



## Testbiotech EU Newsletter 2/2019 (August 2019)

This newsletter provides an overview of current developments in the EU and related Testbiotech activities.

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### **Most important topics:**

**RAGES project to present results; Prospective technology assessment of gene drives; EU Commission authorises seven new genetically engineered plants**

### **Overview of Topics**

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

- RAGES project to present its results at a public workshop on 29 October 2019
- First German-led prospective technology assessment of gene drives
- Patent cartel for the large companies
- Testbiotech comment on EFSA assessment of genetically engineered maize MON 87427 x MON 89034 x MIR162 x NK603 and subcombinations
- Testbiotech comment on EFSA's assessment of genetically engineered soybean MON 87708 x MON 89788 x A5547-127

#### **News from EFSA**

- Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and subcombinations
- Literature review of baseline information on non-coding RNA (ncRNA) to support the risk assessment of ncRNA-based genetically modified plants for food and feed
- Human dietary exposure assessment to newly expressed proteins in GM foods
- Assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations, for food and feed uses
- Assessment of genetically modified soybean MON 87708 × MON 89788 × A5547-127
- EFSA submission guidance for GMO renewal applications
- Assessment of the 2017 post-market environmental monitoring report on the cultivation of

genetically modified maize MON 810

## Current Issues and Activities

### **RAGES project to present its results at a public workshop on 29 October 2019**

The research project RAGES (Risk assessment of genetically engineered organisms in the EU and Switzerland) will hold a public workshop on 29 October at the University of Neuchâtel. The project participants will present the results of the project that started in 2016. Its aim is to evaluate the current EFSA risk assessment of genetically engineered organisms, especially plants. Assessment issues include:

- health risks associated with the consumption of products derived from genetically engineered herbicide-tolerant plants
- environmental risks associated with the cultivation of plants producing Bt-toxins
- health risks associated with the consumption of products derived from genetically engineered plants that are changed in their nutritional composition
- health risks associated with the consumption of products derived from genetically engineered plants with a combination of traits
- environmental risks associated with genetically engineered crops that can persist and spontaneously propagate in the environment
- risks associated with organisms derived from new genetic engineering technologies.

The project is coordinated by Testbiotech and partnered by the European Network of Scientists for Social and Environmental Responsibility (ENSSER), Critical Scientists Switzerland (CSS) and GeneWatch UK. It is funded by Mercator Foundation, Switzerland.

<https://www.testbiotech.org/en/content/research-project-rages>

Program: RAGES workshop, 29 October 2019

<https://www.testbiotech.org/content/invitation-workshop-rages-29-october-2019>

### **First German-led prospective technology assessment of gene drives**

The GeneTip research project was a joint enterprise carried out from 2017 until 2019 by the Universities of Bremen and Vechta, the University of Natural Resources and Life Sciences, Vienna and Testbiotech, Munich. The researchers focussed mainly on risks associated with the uncontrolled spread into the environment of newly designed genetically engineered organisms. In particular, the project examined plants and animals with a so-called gene-drive. The researchers included two detailed case studies, one with genetically engineered olive flies and one with oilseed rape, to substantiate the issues.

The project was funded by the German Federal Ministry of Education and Research (BMBF) and coordinated by the University of Bremen. A presentation of the results has now been published in German, giving a detailed overview of the technical characteristics of gene drives as well as associated risks.

<https://www.testbiotech.org/node/2399>

Report (in German): [https://www.genetip.de/wp-content/uploads/GeneTip\\_Endbericht.pdf](https://www.genetip.de/wp-content/uploads/GeneTip_Endbericht.pdf)

### **EU Commission gives green light for approval of seven new genetically engineered plants**

On 26 July, the EU Commission issued market approval to seven new genetically engineered (GE) plants

that are herbicide-resistant and produce insecticidal toxins. The newly approved genetically engineered plants are:

- Cotton GHB614 x LLCotton25 x MON15985
- Maize 5307
- Maize MON87403
- Maize 4114
- Maize MON87411
- Maize Bt11 x MIR162 x 1507 x GA21
- Soybean MON87751

Further, the Commission approved renewal of authorisation for oilseed rape Ms8xRf3 and maize 1507xNK603, it also approved the import of a carnation to be used as an ornamental cut flower.

[https://europa.eu/rapid/press-release\\_MEX-19-4770\\_en.htm](https://europa.eu/rapid/press-release_MEX-19-4770_en.htm)

<https://www.testbiotech.org/en/news/eu-commission-gives-green-light-approval-seven-new-genetically-engineered-plants>

In May, more than 40 organisations from science, environmental protection, lobby control, food production and agriculture published a joint letter. They warned that the outgoing EU Commission might approve around a dozen genetically engineered plants on the basis of scientifically unacceptable risk assessment before handing over. Further, they demanded higher standards for the risk assessment of genetically engineered organisms.

<https://www.testbiotech.org/en/press-release/stage-set-new-wave-genetically-engineered-plants>

The EU Commission replied to the joint letter. However, the reply received from Commissioner Andriukaitis simply states that the European Food Safety Authority (EFSA) has sole responsibility for risk assessment. This claim is simply incorrect. Rather, it is the responsibility of the EU Commission to ensure that legal requirements are fulfilled before GE plants are approved. This responsibility cannot simply be shifted on to somebody else.

<https://www.testbiotech.org/en/news/eu-commissioner-andriukaitis-sacrifices-science-trade-interests>

### **Patent cartel for the large companies**

The argument that new methods of genetic engineering are cheaper than previous techniques and could, therefore, be used by smaller companies is often put forward in the debate on the introduction of genome editing into breeding. However, what the proponents of this argument fail to mention is that the processes for using tools, such as CRISPR/Cas9 and plants and animals derived thereof, can all be patented. Experience gained from around twenty years of genetic engineering in plant breeding shows that patent law is a main driver of market concentration in breeding business. The introduction of new methods of genetic engineering in plant breeding is threatening to further exacerbate the situation: DowDuPont has not only formed, but also controls a patent cartel. The US corporation (with its agro-biotech sector renamed Corteva) has allegedly signed contracts with all the important owners of basic patents on CRISPR/Cas technology.

<https://www.testbiotech.org/en/news/patent-cartel-large-companies>

**Testbiotech comment on EFSA's assessment of genetically engineered maize MON 87427 x MON 89034 x MIR162 x NK603 and subcombinations**

The EFSA GMO panel assessed the four-stacked maize MON 87427 x MON 89034 x MIR162 x NK603, which is derived from crossing genetically engineered maize events. It contains genes conferring triple resistance to glyphosate and produces three insecticides:

- MON87427 expressing CP4 EPSPS protein for tolerance to glyphosate-containing herbicides;
- MON 89034 expressing the insecticidal proteins Cry1A.105 (artificially synthesized) and Cry2Ab2,
- MIR162 expressing the insecticidal protein Vip3Aa20 and phosphomannose isomerase (PMI) which is a selectable marker;
- NK603 expressing two variants of CP4 EPSPS protein for tolerance to herbicides containing glyphosate.

<https://www.testbiotech.org/en/node/2397>

### **Testbiotech comment on EFSA's assessment of genetically engineered soybean MON 87708 x MON 89788 x A5547-127**

The EFSA GMO panel assessed the triple-stacked soybean MON 87708 x MON 89788 x A5547-127 derived from crossing genetically engineered soybean events. The soybean contains genes conferring resistance to three herbicides:

- MON 89788 expressing CP4 EPSPS protein for tolerance to glyphosate-containing herbicides;
- MON 87708 expressing dicamba mono-oxygenase (DMO), for tolerance to the herbicide dicamba;
- A5547-127 expressing PAT protein, for tolerance to the herbicide glufosinate.

<https://www.testbiotech.org/en/node/2396>

## **News from EFSA**

### **Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and subcombinations**

On 8 August 2019, EFSA published an opinion regarding maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603. The GMO Panel concluded *“that the five-event stack maize and its subcombinations are as safe as its non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.”*

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5774>

### **Literature review of baseline information on non-coding RNA (ncRNA) to support the risk assessment of ncRNA-based genetically modified plants for food and feed**

On 7 August 2019, EFSA published an external report on ncRNA and RNA interference (RNAi). Following topics were examined:

- the stability and degradation of ncRNAs after oral ingestion,
- the passage of ncRNAs from food and feed to human and animal organs and tissues via the gastrointestinal tract and other barriers;
- potential effects on the gastrointestinal tract, the immune system or the entire organism.

The report suggests that non-coding RNA must overcome many barriers to reach the intended target tissue or functional location in sufficient amounts to exert any biological effect. Regarding possible biological effects

of non-coding RNA, the report states: “In summary, supporting and contradicting evidence concerning the existence of systemic effects of dietary plant-derived exogenous ncRNAs is heavily debated. Important aspects such as the precise mechanism/s of transport of plant ncRNAs from food into the systemic circulation, the amount of exogenous ncRNAs reaching tissues or the molecular mechanisms of cellular uptake need to be determined.” Further, major knowledge gaps regarding this issue are described.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5802>

### **Human dietary exposure assessment to newly expressed proteins in GM foods**

On 31 July 2019, EFSA published an assessment of the dietary exposure to new proteins in genetically modified (GM) foods. The EFSA statement provides guidance on how human dietary exposure to newly expressed proteins in GM foods should be evaluated. The document also gives an overview of uncertainties in the assessment and describes the information applicants need to provide.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5802>

### **Assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations, for food and feed uses**

On 8 July 2019, EFSA published an opinion regarding maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations. The GMO Panel concluded “that the four-event stack maize and its subcombinations are as safe as its non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5734>

Testbiotech comment see above.

### **Assessment of genetically modified soybean MON 87708 × MON 89788 × A5547-127**

On 5 July 2019, EFSA published an opinion on soybean MON 87708 × MON 89788 × A5547-127. The GMO Panel concluded “that the three-event stack soybean 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.”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5733>

Testbiotech comment see above.

### **EFSA submission guidance for GMO renewal applications**

On 24 June 2019, EFSA published guidance for applicants on the most appropriate way to prepare and elaborate their applications for the renewal of authorisation of genetically modified food and feed. It provides instructions on how to structure the applications and indications on the type of information and data needed to support applicant requests for authorisation renewal.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1668>

### **Assessment of the 2017 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810**

On 13 June 2019, EFSA published an assessment of the 2017 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810. EFSA identified a list of serious shortcomings

regarding the consent holder's report. Amongst others,

- methodological and reporting shortcomings pertaining to resistance monitoring;
- consent holder did not consider several of EFSA's recommendations on the methodology and analysis of farmer questionnaires;
- no information on the use of existing environmental monitoring networks is provided.

In spite of these shortcomings, the EFSA concluded that the evidence reported in the 2017 PMEM report does not invalidate previous EFSA and GMO Panel evaluations on the safety of maize MON 810.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5742>