



Testbiotech EU Newsletter 4/2015 (October 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: New round of “Stop the toxic soybeans” call / Legal dossier on new techniques in genetic engineering / Large majority of EU Member States choosing to opt-out for cultivation / New report on the uncontrolled spread of genetically engineered organisms

Overview of Topics

Current Issues and Activities

- The call to “Stop the toxic soybeans”
- Legal dossier on new techniques in genetic engineering
- New report on the uncontrolled spread of genetically engineered organisms
- A large majority of EU Member States choosing to opt-out for cultivation
- Still no access to data on glyphosate risk assessment
- Still no response from the EU Commission to complaints against EU authorisations for import
- EU research project GRACE close to being finalised
- Recent comments from Testbiotech on EFSA risk assessments

Scientific news

- EFSA assesses publication on stress test with genetically engineered plants
- EFSA assesses publication on the contamination of feed used for laboratory animals
- Residues from spraying with glyphosate in genetically engineered plants

News from EFSA

- EFSA assesses another genetically engineered soybean
- New consultations at EFSA

New decisions on EU authorisations

- Upcoming votes on glyphosate-resistant maize

- **The call to “Stop the toxic soybeans”**

The EU Commission has stated that they see no need for detailed risk assessment of genetically engineered soybeans that can contain a mixture of probably carcinogenic residues. Monsanto’s genetically engineered soybean MON 87708 × MON 89788 has been engineered to be resistant to a combination of the herbicides, glyphosate and dicamba. Residues from spraying with these herbicides are suspected of being carcinogenic. In July 2015, Testbiotech started an online call for action against the authorisation of the soybeans. Just recently, the Commission replied in a letter. The only conclusion that can be reached from the answer of the EU Commission, is that they plan to authorise the new genetically engineered soybeans without assessing the combination of residues from spraying that may cause cancer. Just recently, the European Food Safety Authority EFSA gave the green light to the authorisation of another genetically engineered soybean produced by Bayer, known as FG72. This soybean is similarly problematic since it has also been engineered to be resistant to glyphosate and isoxaflutole. The residues from isoxaflutole are classified as "likely to be a human carcinogen". This is a further case in which the European Food Safety Authority EFSA has failed to assess the combination of residues from spraying that may cause cancer.

The updated version of the call: www.testbiotech.org/node/1313

The letter from the Commission: www.testbiotech.org/node/1361

The original media release from July 2015: www.testbiotech.org/en/node/1317

- **The legal dossier on new techniques in genetic engineering**

In September, a legal dossier on the status of new methods in genetic engineering was published. The dossier is being presented ahead of a decision due to be announced by the EU Commission within the next few weeks. Industry is demanding that new methods of changing genetic conditions in plants and animals should not be regulated in the same way as genetically engineered plants, and should be allowed onto the market without registration, risk assessment or labelling. Contrary to industry, many civil society organisations are of the opinion that EU regulation has to be applied to these plants and animals in same way as to other genetically engineered plants. The position of the civil society organisations is now set to gain support from the new legal dossier drawn up by Professor Dr Ludwig Kraemer, who is widely regarded to be one of the top experts in environmental law and EU policy. Meanwhile, the German Federal Agency for the Environment has also published a legal analysis which shows that techniques using oligonucleotides have to be considered as genetic engineering.

The legal dossier: www.testbiotech.org/node/1342

The legal dossier of the German Agency for the Environment:

http://bfm.de/fileadmin/BfN/agrogentechnik/Dokumente/Legal_analysis_of_genome_editing_technologies.pdf

- **The new report on the uncontrolled spread of genetically engineered organisms**

Testbiotech published a report providing a global overview of recent cases of uncontrolled spread of genetically engineered organisms able to persist and propagate in the environment. The evidence presented in this report comes from countries such as China (rice), Mexico (maize and cotton), Japan (oilseed rape) South Korea (maize and cotton) and the USA (grasses). Further emerging examples are likely to include eggplant (India/ Bangladesh), trees such as pine and eucalyptus in North and South America and genetically engineered insects (Brazil and Panama). The increasingly serious risks associated with new methods currently being used in synthetic gene technologies to produce organisms that, for example, can act as gene drives, are further exacerbating the situation. The pattern of heredity is manipulated in these organisms to enable the new synthetic DNA to spread much more rapidly than normal into native populations. The report was presented to an Ad Hoc Technical Expert Group (ATEG) on Synthetic Biology organised by the Secretary of the Convention of Biological Diversity (CBD) at a meeting taking place in Montreal (Canada) from 21 - 25 September.

The report: www.testbiotech.org/node/1339

The international call: www.stop-the-spread-of-transgenes.org/

- **A large majority of EU Member States choosing to opt-out for cultivation**

Some months ago, the EU made it possible for countries or regions to individually prohibit the cultivation of genetically engineered plants such as MON810 in an “opt-out”. Most of the Member States have now responded to this new option. Applications to opt-out have been received from 17 countries and four regions. The EU Commission has also set up a new website that gives an overview of applications and agreements. In response, Syngenta has withdrawn some of its applications for the cultivation of genetically engineered plants. Monsanto withdrew all its pending EU applications for the cultivation of genetically engineered plants prior to the opt-out coming into force. At the same time, the European Parliament rejected a proposal by the EU Commission to also allow opt-out for import of genetically engineered plants. Reasons for the rejection were missing practicability of the proposed regulation.

EU Commission website:

http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.htm

- **Still no access to data on the risk assessment of glyphosate**

The EU Commission has informed Testbiotech that the public will still not be allowed to access documents on the risk assessment of the herbicide glyphosate. Testbiotech had previously requested access to the report prepared by the German Federal Institute for Risk Assessment (BfR) on the risk assessment of glyphosate, which was sent to the European Safety Authority (EFSA) several months ago. Now the Commission has told Testbiotech that it is obliged to give access “only to *existing* documents in the possession of the institution” and that “the requested documents do not exist at the time of writing”. The final version of the report will be available only after EFSA has finished its own assessment and thereafter a “redacted version” will be published.

For further information: <http://www.testbiotech.org/en/node/1356>

- **Still no response from the EU Commission to complaints against EU authorisations for import**

Although the deadlines have passed, till 29 October there has still been no response from the EU Commission to complaints against market authorisation for the import of genetically engineered herbicide-resistant oilseed rape and soybeans with altered nutritional quality.

Information about the complaints: www.testbiotech.org/node/1333 & www.testbiotech.org/node/1290

- **EU research project GRACE close to being finalised**

The GRACE project, which has been looking into the risk assessment of genetically engineered plants, is close to being finalised. On 9 and 10 November the final conference will be held in Potsdam, Germany. Testbiotech has criticised several experts involved in the EU project for having very close ties to industry. In April, Testbiotech filed a complaint to the EU Ombudsman, but there is no outcome as yet.

The complaint filed by Testbiotech: www.testbiotech.org/node/1186

The announcement of final GRACE conference: www.grace-fp7.eu/de/content/final-conference-registration-now-open

- **Recent comments from Testbiotech on EFSA risk assessments**

In recent months, Testbiotech has sent several comments to the EU Commission on the risk assessments carried out by European Food Safety Authority, EFSA, in regard to applications for the import of genetically engineered plants:

MON 87708 x MON89788 - soybean resistant to two herbicides, Monsanto, see also “Stop the toxic soybeans”: www.testbiotech.org/node/1314

FG72 - soybean resistant to two herbicides, Bayer, see also “Stop the toxic soybeans”:
www.testbiotech.org/node/1336

NK 603 x T25 - maize resistant to two herbicides, Monsanto: www.testbiotech.org/node/1335

MON87427 - maize resistant to glyphosate, Monsanto: www.testbiotech.org/node/1323

MON87427 maize resistant to glyphosate, Monsanto: www.testbiotech.org/node/1323

MON 87705 x MON89788 - changed oil composition and resistant to glyphosate, Monsanto:
www.testbiotech.org/node/1337

Scientific news

- **EFSA assesses publication on the contamination of feed used for laboratory animals**

An investigation led by the French scientist Gilles-Eric Séralini 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. Further, some of the diets were found to contain up to 50 percent of genetically engineered plants.

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

EFSA has now assessed this study and found several methodological flaws. EFSA has come to the conclusion that although the study provides useful information, it sees no reason to revise its previous conclusions. In its assessment, EFSA appears to be extensively neglecting the real problems. For example, it seems to believe that it is not problematic if the feed used for control groups is heavily contaminated with genetically engineered plants. In general, the EFSA appears to be overlooking the problem that health effects can be masked by contamination of the feed used for the control groups, and is not discussing this problem in sufficient detail.

The assessment by EFSA: www.efsa.europa.eu/en/efsajournal/pub/4258

- **EFSA assesses publication on the stress testing of genetically engineered maize**

In April, scientists from Switzerland and Norway published the results of an investigation into the genetically engineered maize MON810, which produces an insecticidal protein, a so-called Bt toxin (Trtikova et al., 2015). 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. It was a pilot project realised with the support of Testbiotech, and with funding from several foundations. 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: In general, the Bt content was on average higher in one variety compared to the other. Under cold/wet conditions the content of Bt increased in one of the varieties, but not in the other. The activity of the DNA construct inserted into the plants was lowered significantly under hot/dry conditions in one variety, but this had no influence on the Bt content.

EFSA has now assessed the study and stated that the results are not a reason to revise its previous conclusion. By taking this stance, the EFSA is missing the most relevant issue: According to the study, the Bt content in genetically engineered maize cannot be reliably predicted under standard field conditions. Therefore, stress tests under various defined conditions have to be performed.

Currently, risk assessment carried out by the European Food Safety Authority (EFSA) 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. Reliable data on the Bt content are needed to assess potential toxicity in non-target organisms. Because of flaws in the EFSA assessment, Testbiotech now will send another letter to the EU Commission.

The publication: Trtikova, M., Wikmark, O.G., Zemp, N., Widmer, A., Hilbeck, A. (2015) Transgene expression and Bt protein content in transgenic Bt maize (MON810) under optimal and stressful environmental conditions, PLOS one, <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011>

The EFSA assessment: www.efsa.europa.eu/en/supporting/pub/878e

For further information: www.testbiotech.org/en/node/1199

- **Residues from spraying with glyphosate in genetically engineered plants**

A new publication from Norway (Cuhra 2015) has shown that there is currently very little data on genetically engineered plants and the burden of residues from spraying with glyphosate. For example, the data from many feeding trials with herbicide-resistant plants is not made available. Most of the studies are conducted by industry or performed on behalf of industry. The new Norwegian publication contains a reference to data from Testbiotech. The data was derived from an analysis of genetically engineered soybeans grown in Argentina, which showed a surprisingly high level of residues.

Cuhra M. (2015) "Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue", Environmental Sciences Europe 2015, 27:20, www.enveurope.com/content/27/1/20

The investigation of Testbiotech: www.testbiotech.org/node/926

News from EFSA

- **New EFSA opinion on a genetically engineered soybean**

EFSA published an assessment of the genetically engineered soybean MON 87769 × MON 89788. The soybean is changed in its oil composition and made resistant to glyphosate. Testbiotech and GeneWatch have filed a complaint against market authorisation for one of the parental plants due to a lack of relevant data for assessing the health impacts. In the recent risk assessment, EFSA also came to the conclusion that risk assessment cannot be completed due of a lack of adequate data.

The opinion of EFSA: www.efsa.europa.eu/en/efsajournal/pub/4256

The complaint of GeneWatch UK and Testbiotech: www.testbiotech.org/node/1290

- **New consultations at EFSA on future strategy**

Consultation on EFSA Strategy 2020: www.efsa.europa.eu/en/consultations/call/151008

- **New decisions on EU authorisations**

On 10 November, the Appeal Committee (which represents the EU Member States) will discuss the authorisation of two genetically engineered maize events that are resistant to glyphosate: MON87427 and NK603 x T25 (see above). If there is not a sufficient majority amongst Member States to reject both sorts of genetically engineered maize, the EU Commission can issue market authorisations. In this case, these would be the first new market authorisations for genetically engineered plants resistant to glyphosate after the WHO classified the herbicide as "probably carcinogenic to humans".

http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/gm_food_feed_env_risks_en.htm

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