



## **Testbiotech EU Newsletter 1/2017 (April 2017)**

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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### **Most important topics:**

**Vote on cultivation of genetically engineered maize, Soybean 'Intacta': Appeal filed at the European Court of Justice, Testbiotech critical of the newly drafted policy on EFSA independence, Cloned cattle entering the EU, New paper: 'Golden Rice' shows reduced growth and irregular gene expression**

### **Overview of Topics**

#### **Current Issues and Activities**

- German authority undermining decision-making at the European Court of Justice
- Testbiotech critical of the newly drafted policy on the independence of the European Food Safety Authority
- Cloned cattle entering the EU
- Soybean 'Intacta' ruling: Appeal filed at the European Court of Justice
- Testbiotech comment on EFSA opinion regarding insect-resistant and herbicide-tolerant cotton GHB119 from Bayer CropScience
- Testbiotech comment on EFSA opinion regarding insect-resistant soybean DAS-81419-2
- Testbiotech comment on EFSA opinion regarding herbicide-tolerant maize DAS-40278- 9

#### **Scientific news**

- 'Golden Rice' shows reduced growth and irregular gene expression
- Molecular responses of genetically modified maize to abiotic stresses
- Next moves in EFSA dispute with German scientists
- US National Academies' genetically engineered crop study: Conflicts of interest
- Glyphosate, soybean, allergies, reproduction
- Allergenicity of genetically engineered soybean

#### **New decisions on EU authorisations**

- No majority in second vote on new cultivation of genetically engineered maize
- EU Parliament votes against import of Syngenta maize

#### **News from EFSA**

- Scientific opinion on soybean FG72 x A5547-127

- Scientific opinion on herbicide-tolerant cotton MON 88701
- Risk assessment of information on the subcombination Bt11 × MIR162, related to the application for authorisation of maize Bt11 × MIR162 × MIR604 × GA21
- Scientific opinion on herbicide-tolerant soybean DAS-44406-6
- Scientific opinion on herbicide-tolerant soybean DAS-68416-4
- Scientific opinion on application for continued marketing of maize 1507

## Current Issues and Activities

### German authority undermining decision-making at the European Court of Justice

The German Central Committee on Biological Safety (ZKBS) discussed applications for plants engineered using the new nuclease CRISPR-Cas gene technology. The applications were assessed at the request of the German Federal Office of Consumer Protection and Food Safety (BVL). The ZKBS came to the conclusion that not all of these plants have to be regulated under the rules for genetically engineered plants.

[www.testbiotech.org/en/node/1926](http://www.testbiotech.org/en/node/1926)

### Testbiotech critical of the newly drafted policy on the independence of the European Food Safety Authority

The European Food Safety Authority (EFSA) has published a new draft policy on its independence and scientific decision-making, and is inviting comments from the public. Testbiotech is demanding the newly drafted policy is substantially improved. According to Testbiotech, EFSA should give priority to gaining more independence specifically in regard to the influence from agrifood industries. This is not the case with the current draft. [www.testbiotech.org/en/node/1916](http://www.testbiotech.org/en/node/1916)

### Soybean 'Intacta' ruling: Appeal filed at the European Court of Justice

Testbiotech, the European Network of Scientists for Social and Environmental Responsibility (ENSSER) and the environmental organisation Sambucus have together filed an appeal (C-82/17 P) at the European Court of Justice (ECJ) against the decision of the General Court of the EU from December 2016 (T-177/13). The appellants are contesting the ruling of the court, which approved the decision of the EU Commission to allow the import of the soybean. They are seeking clarity on fundamental legal questions concerning EU authorisation of genetically engineered plants. [www.testbiotech.org/en/node/1883](http://www.testbiotech.org/en/node/1883)

Earlier, a new scientific publication authored by Testbiotech experts had shown that health risks associated with Monsanto's genetically engineered soybean "Intacta" were not sufficiently assessed. The soybeans produce an insecticide and are resistant to glyphosate and are allowed to be imported for use in food and feed in the EU. Health risks arising from interactions between the residues left over from the glyphosate formulations and the insecticide were not investigated despite data showing that toxicity can be thus enhanced. [www.testbiotech.org/en/node/1814](http://www.testbiotech.org/en/node/1814)

### Cloned cattle entering the EU

Research conducted by Testbiotech has shown that cows and their offspring stemming from cloned bulls are registered in a professional breeders database in the UK. It is likely that a considerable number of animals stemming from clones have already entered the EU. At present, the EU has no labelling or registration requirements for these kinds of imports, which makes it almost impossible to identify breeding material stemming from cloned bulls. [www.testbiotech.org/en/node/1845](http://www.testbiotech.org/en/node/1845)

### Testbiotech comment on EFSA opinion regarding insect-resistant and herbicide-tolerant cotton GHB119

Testbiotech published a comment on EFSA's opinion regarding cotton GHB119 from Bayer CropScience. The comment concludes that the risk assessment by EFSA should not be accepted because it does not

identify knowledge gaps and uncertainties and fails to assess toxicity as well as the impact on the immune system and the reproductive system. [www.testbiotech.org/node/1860](http://www.testbiotech.org/node/1860)

#### **Testbiotech comment on EFSA opinion regarding insect-resistant soybean DAS-81419-2**

Testbiotech published a comment on EFSA's opinion regarding insect-resistant soybean DAS-81419-2 marketed by Dow AgroSciences. The plants produce two synthetically derived Bt toxins (Cry1Ac (synpro) and Cry1Fa2) and were made resistant to the herbicide glufosinate. Testbiotech raised several issues that were not properly assessed by EFSA. For example, unintended structural changes in the genome or significant compositional changes observed were set aside by EFSA without more detailed investigations. Therefore, Testbiotech comes to the conclusion that market authorisation should not be granted on the basis of EFSA's opinion. [www.testbiotech.org/node/1861](http://www.testbiotech.org/node/1861)

#### **Testbiotech comment on EFSA opinion regarding herbicide-tolerant maize DAS-40278- 9**

Testbiotech published a comment on EFSA's opinion regarding maize DAS-40278- 9 marketed by Dow AgroSciences. The plants confer resistance to 2,4-D and aryloxyphenoxypropionate (AOPP) herbicides. Testbiotech comes to the conclusion that market authorisation should not be granted on the basis of EFSA's opinion. [www.testbiotech.org/node/1862](http://www.testbiotech.org/node/1862)

### **Scientific News**

#### **'Golden Rice' shows reduced growth and irregular gene expression**

A new publication reports unintended effects in genetically engineered rice producing precursors of vitamin A, so-called carotenoids. Crossing Golden Rice with the Indian variety Swarna led to extensive disturbance in their growth. The researchers identified several reasons for this: The new gene constructs interfere with the plant's own gene for producing growth hormones, and the additional gene constructs were not, as intended, active solely in the kernels, but also in the leaves. This led to a substantial reduction in the content of chlorophyll that is essential for vital functions in the plants. [www.testbiotech.org/en/node/1859](http://www.testbiotech.org/en/node/1859)

#### **Molecular responses of genetically modified maize to abiotic stresses**

Scientists from South Africa, Norway and Brazil compared a proteome profile of herbicide-tolerant maize to its near-isogenic conventional variety under drought and herbicide stresses. Twenty differentially abundant proteins were detected between the conventional and the engineered plants under different water deficiency conditions and herbicide sprays. Environment was found to be the major source of variation followed by the genetic transformation factor. The authors recommend improved molecular studies in future risk assessments. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0173069>

#### **Next moves in EFSA dispute with German scientists**

German scientists published a reply to a EFSA statement on the relevance of new data regarding environmental risk assessment and management of Bt-maize events (MON810, Bt11 and 1507) (<http://enveurope.springeropen.com/articles/10.1186/s12302-017-0106-0>).

In two earlier publications, they had claimed that EFSA underestimated the exposure of non-target organisms to Bt-maize pollen. The results implied a need for safety buffer distances in the kilometre range for protected nature reserve areas instead of the 20–30 m range recommended by the EFSA Panel. The EFSA Panel reacted in a report criticising the methods and outcomes of the two published studies and reaffirmed their original recommendations. The German scientists show that the EFSA critique is not justified and confirm the need for specific environmental impact assessments for Bt-maize cultivation with respect to protected habitats within isolation buffer distances in the kilometre range. Again, this new study was assessed by EFSA. Following an urgent request by the EU Commission, EFSA found that no new data were presented and saw no argument that would invalidate their previous assessments. [www.testbiotech.org/node/1932](http://www.testbiotech.org/node/1932)

### **US National Academies' genetically engineered crop study: Conflicts of interest**

A new study published in the journal *PlosOne* examines whether there were financial conflicts of interest (COIs) among the US National Academies' committee members who wrote a 2016 report on genetically engineered crops. The authors show that several panel members had reportable and undisclosed financial COIs. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0172317>

### **Glyphosate, soybean, allergies, reproduction**

A new study evaluated the toxicity of soy milk (supplemented or not supplemented with glyphosate) in male rats. Endocrine disruption was observed in animals treated only with soy and with milk soy milk supplemented with glyphosate. In addition, animals treated with soy milk with glyphosate showed a decrease in spermatids number. The authors conclude that endocrine-disrupting effects are intensified by exposure to soy milk with glyphosate residues and present evidence that glyphosate impairs the male reproductive system. [www.sciencedirect.com/science/article/pii/S0278691516304896](http://www.sciencedirect.com/science/article/pii/S0278691516304896)

### **Allergenicity of genetically engineered soybean**

Scientists from EFSA GMO Panel and other experts published the paper „Assessment of endogenous allergenicity of genetically modified plants exemplified by soybean – Where do we stand?“.

In the publication, current challenges of the endogenous allergenicity assessment are discussed and strategies for future evaluations are proposed. [www.sciencedirect.com/science/article/pii/S0278691517300212](http://www.sciencedirect.com/science/article/pii/S0278691517300212)

## **New decisions on EU authorisations**

### **Vote on new cultivation of genetically engineered maize: no qualified majority**

On 27 March, representatives of the Member States and the EU Commission met to discuss and vote on the cultivation of genetically engineered maize. The EU Commission wants to give new authorisations for the cultivation of genetically engineered maize before the growing season 2017 starts. Three variants of transgenic maize expressing insecticidal toxins, registered as MON810, Maize 1507 and Bt 11, are being considered. Monsanto, DuPont/Pioneer and Syngenta are pushing for the market introduction of the seeds. The meeting didn't end in a qualified majority vote to reach a decision. It is now up to the EU Commission to decide within the next weeks. [www.testbiotech.org/en/node/1829](http://www.testbiotech.org/en/node/1829)

### **EU Parliament votes against import of Syngenta maize Bt11 × 59122 × MIR604 × 1507 × GA21**

On 5 April, the European Parliament voted against an EU Commission proposal to authorise the stacked event Bt11 × 59122 × MIR604 × 1507 × GA21 for use in food and feed. Earlier votes taken by EU member states in January and March failed to reach a qualified majority for or against authorisation. The Parliament's vote is not binding and it is now up to the Commission to make a decision on authorisation.

<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2017-0123&format=XML&language=EN>

## **News from EFSA**

### **Scientific opinion on soybean FG72 x A5547-127**

On 6 April, EFSA published an opinion regarding soybean FG72 x A5547-127 by Bayer Crop Sciences. The plants were made resistant to isoxaflutole, glyphosate, and glufosinate herbicides. EFSA identified data gaps regarding composition, but nonetheless concluded that the plants are „as safe as the non-genetically modified (GM) comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.“

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4744/full>

### **Scientific opinion on herbicide-tolerant cotton MON 88701**

On 30 March, EFSA published an opinion on Monsanto's MON 88701 cotton. The plants were made resistant towards dicamba and glufosinate herbicides. Because of missing data, EFSA could complete neither comparative assessment nor its food/feed risk assessment.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4746/full>

### **Risk assessment of information on the subcombination Bt11 × MIR162, related to the application for authorisation of maize Bt11 × MIR162 × MIR604 × GA21**

On 24 March, EFSA published an assessment on the two-stack maize event Bt11 × MIR162. The plants were part of the application for authorisation of the four-event maize stack Bt11 × MIR162 × MIR604 × GA21, but had not been properly assessed before. The GMO Panel considers that the new information for maize Bt11 × MIR162 does not alter the conclusions of its previous scientific opinion,

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4745/full>

### **Scientific opinion on herbicide-tolerant soybean DAS-44406-6**

On 21 March, EFSA published an opinion on soybean DAS-44406-6 produced by Dow AgroSciences. The plants were made resistant towards glyphosate, 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and glufosinate herbicides. EFSA concluded that the plants are „as safe as its conventional counterpart and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.“

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4738/full>

### **Scientific opinion on herbicide-tolerant soybean DAS-68416-4**

On 16 March, EFSA published an opinion on soybean DAS-44406-6 produced by Dow AgroSciences. The plants are resistant towards 2,4-D and other related phenoxy herbicides, and glufosinate herbicides. EFSA concluded that soybean DAS-44406-6 „is as safe as its conventional counterpart and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.“

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4719/full>

### **Scientific opinion on application for continued marketing of maize 1507**

On 12 January, EFSA published an opinion on the renewal of authorisation regarding insect-resistant and herbicide-tolerant maize 1507. EFSA found no new safety issues.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4659/full>