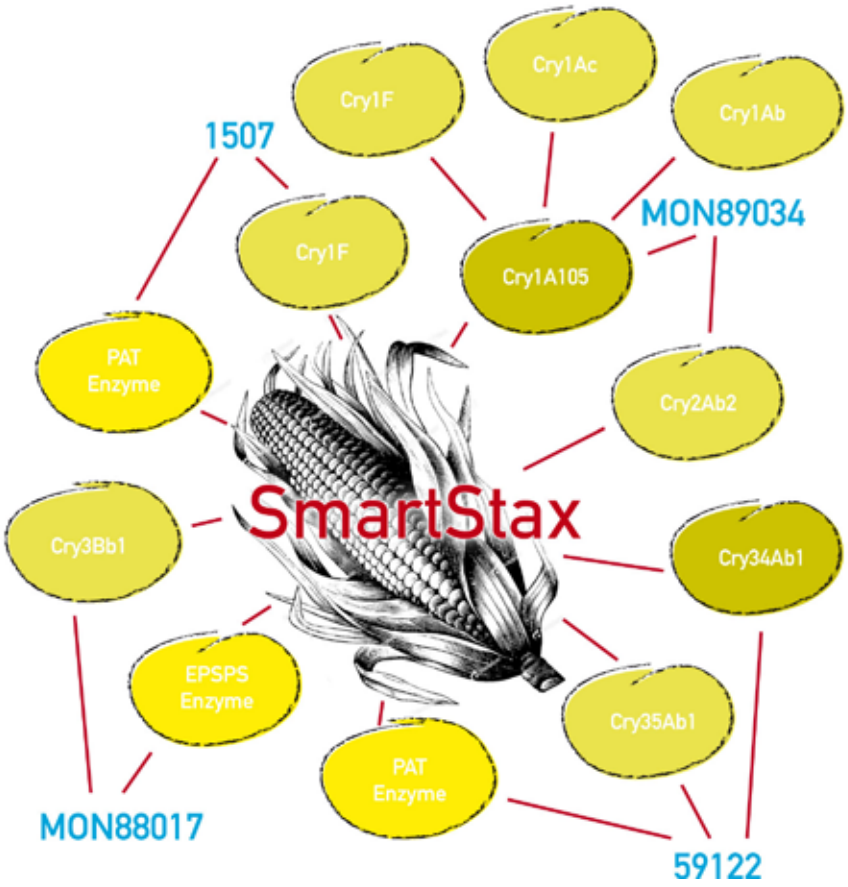

Fig. 1: Overview of all Bt toxins and herbicide tolerances in SmartStax

3. Analysis of the dossiers from industry

3.1 Expression rate of the insecticidal proteins

(Stilwell & Silvanovich, 2007, Phillips, 2008)

General background

It is important to know the rate of expression of the additional proteins in the plant in order to assess their genetic stability as well as environmental and food chain exposure.

Further, it is especially relevant to determine just how much insecticidal toxin is produced in the different parts of the plant, and whether this content is dependent on certain environmental conditions. The plants should, therefore, be exposed to defined environmental conditions to identify factors impacting the rate of expression and the actual range of variation.

It is also important to investigate the persistence of the toxins. The Bt toxins are introduced into the environment via manure and parts of the plants (such as roots, pollen and parts remaining on the field after harvest). It is important to know if they can accumulate and/or persist over longer periods of time in order to assess the exposure of soils and water.

It is absolutely necessary in this context, to define the protocol for measuring the toxins, since different methods for measuring can result in highly varying results. The technical protocols should be fully published and evaluated by independent laboratories to allow other institutions to conduct further measurements to control the exact level of toxins.

The results as presented by industry and their assessment by EFSA

The investigations were commissioned by Monsanto and Dow AgroSciences. No independent laboratories were involved. The results were not published in peer-reviewed magazines.

The data as provided by the applicants show a large range of variations in the Bt content of the maize plants. In several cases the data show a tenfold variation in the Bt content. However, twentyfold and even higher ranges of variation do occur. The exact range of variation under changing environmental conditions and the specific impact factors has not been determined. Thus it is not known if the range of variations in the Bt toxins under specific environmental conditions might be even greater, or whether genetic stability can be expected under stress conditions.

The protocols used by Dow AgroSciences have never been published. The company only ever refers to its own unpublished reports, which are even classified as *"draft method"*. Moreover, the protocols used by Monsanto for conducting the measurements have not been fully published. None of the protocols that are specific to each of the different Bt toxins were evaluated by independent labores. As a result, no independent institution can make comparable measurements to monitor the actual range of Bt concentration in the plants during cultivation and in food and feed products. This in turn excludes adequate monitoring after market authorisation.

There was, in addition, no investigation into the persistence of the Bt toxins. Therefore, the actual exposure of the environment via manure or parts of the plants and the potential accumulation of the toxins in the soil cannot be assessed.

The investigations of industry show some outcomes that give cause for concern: The overall content of the Bt toxins can amount to more than 1600mg/ kg in leaves (dry weight) which is a much higher content of Bt toxins than described in other genetically engineered maize plants.

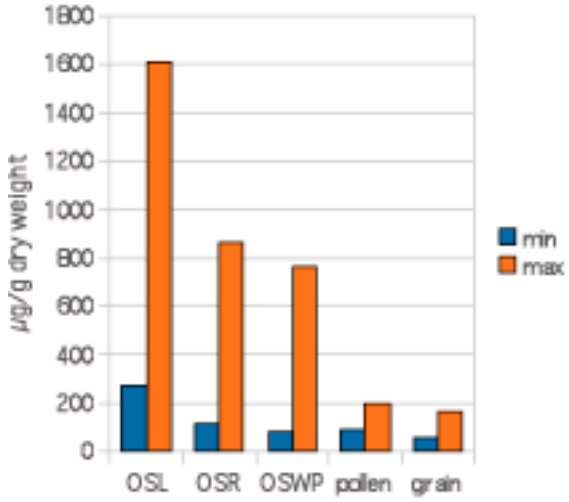

Fig. 2: Overview of ranges of the Bt toxin content in different parts of the plant, using data from parental lines as well as from SmartStax (µg/g dry weight tissue). Original data: Stilwell & Silvanovich, 2007, Phillips, 2008

OSL: over season leaf
OSR: over season root
OSWP: over season whole plant

EFSA did not ask for additional investigations but simply declared the data to be "comparable" with the data from parental events. It did not discuss the huge variations. EFSA also failed to act upon requests from several Member States for more data and a much more detailed investigation.

In conclusion, the investigations of Stilwell & Silvanovich (2007) Phillips (2008) do not render the necessary scientific evidence. The quality of the data is not reliable. Because the expression rate of the foreign protein is a very basic element in risk assessment of genetically engineered plants, the overall risk assessment of SmartStax suffers from unacceptable deficiencies.

3.2 Potential synergies that can enhance toxicity

Levine et al (2008) and MacRae (2008)

General Background

It is well known that synergistic and additive effects both between Bt toxins and other compounds do occur. In general, synergistic effects can be characterised by findings that exceed those that can be predicted from those of the single components. These effects are under discussion as to whether they could be used commercially to enhance the toxicity of Bt toxins in pest insects. However, it is also known that in some cases toxicity in non-target organisms may be enhanced, causing unexpected risks for the environment and human health.

Synergistic effects may not only arise from the interaction of Bt toxins, but also from plant components or abiotic stressors (such as residues from spraying or toxic heavy metals e.g. cadmium). For example, some plant enzymes that diminish the digestion of proteins (protease inhibitors) can strongly enhance the toxicity of Bt toxins. Even the presence of very low levels of protease inhibitors can multiply the insecticidal activity of some Cry toxins. It is known that maize produces such inhibitors.

It is also known that synthetically produced Bt toxins can show much higher toxicity than native proteins. Even small changes in the structure of the proteins can cause huge changes in their toxicity. In SmartStax, the structure of the proteins is modified, Cry1A.105 is even produced synthetically.

These effects render higher toxicity and give rise to unexpected risks. They can only be investigated by experimental investigations since the specific mixture of Bt toxins does not occur in nature, and the structure of the Bt toxins is different from native sources.

The results as presented by industry and their assessment by EFSA

The investigations presented by the applicants, were commissioned and paid for by Monsanto. They were conducted in Monsanto Laboratories. No independent laboratories were involved. The results were not published in peer-reviewed magazines.

Levine et al and McRae investigated synergistic effects in pest insects only. Levine et al tested combinations of Bt toxins as produced in SmartStax on the European corn borer. MacRae worked with some Bt toxin sub-combinations (Cry34Ab1 and Cry35Ab1 in combination with Cry3Bb1) on the Southern corn rootworm. The investigations did reveal additive effects, but no synergistic or antagonistic effects in the pest insects.

Levine et al and McRae did not perform any testing aimed at showing there is no toxicity risk for humans and animals from the interaction of the Bt toxins. Further potential synergies with the residues from herbicide spray, the plant components or external additional factors were not considered. There was also no data made available to establish whether the combined ingestion of the toxins and residues from spraying can lead to a change in the composition of the intestinal flora, and therefore impact on the health of humans and animals.

EFSA does not even mention the investigations of Levine et al and McRae in their opinion. It is only very vaguely stated that EFSA considers it unlikely that interactions between the Bt toxins would occur that would give rise to safety concerns:

"(…) the EFSA GMO Panel considers it unlikely that interactions between these proteins would occur that would raise any safety concern."

Contrary to EFSA, experts from EU Member States such as Austria, Belgium and Germany are advocating the need to carry out feeding studies to test for synergistic effects. Austrian experts describe it thus:

"But the safety of all newly expressed proteins in animal models applied simultaneously and combined was not assessed in the dossier. Insecticidal Cry proteins produced by GM plants as well as transproteins conferring tolerance to herbicides constitute a sum of new plant constituents possibly interacting within the organism. So far, there is absolutely no scientific knowledge about such those in the respective new combinations and possibly resulting additive and/or synergistic effects."

3.3 Interaction between the plants and the environment

(Rosenbaum, 2008)

General Background

Genetically engineered plants inherit technically derived features that are not controlled by the plant's gene regulation. Technical failures such as genetic instabilities and/or occurrence of undesired components can be triggered by specific environmental conditions. Relevant effects have already been observed in various genetically engineered plants. In general, it is known that genetically engineered plants can show unexpected effects in reaction to environmental conditions such as climate, soil quality and various stressors. Interaction with the environment can impact the plant genome, plant metabolism, cause changes in phenotype and affect different biological properties of the plant (e.g. higher invasiveness and fitness).

In general, the investigation of interaction between the plants and the environment provides insight into the genetic stability of the genetically engineered plants, and is an important starting point in risk assessment. The interaction between the genome and the environment is also relevant to the risk assessment of food and feed, since the composition of the plant's compounds can be affected.

These reactions can and should be measured under controlled conditions, e.g. under laboratory or greenhouse conditions, to identify relevant impact factors before the plants are released in experimental field trials, or used for large scale cultivation.

The results as presented by industry and their assessment by EFSA

The investigations were commissioned and paid for by Monsanto. They were conducted in Monsanto Laboratories. Regarding quality control - no independent laboratories were involved, data were not published in peer reviewed magazines and the wording of the report even indicates manipulation of the data.

The investigations were only performed for one season and on relatively small plots. Rosenbaum only considered the question of whether the plants showed a higher degree of fitness or invasiveness and whether their agronomic properties could be compared to other maize plants.

No food and feed related risks were explored. Neither were there any investigations into metabolic changes within the plants or gene activity, nor were there any detailed analyses of compositional changes throughout the season. Risks related to food and feed cannot be concluded from the data that was presented.

Relevant agronomic criteria were not taken into account (e.g. the date of flowering or viability of pollen). Some significant findings that indicate interactions with the environment or an overall change in gene activity and plant metabolism were dismissed without any further investigations. For example, a higher incidence of plant disease was found in one site. Further, six criteria were found to be significantly different (e.g. pollen shed, ear height, plant height and grain moisture) in comparing the findings with the control plants at the individual sites. None of these findings were investigated further.

Apparently, several individuals were involved in data collection and data evaluation:

> *"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."*

There is no explanation as to who these experts were or how the data were made consistent with expectations. This wording indicates a possible manipulation of the data. Only a Monsanto member of staff is mentioned under acknowledgements for *"assistance with the statistical analysis of the data"*.

In its opinion EFSA does not discuss Rosenbaum's results in detail. EFSA mentions only very generally that no signals for altered fitness and invasiveness were found, or that they did not consider any other data on unexpected plant reactions caused by genome (x) environment interaction and risks related to food and feed.

According to the statement of experts from Member States, more data and specific data on environmental interactions should be provided. Further, more specific environmental conditions should be taken into account such as abiotic stress through compaction, drought and frost or a higher likelihood of diseases. There was also no comparison made between those plants that were sprayed and those that were not sprayed. Experts from Member States believe that since the relevant raw data is not available, no decisive conclusion can be drawn from the report that was presented. There was also criticism of the small scale of the field trials, as well as the overall design of the study which was not deemed to be representative for real conditions under commercial cultivation. The experts further criticise the fact that significant findings should not have been dismissed without further examination. More than one season should have been included in the trials as well as other important criteria such as flowering time, pollen size and production or the duration of pollen viability.

3.4 Feeding study

D. 2008[3]

General Background

As already explained, risk assessment of SmartStax is highly complex: The genetically engineered plants inherit a unique combination of insecticidal toxins that are technically modified and even artificially synthesised. These proteins are not sufficiently characterised in regard to their toxicity, selectivity, efficacy and their interactivity. Some of them are known to show immunological activity: The toxin Cry1Ac that is one of the Bt proteins used for the production of the synthetic toxin Cry1A.105, is known to be a potent immune stimulator.

To assess their actual risks, the plant's components and other compounds in food and feed products should be taken into consideration because they might display synergistic effects with the insecticidal toxins such as protease inhibitors.

There should also be some discussion on the residues of the herbicide glyphosate and its additives which may have a negative impact on health at very low dosages (e.g. hormone disruption). Because of potential health risks, farmers in Germany are advised not to use certain mixtures of glyphosate for the production of food and feed.[4] The usage of herbicide glufosinate will soon be banned in the EU because of its effects on health. A significant level of residues from these herbicides can be expected in the plants because they were created to be tolerant to these chemicals and they are sprayed as part of agricultural practice.

Additional important issues need to be considered in this context: The continuous ingestion of the combined Bt toxins and the residues from spraying can lead to a change in the composition of the intestinal flora, and thereby indirectly cause severe health hazards in humans and animals. Further, the gene constructs as introduced into the plants and their parts, such as promoters from viral sources, have to be taken into account because these elements might still be biologically active after ingestion. Finally, undesirable components in the plants might emerge because of genetic engineering methods.

Given the complexity of risk assessment for food products made from genetically engineered plants, Testbiotech proposes conducting extensive step by step investigations, starting at the laboratory level and including the usage of *in vitro* systems (for example using human cells). These *in vitro* systems can be used to explore toxicity, including potential synergistic effects as well as hormone disruptive reactions. Once these first steps of risk assessment have been passed, Testbiotech proposes conducting animal feeding studies that include several generations of the animals. In general, the risk analyses should follow a coherent step by step procedure that includes ethical questions and a socio-economic assessment.

As the analysis of the dossiers from Stilwell & Silvanovich, (2007), Phillips, (2008), Levine et al. (2008), MacRae (2008) und Rosenbaum (2008) shows, the relevant risks were not investigated or only

3 Name of the author is known to Testbiotech, but EFSA considers this information to be confidential.

4 www.bvl.bund.de/DE/04_Pflanzenschutzmittel/05_Fachmeldungen/2010/psm_anwendungsbestimmungen_tallowamin-Mittel.html

explored very poorly. Further, there was no adequate determination of the expression rate of the toxins or potential impact of environmental conditions on the composition of the plants. The amount of residues from spraying with herbicides was not determined. Therefore, feeding studies to investigate effects on health would be of major importance before any usage in the food chain and feed could be considered. In the case of SmartStax, some of the parental lines used to produce the final stacked event were tested in animal feeding studies and showed some signs of toxicity that need further investigation. Laboratory animals fed with maize DAS1507 and DAS59122 showed some significant differences in blood parameters compared to their control groups. Rats fed with MON89034 showed signs that their kidney function might be impacted. (see data from market applications). Furthermore, other genetically engineered crops with similar proteins also showed signs of toxicity that need further investigations.

Nutritional studies have almost no relevance to possible health risk assessment. Parameters such as weight or meat composition are determined in nutritional studies. In the case of SmartStax, only one nutritional feeding study was performed by industry, there was no feeding study to investigate the effects on health .

The results as presented by industry and their assessment by EFSA

Monsanto and contractors carried out a feeding study to assess Smartstax. This focussed on creating nutritional data, no health effects were investigated.

In the 42 day nutritional study on broiler chickens, 900 animals were fed diets containing 61-64% of one of eight maize lines. According to the study data, only 100 chicken were fed a mixed diet containing SmartStax maize, while all the others were fed diets containing conventional maize. Parameters tested were characteristics such as weight of the carcass and composition of thigh and breast meat (fat,moisture, protein). According to the applicants, there were no biologically relevant differences in broiler performance, carcass yield or meat composition. In its opinion on SmartStax maize, the EFSA GMO panel agreed with the applicants on the nutritional equivalence of SmartStax. EFSA further declared that no further safety tests (for allergenicity or toxicity) were necessary.

Criticism was voiced by Experts from several Member states. Some of the criticism regarding the study was:

- lack of any data on potential health effects
- lack of independent controls for the data that was presented
- insufficient statistical analysis of the data presented
- no investigation of effects on the immune system, despite the fact that Cry toxins are known to show immune reactions.

EFSA rejected the requests made by the Member States. This was justified with reference to their own guidelines and standards set by the Codex Alimentarius. Thus, EFSA hardly deals with the specific scientific arguments, it just makes very general statements.

4. Conclusion and recommendations

The dossiers from industry should be completely rejected for being wrongly designed, their lack of scientific standards and the lack of independent quality control. There are even indications of systematic fraud. The application and the opinion of EFSA should be rejected to ensure the high standards of consumer protection as foreseen by European regulations.

The dossiers not only have major deficiencies, they also have to be interpreted as an attempt to deliberately undermine the risk assessment of genetically engineered plants. They harm the interests of consumers, farmers, food producers and retailers. The risks relevant for consumers were not properly examined. The investigations as presented are restricted to synergistic effects in pest insects (Levine et al., 2008; MacRae 2008), higher fitness of the plants and their agronomic features (Rosenbaum, 2008) and finally a nutritional study in poultry (D., 2008). None of these investigations address specific risks to human health.

Further, other investigations presented to support market authorisation but not discussed in this paper were also inadequate. These investigations were (1) a comparative analysis of plant compounds (2) a description of where the additional gene constructs were inserted into the plant genome (3) acute toxicity tests with the single isolated Bt-toxins and (4) data on allergenic risks was compared with data banks. These kind of investigations can give *indications on health* risks but cannot be seen as adequate to actually *examine health risks*. Some of these additional tests have even more scientific deficiencies. For example, a data bank from industry was used for the comparative compositional analysis – even the members of the EFSA GMO-Panel think this data bank is unreliable.[5]

Demands for more detailed risk assessment were rejected by EFSA with reference to the guidelines that they themselves created and to the international minimum standards of the codex alimentarius. Referring to these standards in such a formalistic way means that very often, the actual need for further data or more detailed investigations is not discussed in substance.

Regarding the expected market authorisation of SmartStax, the EU Commission has already asked EFSA for further data. In a letter dated November 2010, DG Sanco asked EFSA to carry out a new assessment which should also cover all sub-combinations of SmartStax maize.[6] However, this request is not directed at the standards and the quality of the investigations on health risks already presented. Thus, substantial amendments cannot be expected. If market authorisation is given under these conditions, a legal challenge at the European Court of Justice should be considered in order to protect the rights of consumers, farmers, food producers and retailers to have sufficiently tested products. The EU regulations for post- market monitoring must also be taken into account in this context.

Further initiatives should be considered in regard to similar events that were assessed by EFSA using same standards. There are already ten authorisations of events that contain the Bt toxins used in SmartStax. More of these events have already been assessed by EFSA as bearing no relevant risks. In March 2011, the Council of Ministers voted on Monsanto's "VT Triple Pro Corn" which was produced

5 EFSA used the ILSI databank (http://www.cropcomposition.org/query/index.html), but according to J.N.Perry from the EFSA GMO-Panel (who gave a talk at the EFSA meeting on 31 March, http://www.efsa.europa.eu/en/events/event/gmo110331.htm) the quality of the data is inadequate.

6 available through the register of questions, http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO

by using two of the events (MON89034 and MON89017) combined in SmartStax.[7]

As yet, there is neither sufficient risk assessment of health risks from single events nor of the risks that may emerge from the combination of the events by mixing them in food and feed or by producing stacked events. There is a lack of clearly defined standards on how to assess synergistic effects or interaction with the environment. Currently, there is not even a requirement for companies to provide reliable test methods for the measurements of the Bt toxins produced in the plants.

In the light of these findings Testbiotech demands:

- A new concept for risk assessment that is targeted at specific risks related to genetically engineered plants and is not based on comparative risk assessment. This risk assessment should be performed step by step and also include ethical questions and socio-economic criteria.[8]
- Definition of scientific standards for investigations into risks and related quality control. These standards must be permanently adopted to further development in research.
- Definition of reliable protocols for determining the content of foreign proteins produced in the plants
- Rejection of the current applications of SmartStax and similar products such as VT Triple Pro Corn, reassessment of already authorised market applications.
- Publication of all data and results of relevant investigations.

Appendix and further resources:

Annex 1: Dossiers of Stilwell & Silvanovich (2007) Phillips (2008) and their detailed analysis
Annex 2: Dossiers of Levine et al. (2008) MacRae (2008) and their detailed analysis
Annex 3: Dossier of Rosenbaum (2008) and its detailed analysis
Annex 4: Dossier of D. (2008) and its detailed analysis

EFSA, 2010 a, Scientific Opinion on application (EFSA-GMO-CZ-2008-62) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON89034 x 1507 x MON88017 x 59122 and all subcombinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC), No 1829/2003 from Dow AgroSciences and Monsanto, EFSA Panel on Genetically Modified Organisms (GMO), http://www.efsa.europa.eu/en/efsajournal/pub/1781.htm

EFSA, 2010b, Application EFSA-GMO-CZ-2008-62 (MON89034 x 1507 x MON88017 x 59122 maize) Comments and opinions submitted by Member States during the three-month consultation period, accessed via http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO

7 http://www.testbiotech.org/node/458
8 See for example: http://www.testbiotech.de/node/503

TEST BIOTECH

Testbiotech e. V.
Institute for Independent Impact Assessment in Biotechnology

„... ensured that the data were consistent with expectations..."

How industry and EFSA have been systematically undermining the risk assessment of 'SmartStax'

Testbiotech Report by
Christoph Then and Andreas Bauer-Panskus

June 2011

grassroots foundation