

Testbiotech EU Newsletter 4/2016 (December 2016)

This newsletter provides an overview of current developments in the EU and related Testbiotech activities. The newsletter is published every three months and more often where appropriate. It is supported by the Software AG Foundation.

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<u>Most important topics:</u> EU Court of Justice throws out legal action against genetically engineered soybeans / Dossier: Cultivation of genetically engineered maize in the EU has to be suspended / New scientific papers on metabolic changes in genetically engineered plants and conflicts of interest in transgenic crop science / Genetically engineered oilseed rape hard to remove from the EU market

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Current Issues and Activities

EU Court of Justice throws out legal action taken against the authorisation of genetically engineered soybeans

On 15 December, the Court of Justice of the EU (CJEU) ruled on legal action brought against the import of genetically engineered Monsanto Intacta soybeans (T-177/13). According to the ruling, these genetically engineered soybeans were risk assessed in accordance with EU regulations. The ruling means that the court has given a stamp of approval to European Food Safety Authority (EFSA) risk assessment and EU Commission decision-making.

It is the first time that the CJEU has had to rule on legal action filed by non-profit organisations against the import of genetically engineered plants. Testbiotech filed the legal action together with the European Network of Scientists for Social and Environmental Responsibility (ENSSER) and the German non-profit organisation Sambucus against the EU Commission in 2013. The opposing side was jointly supported by the European Food Safety Authority, EFSA, the UK government and Monsanto. https://www.testbiotech.org/en/node/1788

Legal dossier: Cultivation of genetically engineered maize in the EU has to be suspended

According to a legal dossier drawn up by the environmental law expert Ludwig Kramer, the pending applications for the cultivation of genetically engineered maize in the EU suffer from crucial deficiencies. Consequently, the pending applications must be rejected and the existing authorisation for the cultivation of maize MON810 withdrawn. The applications were filed by Monsanto, Pioneer/DuPont and Syngenta. They have wholly ignored recent developments and failed to properly address the risk of the transgenes spreading to other plant species.

These latest problems have emerged in connection with the spontaneous occurrence of a plant species known as teosinte. Teosinte is spreading in maize fields in Spain, the country where the most genetically engineered plants are grown in the EU. Teosinte is a plant species that can hybridise with maize and produce viable offspring, which means that transgenes can be transferred from maize into teosinte populations. The dossier was commissioned by Testbiotech.

http://www.testbiotech.org/node/1773

Testbiotech comment on planned amendment of EU Directive 2001/18

Testbiotech filed a comment on the planned EU Commission Directive amending Directive 2001/18/EC regarding the environmental risk assessment of genetically modified organisms. In its analysis, Testbiotech reject the current proposal of the EU Commission in most of its elements and makes several recommendations for future environmental risk assessment.

https://www.testbiotech.org/en/node/1776

Scientific News

New study explores epigenetic changes in transgenic crops

In a recently published scientific paper ("Levels of DNA methylation and transcript accumulation in leaves of transgenic maize varieties"), scientists from Norway, Germany and Brazil examined epigenetic effects in commercialised genetically engineered maize events MON89034 and MON89034 x NK603. MON89034 produces the Bt toxins Cry1A.105 and Cry2Ab2, which are active against lepidopteran insects; maize NK603 is tolerant to glyphosate herbicides. The scientists compared different MON89034 or MON89034 x NK603 varieties with the respective isogenic varieties.

The results show epigenetic changes occur in transgenic maize. For example, the scientists showed that DNA methylation levels of transgenic sequences vary among single GM maize varieties and between single and stacked GM maize varieties.

The authors come to the conclusion that although the detection of changes in DNA methylation levels and transgenic accumulation levels does not present a safety issue per se, it demonstrates the need for additional studies that address the biological relevance and the possible safety implications of such changes. http://enveurope.springeropen.com/articles/10.1186/s12302-016-0097-2

Proteomics study: Maize NK603 not substantially equivalent

Significant changes in a genetically engineered event were also found in another study applying contemporary molecular profiling methods. Using some of the latest proteomics methods, Mesnage et al. showed imbalances in energy metabolism, changes in proteins and metabolites indicative of increased oxidative stress as well as an increase in polyamines. According to the authors, maize NK603 cannot be regarded as substantially equivalent to its isogenic line.

http://www.nature.com/articles/srep37855

Conflicts of interest in Bt crop studies

Scientists from the French institute INRA published a study examining the effects of ties between academic research and biotech industry. The authors found that ties between researchers and industry were common. Indications of conflicts of interest (COI) were found in about 40% of the articles. They also found that conflicts of interest were associated with a 50% higher frequency of outcomes favourable to the interests of industry.

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0167777

The findings correspond with an analysis published by Testbiotech in 2014. Taking Bt maize event 1507 as an example, Testbiotech showed that a great proportion of peer reviewed papers regarding this event were dominated by industry or scientists with close ties to biotech companies.

https://www.testbiotech.org/node/1030

News from EFSA

EFSA opinion on insect-resistant and herbicide-tolerant soybean DAS-81419-2

On 5 December, EFSA published an opinion on soybean DAS-81419-2 produced by Dow AgroSciences. The plants express the Cry1F and Cry1Ac proteins to confer resistance to lepidopteran species and PAT protein that confers tolerance to glufosinate. According to EFSA, the soybean plants are as safe and as nutritious as their conventional counterparts.

http://www.efsa.europa.eu/en/efsajournal/pub/4642

EFSA opinion on herbicide-tolerant maize DAS-40278-9

On 5 December, EFSA published its first opinion on a transgenic crop engineered to withstand 2,4-D as well as aryloxyphenoxypropionate (AOPP) herbicides. Even though no toxicological study for this new type of transgenic plant was provided, EFSA came to the conclusion that maize DAS-40278-9 is as safe and as nutritious as its conventional counterpart.

http://www.efsa.europa.eu/en/efsajournal/pub/4633

EFSA statement on the risk assessment of new sequencing information on maize DAS-59122-7

On 5 December, EFSA published a statement on new sequencing information for maize DAS-59122-7. This maize event was authorised in the EU in 2007. It produces the Bt toxins Cry34Ab1 and Cry35Ab1 and is resistant to glufosinate herbicides. The applicant (Pioneer/DuPont) informed EFSA of three base pair (bp) differences compared to the sequencing data originally provided. According to EFSA, the new sequencing data and the bioinformatic analyses performed on the new sequence raise no safety issues. http://www.efsa.europa.eu/en/efsajournal/pub/4639

Other

Industry: Genetically engineered oilseed rape hard to remove from the market

According to a recently published decision by the EU Commission, industry is finding it very difficult to remove genetically engineered oilseed rape events Ms1×Rf1, Ms1×Rf2 and Topas 19 from the market. These lines were authorised in the EU for import and usage in food and feed, but were withdrawn from the market in 2007. In such cases, EU law foresees a certain time span in which traces of the respective plants are tolerated. However, according to Bayer CropSciences, the producer of the oilseed rape lines in question, the company is still unable to eradicate traces of the oilseed rape. According to the Commission decision, minute traces have been still detected in oilseed rape commodities in recent years. This persisting presence of traces can be explained by the biology of oilseed rapes which can remain dormant for long periods as well as by farm practices which have been employed to harvest the seeds which may have resulted in accidental spillage". The transitional period for the removal of the oilsee rape lines, which should have ended in 2012, was therefore extended for another three years until 31 December 2019.

 $\underline{https://publications.europa.eu/en/publication-detail/-/publication/78ad7ff6-c35d-11e6-a6db-01aa75ed71a1/language-en}$