TESTBIOTECH Background 09 - 01 - 2014

Reasons for the complaint against the decision of the EU Commission to give market authorisation to SmartStax for usage in food and feed

Christoph Then for Testbiotech, January 2014, www.testbiotech.org

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Summary

SmartStax is a joint Monsanto and Dow AgroSciences genetically engineered maize that produces six insecticidal proteins (Bt toxins) and is tolerant to two herbicides (glyphosate and glufosinate). One of the insecticidal proteins is derived from synthetic DNA that does not have a natural variant.

In November 2013, the EU Commission allowed this maize to be used in food and feed in the EU. Testbiotech filed its complaint in January 2014. By filing this complaint, Testbiotech wants the EU Commission to withdraw market authorisation for SmartStax. According to EU regulations, the EU Commission has two months to respond. After the complaint has undergone due process, it might be possible to forward the case to the Court of Justice of the European Union (CJEU)

SmartStax combines several genetically engineered plants into one plant, making pyramiding risks and uncertainties inevitable. Nevertheless, there was hardly any investigation into the combinatorial

effects. No feeding study was performed with the stacked maize to investigate potential effects on health and no investigation was carried out to examine the impact of long-term exposure.

SmartStax has a much higher Bt content than any other genetically engineered plant to date. Health risks associated with Bt toxins are of concern because of potential toxicity as well as its impact on the immune system. For example, there are studies indicating that consumption of such plants could provoke or enhance the risk of inflammatory diseases of the intestine. This risk was not assessed by EFSA.

A further matter of concern is the scientific quality of the data, which were provided for risk assessment: The investigations used in the risk assessment were conducted by and/or commissioned and paid for by industry. No independent laboratories were involved, data were not published in peer-reviewed magazines and the wording of some reports even indicates manipulation of the data.

EU regulation requires a high level of protection for human health and the environment, and a risk assessment of the highest possible standard (Regulation 1829/2003). Since the market authorisation of SmartStax is in conflict with this EU regulation, it must be withdrawn.

What is SmartStax?

In November 2013, the EU Commission allowed products from genetically engineered maize MON 89034 × 1507 × MON88017 × 59122 sold under the brand name “SmartStax” to be used in food and feed in the EU.

SmartStax is a joint Monsanto and Dow AgroSciences genetically engineered maize that produces six insecticidal proteins and is tolerant to two herbicides (glyphosate and glufosinate). The maize is grown in the US on a large-scale. The combination of toxins and herbicides are meant to overcome increasing problems with herbicide resistant weeds and pressure from pest insects that occur due to the extreme industrialisation of US agriculture.

Bt toxins occur naturally in soil bacteria (*Bacillus thuringiensis*) and have been used in agriculture for several decades. However, the structure of the toxins as produced in the plants is changed by genetic engineering. Contrary to its native toxin variants, the toxins in the plants are already

solubilized and activated. One of the toxins, classified as Cry1A.105 is fully synthetic and does not have a native variant.

There are substantiated health concerns associated with the use of the herbicide glufosinate, which is marketed under brand names such as Basta and Liberty. It will only be allowed in EU agriculture until 2017. It has to be expected that residues from spraying with the herbicide will be routinely found in the plants that are resistant to this herbicide. The same is true for mixtures of glyphosate, known under brand names such as Roundup, which are, amongst other things, suspected of causing adverse effects on health by interfering with the hormonal system.

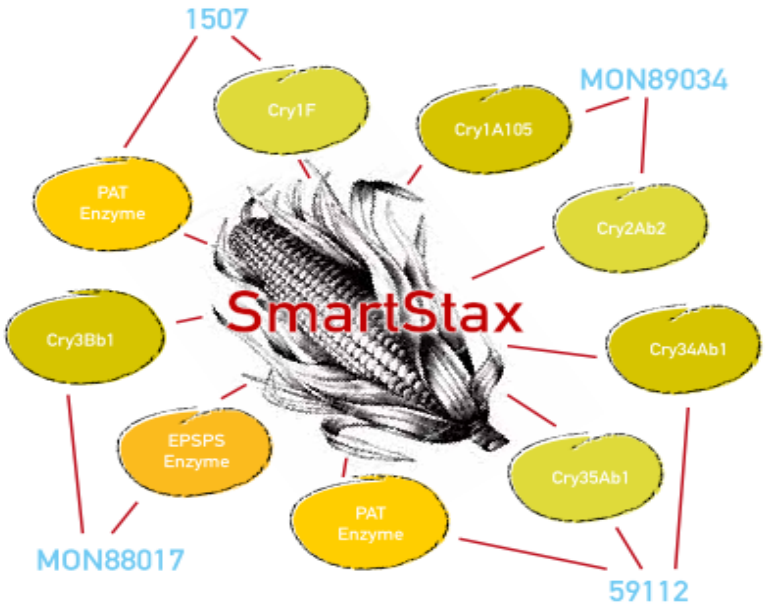

Figure 1: SmartStax, produced by Monsanto and Dow AgroSciences. This maize is a combination of four genetically engineered events (MON88017, MON89034, 59122, 1507), produces six insecticide-producing toxins (Cry toxin is derived from several strains of Bacillus thuringiensis, one of which, Cry1A105, is synthetically manufactured) and is tolerant to two herbicides (glufosinate through the PAT enzyme and glyphosate through the EPSPS enzyme) (source: Testbiotech).

What mistakes did EFSA make?

Although dossiers from the industry showed substantial flaws, the European Food Safety Authority (EFSA) in 2010 viewed market authorisation for SmartStax favourably. There was, for example, never any investigation into the combinatorial effects between the insecticidal toxins and the residues from spraying with the herbicides. No feeding study was performed with SmartStax to investigate potential effects on health and no investigation was carried out to examine the impact of long-term exposure.

Testbiotech examined EFSA´s opinion and the decision of the EU Commission in detail. The examination showed that the requirements of EU Regulations were not fulfilled. This can be exemplified by the risks of insecticidal Bt-toxins as produced in the plants:

- Several publications show that Bt toxins can have an effect on the health of mammals. These effects are likely to be less than those observed in insects, but they still have to be assessed thoroughly. For example, a study shows that Bt toxins in the blood system of mice can be a cause of death. The mode of action of the Bt toxin is different for each of the toxins and is not known in detail, thus the risks to health from SmartStax have to be assessed with specifically targeted investigations. This is especially relevant for the synthetic toxin Cry1A.105. It is known that even small changes in the structure of the proteins can cause huge changes in toxicity. In the case of Cry1A.105, there is evidence that toxicity is enhanced: A patent application by Monsanto reports unexpected changes in the toxicity of the Bt protein, but these results were ignored by EFSA. Further, EFSA did not take into account that various compounds can interact with Bt toxins and enhance its toxicity. Empirical studies using human cells etc. should have been carried out to assess the toxicity of Bt toxins in mammals. But no such studies were requested. The only studies, which were carried out are so-called acute toxicity studies with mice fed with a high dosage of an isolated Bt toxin over short period of time. However, even EFSA is of the opinion that such experiments are of little value. These studies are far removed from real exposure with Bt toxins in the food chain with minor dosages but with long-term and repeated exposure.

- It is known that Bt toxins, besides functioning as an insecticide, can also invoke and boost immune reactions in vertebrates. Signs of immune reactions have been found in several feeding studies, using fish, mice, rats and pigs. These effects are likely to be dependent on the dosage of Bt toxins. SmartStax has a much higher concentration of Bt toxins than other plants such as the Parental Plants which were tested in feeding studies. Furthermore, it is

evident, that Bt toxins can survive digestion to a much higher degree than has been assumed so far. Consequently, there is substantiated concern that the plants can have adverse effects on the immune system. For example, consuming these plants might cause inflammatory diseases of the intestine. However, there has been no investigation into the impact of Bt toxins as produced in SmartStax on the immune system.

In general, the data used for risk assessment by EFSA cannot be used to draw reliable conclusions on the safety of SmartStax. For example, assumptions on the concentration of the Bt toxin in the food chain and the exposure of consumers to the insecticidal protein suffer from basic flaws, since

- no sufficiently reliable methods were made available for measuring its concentration in the plants;
- the true rate of Bt production in the plants under various environmental conditions was not determined;
- the assumption that the Bt toxin is digested quickly in the gut is simply wrong.
- combinatorial effects known to multiply toxicity or reactions of the immune system were not taken into account.

In addition to the gaps and flaws in the risk assessment as performed by EFSA, the quality of the data, which were used for risk assessment are a very great matter of concern:
The investigations used in the risk assessment were conducted by and/or commissioned and paid for by the companies (Monsanto and Dow AgroSciences). No independent laboratories were involved, data were not published in peer-reviewed magazines, and the wording of some reports even indicates manipulation of the data. For example, a dossier prepared by Monsanto to assess the agronomic performance of SmartStax explicitly states that, “oversight ensured that the data were consistent with expectations”. This means that the outcome of the experiments was brought into line with the expectations of the companies. However, EFSA accepted the dossier without any criticism.

Since many of the flaws in the Commission’s decision and the opinion of EFSA also can be observed in the single Parental Plants, the conclusion that SmartStax is safe conflates a whole series of substantial flaws and uncertainties. Consequently, the Commission’s decision and the opinion of EFSA is based on pyramiding flaws and uncertainties from previous opinions and decisions on the

Parental Plants. This is shown in Figure 2, which summarises some of the risks and uncertainties in regard to the Bt toxins as produced in the plants.

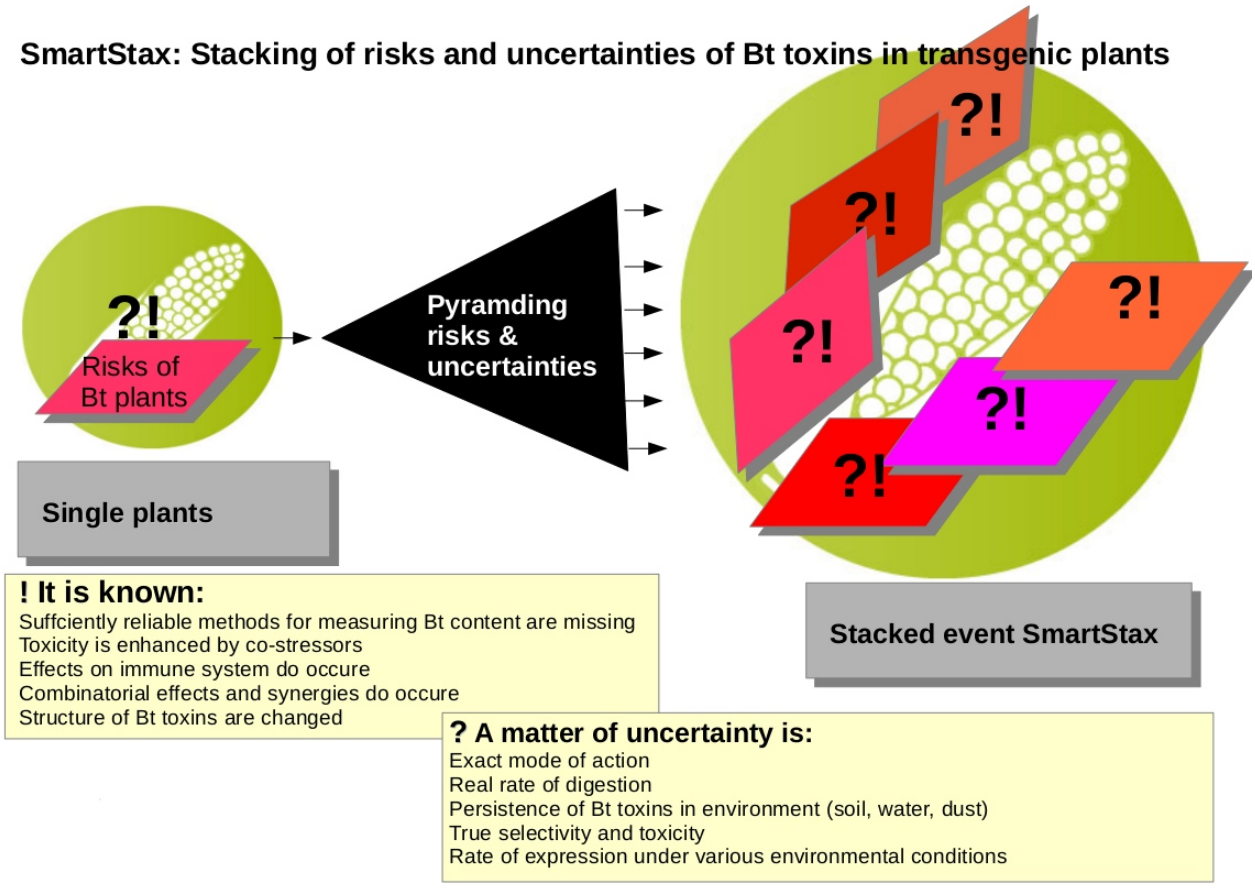

Figure 2: Overview of some risks and uncertainties related to the single genetically engineered plants and their combination in SmartStax.

What are the risks for consumers?

The EU authorisation for SmartStax it is not restricted to specific use in feed or food. The products can be used in all relevant products and can be combined with other genetically engineered plants. Observers expect an increase of maize imports into the EU within next years. At the moment, the food industry in Europe is trying to avoid products from these plants which have to be labelled. However, this might change in future and consumers might find themselves in a situation where SmartStax is indeed part of their daily food intake.

Consequently, EU consumers would be exposed to products, which only appear to have passed a rigorous risk assessment but in fact never did. This should be taken very seriously. There are too many risks and uncertainties and the arguments from industry that there have so far not been any observable adverse effects on health from the consumption of SmartStax are not convincing. As the EU Commission stated in 2005, without a detailed long-term study these effects are likely to escape notice if they do not occur alongside symptoms of acute toxicity. There were no such investigations.

According to current knowledge, risks for consumers cannot be denied. This is also underlined by two recent studies carried out by the University of Manchester showing that the risks to the immune system have been underestimated. The studies were commissioned by EFSA, which disregarded these issues and did not take them into account while assessing SmartStax.

One of the new studies from the University of Manchester examines the tests currently used to show digestibility of Bt proteins in the laboratory. The experts from the University of Manchester conclude that most of the tests currently used are unreliable and do not provide realistic results. This study confirms findings from previous studies, which showed that a high percentage of the Bt toxins can persist during digestion, while EFSA assumes the opposite.

The second publication examines the immune reactions and diseases that can be provoked by immune reactions in the gut. The experts from the University of Manchester conclude that several inflammatory diseases (such as enterocolitis) have to be considered.

These findings are highly relevant for SmartStax, which contains a much higher concentration of Bt toxins than any other genetically engineered plant placed on the market.

Consequently, there is substantiated concern that the consumption of the plants can have adverse effects on health. These risks are especially relevant for infants or individuals with an impaired immune system such as elderly people.

However, these risks for relevant groups were left aside during EFSA risk assessment.

Why did Testbiotech file a complaint against the decision of the EU Commission?

The EFSA is responsible for the market authorisation of genetically engineered plants, but it is the Commission, which makes final decision. The Commission is not bound by the opinion of EFSA but has to take a political decision that takes into account all relevant issues, including those, which

were disregarded by EFSA. Overall, it is the responsibility of the EU Commission to provide a high level of protection for consumers and the environment as required by EU Regulations.

EU regulations require that the precautionary principle takes precedence if there are gaps in knowledge and uncertainties that do not allow final conclusions upon the safety of the food products. Thus, in the case of SmartStax the market application should have been rejected.

The Commission failed by allowing SmartStax for usage in food and feed on the basis of risk assessment as performed by industry and EFSA. A further failure is that the Commission did not request targeted monitoring of the effects on health from the maize at the stage of consumption. Without targeted monitoring, effects that contribute to complex or chronic diseases will escape notice. But in the case of SmartStax no such monitoring is required. There are not even any adequate methods available to trace and identify SmartStax in the food products.

Testbiotech filed its complaint in January 2014. By filing a complaint, Testbiotech wants the EU Commission to withdraw market authorisation for SmartStax. According to EU regulations, the EU Commission has two months to respond. After due process of the complaint, it might be possible to forward the case to Court of Justice of the European Union (CJEU).

References: See the text of the Testbiotech complaint: www.testbiotech.org/node/995