



## Testbiotech EU Newsletter 2/2015

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: Pending mass authorisation of genetically engineered plants for import / Authorisation of GE maize 1507 delayed / Glyphosate might cause cancer / Complaint filed against EU project GRACE**

### **Overview of Topics**

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

- Complaint against GRACE project
- Authorisation of GE maize 1507 delayed
- EU Parliament keeps up the pressure on EFSA
- EU Commission plans for the mass authorisation of genetically engineered plants
- EU project PRICE under criticism
- Cibus RTDS oilseed rape controversy

#### **Scientific news**

- Glyphosate might cause cancer
- Genetically engineered soybean impacts health of kid goats
- EFSA to examine publication on soybean Intacta
- Bt plants: Advantage for pest insects

#### **Votes taken on EU authorisations**

- Carnations genetically engineered for petal colour
- Cotton MON 531, MON 1445 and MON 531 x MON 1445
- Cotton MON 15985

#### **New EFSA opinions**

- Monitoring report MON 810

## Current Issues and Activities

- Testbiotech complaint to the EU Ombudsman about GRACE project

Testbiotech has filed a complaint to the European Ombudsman against the EU Commission. This is because the EU Commission has several times refused to take action despite Testbiotech submitting evidence of incorrect or inadequate statements regarding the declaration of interests of experts involved in the so-called GRACE project. GRACE was initiated to investigate the risk assessment of genetically engineered plants. [www.testbiotech.org/en/node/1185](http://www.testbiotech.org/en/node/1185)

- Authorisation of GE maize 1507 delayed once more

There are signs that the EU Commission has stopped the market authorisation of genetically engineered maize 1507 for cultivation after Testbiotech, together with Friends of the Earth Europe, raised awareness that the European Food Safety Authority (EFSA) had started to re-evaluate its own risk assessment. The reason for this are findings from the largest study published to date on the distribution of maize pollen in the environment. The researchers collected data and monitored over a 10-year period how far maize pollen can travel. To protect sensitive species against the insecticide-containing pollen of the genetically engineered maize, the scientists recommend establishing much larger buffer zones than planned so far. [www.testbiotech.org/en/node/1167](http://www.testbiotech.org/en/node/1167)

- EU Parliament keeps up the pressure on EFSA

The budget committee in the EU Parliament is keeping up the pressure on EFSA. While it is expected that the Parliament will vote in favour of approving EFSA's budget for 2013, many MEPs have requested further improvements to ensure EFSA independence. Some MEPs have complained about loopholes in EFSA's independence policy. For example in 2015, the European Ombudsman stated that EFSA had not sufficiently assessed the background and conflicts of interest of experts involved in its working group dealing with the risks of genetically engineered insects. [www.ombudsman.europa.eu/cases/decision.faces/en/58868/html.bookmark](http://www.ombudsman.europa.eu/cases/decision.faces/en/58868/html.bookmark)

- EU Commission plans for the mass authorisation of genetically engineered plants

The EU Commission is expected to authorise around a dozen genetically engineered plants (soybean, maize, oilseed rape and cotton) for import and use in food and feed in April. Amongst these are GE soybeans with supposed health benefits, although this has never been proven or tested. It also includes a transgenic oilseed rape that is expected to spread uncontrolled into the environment. If this mass authorisation goes ahead, the number of events authorised for import in the EU would jump to around 60. Nobody has ever tested such a mixture of plants and their accumulated effects on health. Testbiotech is considering filing a complaint at the EU Commission if the authorisations are issued. <http://www.testbiotech.org/en/node/1083>, <http://www.testbiotech.org/en/node/1065> (see also [www.testbiotech.org/sites/default/files/Testbiotech\\_EU\\_Nachrichten\\_1\\_2015.pdf](http://www.testbiotech.org/sites/default/files/Testbiotech_EU_Nachrichten_1_2015.pdf))

- EU project PRICE under criticism

In a media release of 19 March, experts involved in the EU project PRICE presented the outcome of the project. They concluded that current EU regulations are sufficiently robust to avoid major problems with contamination from genetically engineered plants. However, they do not mention findings from investigations in Portugal, where bakery products were found to be contaminated with genetically engineered maize, in some cases to quite a high level: PRICE experts had taken samples from bread baked with maize and sold in Portugal. Altogether, they analysed 16 bread samples from seven regions. All the samples were contaminated with genetically engineered maize

MON810 and NK603. Some of them showed a content of genetically engineered maize of up to ten percent. The coordinator of PRICE is Justus Wesseler from Wageningen University in the Netherlands. Another PRICE expert is Joachim Schiemann from the Julius Kühn-Institute in Germany. Both experts are also involved in the EU project GRACE, which has several times drawn criticism from Testbiotech for its lack of adequate standards in avoiding conflicts of interest. Justus Wesseler and Joachim Schiemann are members of several other organisations which have close affiliations with industry such as PRRI (Public Research and Regulation Initiative). PRRI received funding from the Syngenta Foundation, CropLife International, the US Grain Council, Monsanto and Arborgen. [www.testbiotech.org/en/node/1190](http://www.testbiotech.org/en/node/1190)

- Cibus RTDS oilseed rape controversy

RTDS or Rapid Trait Development System developed by Cibus involves inserting small sequences of synthetic DNA into plant cells. The DNA is altered in some detail in comparison to the plant's original DNA. According to the EU Directive 2001/18, "*techniques involving the direct introduction into an organism of heritable material prepared outside the organism*" have to be considered as methods of genetic engineering that need to be regulated. This means that the plants have to undergo risk assessment before any release is allowed. But the German Minister of Agriculture is of the opinion that so-called RTDS is not a method of genetic engineering within the definition of law. The decision means that plants made resistant to herbicides with this technology can now be grown without any further risk assessment, registration or labelling. This assessment is in line with interests of biotech-industry, which aims to get rid of the current EU regulations on labelling and risk assessment in context of free trade agreements TTIP and CETA. Several civil society organisations and companies have appealed against the decision.

[www.testbiotech.org/en/node/1181](http://www.testbiotech.org/en/node/1181)

## Scientific news

- Glyphosate might cause cancer

According to a review presented by the International Agency for Research on Cancer (IARC) in the scientific journal The Lancet, the herbicide glyphosate has been reclassified as "probably carcinogenic". According to the agency, animal experiments have also shown that glyphosate can cause DNA and chromosome damage. The IARC evaluation on the health risks associated with glyphosate contrasts sharply with its previous classification of the active substance in the EU. A Testbiotech report published in 2014, highlighted the gaps in risk assessment carried out by the German authorities and showed that the risks were not sufficiently taken into account.

[www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2815%2970134-8/abstract](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2815%2970134-8/abstract),  
[www.testbiotech.org/en/node/1094](http://www.testbiotech.org/en/node/1094)

- Genetically engineered soybean impacts health of kid goats

A recent scientific publication has reported significant impacts on the offspring of goats fed with genetically engineered soybeans. According to the publication prepared by the University of Naples (Italy), there were changes in the composition of the goats' milk and the weight of the kids was significantly reduced. DNA sequences stemming from genetically engineered soybeans were resistant to digestion and subsequently found in the milk. The study showed that feeding genetically engineered herbicide resistant soybeans to the goats led to a significant reduction of immunoglobulins in the milk just after birth, which then led to the reduced weight in kids. The scientists had already in a previous study reported finding specific DNA sequences in goats' milk and specific changes in the blood chemistry of kids fed with the milk.

[www.testbiotech.org/en/node/1152](http://www.testbiotech.org/en/node/1152)

- EFSA to examine publication on soybean Intacta

In October 2014, Testbiotech reported on a new scientific publication co-authored by Monsanto employees, which warned that the cultivation of the genetically modified soybean Intacta (MON 87701 × MON 89788) could promote the spread of specific pest insects. According to the authors, the effects are likely to be caused by unintended effects in the plants, possibly arising from the insertion of the additional DNA. The genetically engineered soybean produced by Monsanto is resistant to herbicides containing glyphosate and produces a Bt insecticide. Testbiotech is in the process of bringing the case before the EU Court of Justice to stop the authorisation of this soybean for import. In a letter to EFSA sent in February 2015, the EU Commission requested EFSA to assess the new publication, however EFSA did not find any reason to change its previous assessment. [www.testbiotech.org/en/node/1099](http://www.testbiotech.org/en/node/1099), [www.efsa.europa.eu/en/supporting/doc/791e.pdf](http://www.efsa.europa.eu/en/supporting/doc/791e.pdf)

- Bt plants: Advantage for pest insects

Testbiotech has reported several times on pest insect resistance to Bt plants. Now for the first time, the US environmental agency, EPA, is looking at the consequences. Cultivation of the genetically engineered maize which produces an insecticide but which in effect cannot control the rootworm, might be limited. This measure would especially concern Monsanto.

[www.wsj.com/articles/limits-sought-on-gmo-corn-as-pest-resistance-grows-1425587078](http://www.wsj.com/articles/limits-sought-on-gmo-corn-as-pest-resistance-grows-1425587078),  
[www.testbiotech.org/en/node/1076](http://www.testbiotech.org/en/node/1076)

### **Votes taken on EU authorisations**

On 31 March the appeal committee voted on renewing the authorisation for the import of genetically engineered cotton MON 531, MON1445 and its stacked event (MON531 x MON1445). Further, they voted in favour of a new authorisation for cotton MON15985 for import. Testbiotech commented on EFSA's opinion on MON15985 in September 2014.

[www.testbiotech.org/en/node/1097](http://www.testbiotech.org/en/node/1097)

In addition, carnations genetically engineered for petal colour were on the agenda. No qualified majorities were reached. Now it is up the EU Commission to make a decision.

### **New EFSA opinions**

EFSA gave an opinion on the Monsanto monitoring report for 2013 on the cultivation of maize MON 810.

[http://ec.europa.eu/food/plant/gmo/reports\\_studies/docs/report\\_2013\\_mon\\_810/report\\_2013\\_mon\\_810\\_en.pdf](http://ec.europa.eu/food/plant/gmo/reports_studies/docs/report_2013_mon_810/report_2013_mon_810_en.pdf)

According to EU Directive 2001/18, if genetically engineered plants are cultivated for commercial reasons the company has to regularly produce a monitoring report on potentially adverse effects on human health and the environment. According to EFSA, Monsanto did not fulfil its obligations, and therefore EFSA has said that their experts "cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013".

[www.efsa.europa.eu/en/efsajournal/doc/4039.pdf](http://www.efsa.europa.eu/en/efsajournal/doc/4039.pdf)

There are some particular concerns that the cultivation of MON 810 could affect rove beetles of which there are a large number of different kinds, some of which are rare and many of which are characterised as useful predators. The EFSA has in recent years criticised Monsanto on the issue of its reports. But in 2013, the company presented even less information. The EU Commission as responsible risk manager should now take measures to enforce the monitoring or to stop cultivation of MON 810.

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