



Testbiotech EU Newsletter 3/2015 (July 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: Complaint against market authorisation of genetically engineered plants / EU Commission does not intend to stop cultivation of MON810 / EU research projects: upcoming meetings / New EFSA guidance / EFSA assesses new study on maize MON810

Overview of Topics

Current Issues and Activities

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- EFSA assesses new publications on Bt maize
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- Opinions on genetically engineered soybeans with resistance to the herbicides dicamba and glyphosate and herbicide resistant maize (glyphosate)

Current Issues and Activities

- Complaints filed against EU authorisations for the import of genetically engineered plants
Several organisations filed requests for the EU Commission to review market authorisations for the import of genetically engineered plants for usage in food and feed in the EU, that were issued at the end of March. The complaints concern a genetically engineered oilseed rape produced by Monsanto that is engineered to be resistant to the herbicide glyphosate (MON88302), as well as three soybeans produced by Monsanto and Pioneer, in which the composition of the oil they contain has been changed (MON87769, MON87705 and DP305423). The complaints were filed according to EU regulation 1367/2006. The EU Commission has 12 weeks to respond to the complaints. After that the cases may be filed at the European Court of Justice. A similar case regarding the import of the genetically engineered soybean Intacta, which produces an insecticidal protein, has is pending at the European Court of Justice since 2013.

Technical dossier on herbicide resistant oilseed rape: www.testbiotech.org/node/1283

Technical dossier on soybeans with altered oil composition: www.testbiotech.org/node/1284

Pending court case against soybean Intacta: www.testbiotech.org/node/772

- EU Commission does not intend to stop the cultivation of maize MON810

At the end of April, Testbiotech asked the EU Commission to stop the cultivation of genetically engineered maize MON810 because the company had not fulfilled the legal requirements for post market monitoring. In essence, the problems concern a lack of screening of potentially negative consequences for human health and the environment (www.testbiotech.org/node/1224). There has now been a response from the EU Commission (www.testbiotech.org/node/1292). According to the Commission, Monsanto has filed a new set of data. EFSA has not yet assessed the new data. The new monitoring report from Monsanto can be found at:

http://ec.europa.eu/food/plant/docs/plant_gmo_report_studies_report_2013_mon_810_revised_en.pdf

- EFSA assesses new publications

In its letter the EU Commission also says (www.testbiotech.org/node/1224) that EFSA will assess a new publication on the reaction of maize MON810 to stressful climatic conditions (see below). The study was published at the end of April and raised serious doubts about the genetic stability of the maize (www.testbiotech.org/node/1198). According to EFSA, this assessment might not be finished before October.

EFSA has assessed a further publication which shows that the pollen of a genetically engineered maize producing an insecticidal toxin can be distributed in the environment over much larger areas than previously thought. Nevertheless, EFSA is still of the opinion that distances between fields and areas with larvae of protected butterflies of up to 20 or 30 meters are sufficient (www.efsa.europa.eu/en/efsajournal/pub/4127.htm). Testbiotech has several times pointed out that existing data are not sufficient to support the EFSA assumption. Amongst others, reliable data on the real toxicity of the pollen from insecticidal maize 1507 are still missing.

- EU Commission stops German authorities from allowing the cultivation of Cibus oilseed rape

A letter sent by the EU Commission in mid-June to the relevant authorities of EU Member States clearly confirms that a decision made by the German Federal Office of Consumer Protection and Food Safety (BVL) on the release of a genetically engineered oilseed rape produced by the US company Cibus, cannot be implemented (www.testbiotech.org/node/1281). The letter strongly contradicts the

decision made by the German authority in February 2015, which would have allowed the release of Cibus oilseed rape without it being subject to regulation required for genetically engineered organisms. This particular oilseed rape is produced using so-called oligonucleotids, short synthetic DNA sequences. The letter sent by the EU Commission now advises Member States not to allow the release of plants produced using oligonucleotids. The EU Commission wants to decide upon regulatory measures for this product by the end of the year.

The German authority argues that the method used to produce Cibus oilseed rape should be classed as mutagenesis, which – according to EU regulation – is not subject to regulation. Mutagenesis has been used for many years in plant breeding. In contrast, the use of oligonucleotids is a technique used in 'genome editing' or 'synthetic genetic engineering' and is covered by EU regulation 2001/18: It involves the insertion of nucleic acid molecules produced in the laboratory into an organism. The nucleic acid molecules are inserted into the cells to change the DNA at targeted sites. The intended changes are made at specific sites and can be carried out repeatedly leading to an extensive alteration of genome. The mechanisms of the genetic alteration are currently not fully understood and off-target effects have been reported. A new study from Norway emphasises the need for more biosafety research (<http://genok.no/arkiv/4294/>).

- Committee in the European Parliament against the cloning of animals for food production

A draft law to ban the cloning of all farm animals, their descendants and products derived from them, including imports, in the EU, was voted through by the Environment and Agriculture committees. MEPs reinforced the European Commission's initial proposal, citing high mortality rates at all development stages of cloning and EU citizens' animal welfare and ethical concerns (www.europarl.europa.eu/news/en/news-room/content/20150617IPR67269/html/Ban-not-just-animal-cloning-but-cloned-food-feed-and-imports-too-say-MEPs).

The European Parliament is now scheduled to vote on the proposal between 7 - 9 September in Strasbourg. After that, a joint position of Member States and the EU Commission has to be negotiated. In May, the German Parliament also voted for stricter regulation (<http://dip21.bundestag.de/dip21/btd/18/048/1804808.pdf>). However, a Testbiotech report shows that planned free trade agreements such as TTIP and CETA could make it difficult to implement prohibitions and/or mandatory labelling: www.testbiotech.org/sites/default/files/Testbiotech_TTIP_CETA%20%26%20GMOs_en.pdf

- EFSA reappoints “well-known” experts to its GMO panel

On 8 June, the European Food Safety Authority EFSA published the names of the new members joining its expert panels for the period up until 2018. One of the panels with new members is the Panel on Genetically Modified Organisms (GMO Panel), which in recent years has been under significant public pressure because several of its members were shown to have links to organisations with close ties to industry, such as the International Life Sciences Institute (ILSI). It is therefore surprising that many former members of the above-mentioned GMO Panel have been reappointed after an absence of several years, especially because these same experts are the ones who contributed to the committee's industry-leaning reputation: www.testbiotech.org/en/node/1273

The panel at EFSA: www.efsa.europa.eu/de/gmo/gmomembers.htm

- Overview of upcoming meetings on EU research projects

EU research project MARLON, which deals with monitoring of potential health impacts of feeding genetically engineered plants to livestock, meets on 16 and 17 July in Brussels: web.spi.pt/marlon/

EU research project GRACE, which amongst others conducted feeding trials with genetically engineered maize MON810, presents its results on 5 - 8 October in Vienna and on 9 -10 November in Potsdam: www.grace-fp7.eu/.

The EU research project G-TwYST has published its plans for a two year feeding study with genetically engineered maize NK603: www.g-twyst.eu/.

Testbiotech has several times criticised the fact that many of the experts involved in these projects have very close links to industry and has therefore filed a complaint with the EU Ombudsman: www.testbiotech.org/node/1185.

Scientific news

- Stress test performed on genetically engineered maize

Scientists from Switzerland and Norway have published the results of an investigation into genetically engineered maize MON810, which produces an insecticidal protein, a so-called Bt toxin (Trtikova et al., 2015, <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011>). In the investigation, two varieties of maize MON810 were grown in climate chambers and subjected to defined stress conditions i.e. cold/wet and hot/dry. According to the authors, this is the first study to report on whether there is a relationship between transgene expression and protein production in Bt maize under changing environmental conditions. The results are surprising: They show that the stress reactions of maize containing the DNA for the MON810 event are not predictable in reliable way (www.testbiotech.org/en/node/1200). Currently, European Food Safety Authority (EFSA) risk assessment does not include any in-depth investigation of interactions between the transgenic plant genome and the environment. There are, for example, hardly any data at all on how genetically engineered plants could react to ongoing climate change. Driven by additional promoters, the DNA inserted into the plants could escape the plant's gene regulation. Further, the transgenic plants are not adapted to the newly inherited metabolism. Consequently, environmental stressors such as heat, drought, saline soils or diseases might trigger genetic instabilities or unpredictable changes in the metabolism of the plants. Several studies with genetically engineered plants such as petunia, cotton, potato, soybean and wheat have reported unexpected reactions to environmental stress conditions.

This pilot project was realised with the support of Testbiotech and with funding from the Manfred Hermsen Umweltstiftung. Further funding was made available by the Altner-Combecher-Foundation, the GEKKO Foundation and the Foundation on Future Farming. A Testbiotech Backgrounder: www.testbiotech.org/en/node/1199

- Genetically engineered wheat fails in field trials

According to the scientists involved, a controversial field trial conducted in the UK with genetically engineered wheat ended up by "yielding more questions than answers". The wheat was genetically engineered to release a pheromone which is naturally produced by aphids if attacked by predators. The goal was to reduce aphid infestation in the wheat. The effect could be demonstrated in the laboratory but could not be reproduced in the field trial. The reasons behind the failure could not be identified. The publication: www.nature.com/srep/2015/150625/srep11183/full/srep11183.html

This is the second time that genetically engineered wheat has failed under experimental conditions. In 2010, a publication on genetically engineered wheat showed a complex reaction of reduced fitness, a higher incidence of fungal disease and a higher burden of toxic residues from the fungal disease. These effects only occurred in the field trials, but not in the greenhouse. The effects were explained by environmental differences between greenhouses and field conditions and interaction with the plants genome. The study from 2010: www.plosone.org/article/info:doi/10.1371/journal.pone.0011405

- Laboratory rodent diets contain a broad range of environmental contaminants and genetically engineered plants

An investigation led by the French scientist Gilles-Eric Seralini has found a broad range of environmental contaminants such as pesticides, heavy metals and PCBs in feed used for laboratory animals such as rats and mice. The contaminants were detected in standard diets used for purposes such as raising the animals and feeding the control groups in toxicological studies. Feed with a high level of contaminants can mask relevant effects in feeding studies when given to control groups, which means that potentially hazardous effects can remain undetected. Some of the concentrations that were measured were above existing limits and the mixtures of contaminants could be said to be a health risk. Further, some of the diets were found to contain up to 50 percent of genetically engineered plants. Testbiotech has often found remarks in the dossiers that the feed used for a control group was contaminated with genetically engineered plants.

The study: <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0128429>

News from EFSA

EFSA published opinions on two genetically engineered Monsanto events. The plants are maize 87427, made resistant to glyphosate (www.efsa.europa.eu/en/efsajournal/pub/4130.htm) and stacked soybean MON 87708 × MON 89788, made resistant to the herbicides dicamba and glyphosate (www.efsa.europa.eu/en/efsajournal/pub/4136.htm). It is possible to comment on these opinions up until July 20: http://ec.europa.eu/food/plant/gmo/new/public_consultations/index_en.htm

Further, EFSA has published new guidance on how to assess agronomic and phenotypic characteristics of genetically engineered plants. Testbiotech commented on the draft guidance saying that there has been some improvement of the criteria applied in this context because they have been defined more precisely. However, Testbiotech does believe that the guidance is not sufficient to investigate the genetic stability of genetically engineered plants under the conditions of ongoing climate change (www.efsa.europa.eu/en/efsajournal/pub/4128.htm).

New guidance on the renewal of applications for genetically engineered plants has been published: www.efsa.europa.eu/en/efsajournal/pub/4129.htm

EFSA organised a workshop on allergenic risks stemming from genetically engineered plants and now plans further public consultation on the issue: www.efsa.europa.eu/en/events/event/150617.htm

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