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SmartStax:

Illegal imports of genetically engineered maize into the EU?

SmartStax, a genetically engineered maize produced by Monsanto and Dow AgroSciences, was developed by cross-breeding several genetically modified maize plants. It produces six different insecticides and is resistant to two herbicides (glyphosate and glufosinate).

EFSA assessed SmartStax in 2010 but it was not authorised in the EU. Imports are not allowed without authorisation. However, research conducted by Testbiotech shows that it is very likely that there have been imports of SmartStax since 2010, and that it has, moreover, been introduced into the food chain.

What is SmartStax and why is it grown?
Genetically engineered maize crops producing Bt toxins have been grown since 1996. Bt is an acronym for *Bacillus thuringiensis*, a group of soil bacteria which produce different insecticidal proteins. Some of these toxins kill the caterpillars of certain butterflies or bugs.

During the last few years, extensive cultivation of genetically engineered Bt crops has led to increasing problems. For example, pest insects have tended to become resistant to some of the Bt toxins, and the rise of secondary pests has been observed in some regions (overview in Then, 2010[1]).

Industry's strategy to combat these developments is to combine several Bt toxins into one genetically engineered plant. In the case of SmartStax, six different insecticidal proteins are combined in one plant to target the caterpillars of butterflies (*Lepidoptera*) and bugs (*Coleoptera*). One of the toxins (Cry1A105) was artificially synthesised from several insecticidal toxins so that there are no natural variants of this toxin. SmartStax is also tolerant to two different herbicides. It was developed and is jointly marketed by Dow AgroSciences and Monsanto.

[1] Then, C., (2010), New pest in crop caused by large scale cultivation of Bt corn, in: Breckling, B. & Verhoeven, R. (2010) Implications of GM-Crop Cultivation at Large Spatial Scales. Theorie in der Ökologie. Frankfurt, Peter Lang.

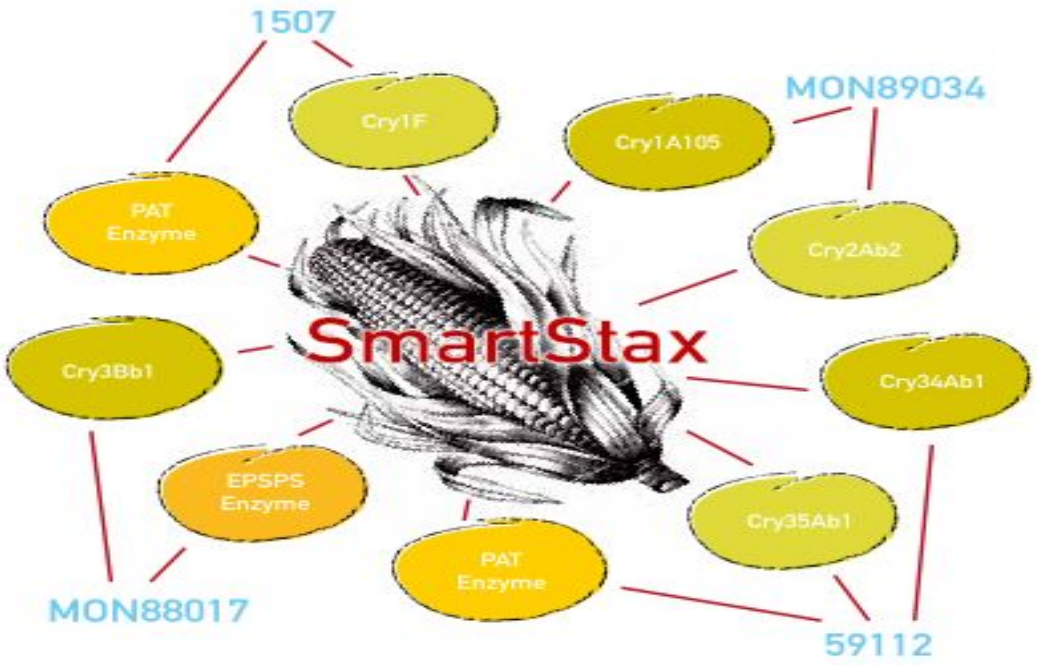

Fig. 1: SmartStax is a product of Monsanto and Dow AgroSciences. It combines four genetically engineered events (MON88017, MON89034, DP59122, DP1507) and produces six insecticides (Cry-toxins from different strains of Bacillus thuringiensis, of which, one, Cry1A105, is produced synthetically) and is resistant to two herbicides (glufosinate through the PAT enzyme and glyphosate through the EPSPS enzyme). Source: Testbiotech

Where is SmartStax being cultivated?

SmartStax was authorised in the USA in 2009, and has been cultivated on several million hectares each year since then. In 2011, for instance, Monsanto planned to sell seeds for 6 million hectares, although the actual acreage was probably lower[2].

Accurate and independent figures on the cultivation of SmartStax are not available. The best indications can be drawn from cultivation data on so-called „triple stacks“. Triple stack plants are produced by cross-breeding genetically engineered plants. They are generally referred to as “stacked events” (a combination of different traits of genetically engineered plants). A triple stacked plant contains three different traits:

(1) Resistance to herbicides

(2) Toxic to pests insects damaging the plant above-ground, as well as

(3) toxic to pest insects, which damage the plant underground

[2] http://www.thestreet.com/story/10867388/1/will-monsanto-need-to-cut-targets-again.html

According to the National Agricultural Statistics Service (NASS), maize was cultivated on almost 89 million acres (36 million hectares) in the USA in 2012, which corresponds to a 5% increase in acreage compared to 2011[3]. The yield amounts to about 270 million tonnes. Genetically engineered maize represents 88% of acreage, stacked crops (double stacked, triple stacked) about 52% of total maize acreage[4]. Edgerton et al., (2012)[5], who are Monsanto employees, assume that in 2010, 17.8 million hectares of triple-stacked maize were cultivated in the USA.

Additionally, SmartStax is grown in Canada, although exact figures are not available for this region.[6]

Does SmartStax enter the EU?

In 2011, the EU imported 839.000 tonnes of maize from the USA, which was, amongst other things, mainly intended for use in animal fodder. In 2010, 266 million tonnes were imported[7]. There is an increasing demand in the EU for imports of maize and in 2012/2013 it is possible that for the first time more than 10 million tonnes will be imported[8]. In 2012, US maize was still exported into the EU even though the harvest was lower due to a severe drought; US maize exports will probably only be down by around 20 percent, from 38 million to 31 million tonnes[9].

SmartStax maize is not systematically separated from the rest of the harvest in the US. There is some information for farmers about which varieties are allowed for export[10], but there are no controls by the authorities. Neither are there any public registers established in the US to show where and which genetically engineered plants are being grown. As a result, it is left up to the feed industry to decide to which extent separation is implemented.

Efficient and independent controls are hardly possible since SmartStax is difficult to identify. It consists of several genetically engineered maize events, which are authorised as single plants and can therefore be easily mistaken. If findings indicate the presence of SmartStax, further in depth investigations would be required for confirmation. These kinds of tests are not applied in practice. Inevitably, we must conclude that SmartStax is being imported into the EU in US maize imports.

Testbiotech believes that industry is aware of the imports of SmartStax into the EU and that it hopes to escape the attention of the authorities due to the lack of effective detection methods.

What are the legal aspects ?

EU legislation requires that so-called stacked events (cross-bred genetically engineered plants) may only enter the European market if they are legally approved. Ahead of approval, there has to be a

3 2011-2012: U.S. Dept of Agriculture, National Agricultural Statistics Service (NASS). Acreage. June 29, 2012, http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000.

4 2011-2012: U.S. Dept of Agriculture, National Agricultural Statistics Service (NASS). Acreage. June 29, 2012, http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000.

5 Edgerton et al., *Transgenic insect resistance traits increase corn yield and yield stability*, Nature Biotechnology 30, 2012, S. 493.

6 http://www.isaaa.org/resources/publications/briefs/42/download/isaaa-brief-42-2010.pdf

7 http://epp.eurostat.ec.europa.eu/portal/page/portal/international_trade/data/database

8 http://www.agrarheute.com/strategie-grains-mais

9 http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1487

10 http://www.ncga.com/for-farmers/know-before-you-grow

risk assessment in which the applicant has to show that, for example, there are no unexpected or combinatorial effects. The European Food Safety Authority (EFSA) assessed SmartStax in 2010 but the EFSA opinion was criticised for several reasons. SmartStax is not approved for commercial purposes in the European Union and can, therefore, not be imported. At the same time, the EU Commission has so far not taken any measures to prevent imports this from happening.

The case takes on even greater implications because industry can rely on the expectation that EU controls will not be able to identify SmartStax in imports. According to EU regulation, each applicant of genetically engineered plants has to make available a method for identifying the particular plants. Traceability is required for all products derived from these plants according to EU regulation 1830/2003. As far as stacked events are concerned, these legal requirements are permanently violated. Up to now, the EU has approved 22 plants with stacked events with combinations of additional DNA that do not allow their identification under practical conditions. As highlighted by the case of SmartStax, the consequences are that here is no certainty for the authorities, food producers and farmers if, and to which extent, SmartStax has already entered the food chain. Seemingly, EU authorities have already partially lost control of genetically engineered plants in food and feed production.

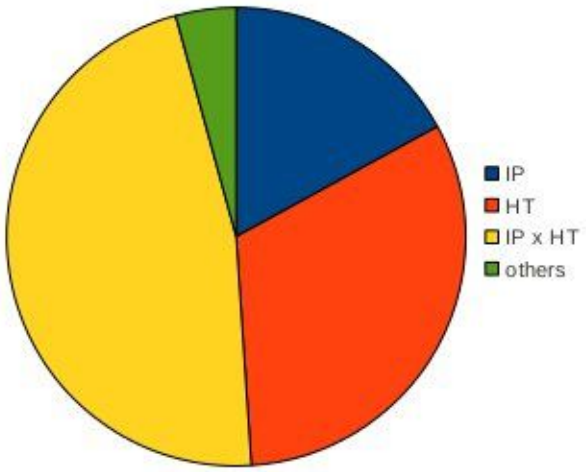

Fig. 2 Genetically engineered plants authorised in the EU (for usage in food & feed) up to November 2012. IP: Insecticidal toxin producing plants; HT: Herbicide tolerant plants; IP x HT: Stacked Events. Others: 1 x potato for production of starch, 1x male sterility. Data source: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm, & www.testbiotech.org/node/593

Effective measures must be taken to solve the recent problems with SmartStax. If US maize importers cannot prove that their shipments do not contain SmartStax, the imports have to be rejected.

Further, there must be a re-examination of how the current practise of market authorisations for stacked events can be changed to bring it in line with EU regulations. At the moment, there are products on the market with a substantial potential for health risks which do not fulfil traceability requirements and thus lack transparency on its real usage within the food chain.

Testbiotech is concerned that the feed and biotech industry will once more try to circumvent existing regulations. In all likelihood, industry will try to introduce regulations such as those in the US, which do not require any risk assessment and registration for stacked events. Once more, the EU institutions will have to show if they are ready to protect consumers and the environment.

How safe is SmartStax?

Testbiotech addressed the gaps in the risk assessment of the crops in depth[11]. The analysis shows that the documents submitted by the industry are unsuitable for assessing health risks for humans and animals. Among others, necessary independent quality controls are missing. There are even indications that Monsanto manipulated the data.

There was insufficient examination of the combinational effects of the toxins present in the plants. For example, feeding trials were performed with poultry to assess weight gain, but no results from feeding trials to investigate health effects were forwarded to the authorities for the market application in EU.

In 2011, Testbiotech approached the commission and informed them about the flaws in the risk assessment. Subsequently, the EU commission consulted EFSA, which however did not reply to the concerns raised by Testbiotech in substance[12].

Testbiotech concludes that risks for humans and the environment have not been adequately assessed. Testbiotech is demanding a new, comprehensive risk assessment of SmartStax and efficient measures to stop its import into the EU.

[11] http://www.testbiotech.de/node/514
[12] http://www.testbiotech.de/node/748