



Testbiotech EU Newsletter 1/2019 (May 2019)

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

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Most important topics:

Stage set for new wave of genetically engineered plants to be approved and imported after EU elections / Testbiotech report on regulation of genome editing / EU Parliament votes against new GMO import approvals / New scientific publication on differences between genome editing and breeding

Overview of Topics

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- EU Commission authorises new maize events

Current Issues and Activities

New Testbiotech report: The US example shows why new methods of genetically engineering crop plants need to be regulated

According to research carried out by Testbiotech, by the end of 2018, the United States Department of Agriculture (USDA) had already given non-regulated status to more than 20 plants genetically engineered with so-called genome editing techniques. None of the applications registered at USDA were referred for further more detailed assessment. The Testbiotech report published today shows that there are however significant differences in methods of production, traits and risks of the non-regulated plants in comparison to those derived from conventional breeding.

<http://www.testbiotech.org/en/node/2348>

Stage set for new wave of genetically engineered plants to be approved and imported after EU elections

Several science, environmental protection, lobby control, food production and agriculture organisations have expressed their concern about the risks of genetically engineered (GE) plants, and have today sent a joint letter to the EU Commission. They warn that the outgoing EU Commission might approve around a dozen genetically engineered plants on the basis of scientifically unacceptable risk assessment before handing over.

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

EU Parliament votes for “transparency and sustainability of the EU risk assessment in the food chain”

The EU Parliament has adopted a “new regulation on transparency and sustainability of the EU risk assessment in the food chain”. The regulation requests industry and authorities to improve access to data with relevance for food safety and the environment. Most observers positively note that relevant data from industry must in future be registered in a publicly available database. Further, the EU Commission can now request specific investigations to resolve uncertainties and open questions regarding risk assessment. However, it remains problematic that industry can continue to hamper access to information on processes in

developing genetically engineered organisms and exact genetic changes by referring to commercial interests.
www.testbiotech.org/en/news/eu-parliament-votes-transparency-and-sustainability-eu-risk-assessment-food-chain

GMO imports: How safe are glyphosate residues in genetically engineered plants?

Testbiotech is demanding a detailed re-assessment of all import approvals for genetically engineered glyphosate-resistant plants after a US federal court confirmed that glyphosate mixtures, such as Roundup, can be a contributory risk factor for cancer. The plants can be sprayed with very high dosages of glyphosate, and in the countries where they are grown, such as South America and the US, herbicide mixtures can be applied that are not approved in the EU. In 2015 and 2018, the European Food Safety Authority (EFSA) stated that the available data were not sufficient to draw final conclusions on the health risks of such imports. Nevertheless, the EU Commission has refused to request more data and detailed investigations.

www.testbiotech.org/en/node/2350. As a new paper (again) shows, glyphosate mixtures containing additives like POE tallowamines are much more toxic than the active ingredient glyphosate alone.

www.sciencedirect.com/science/article/pii/S0278691519301814

Further genetically engineered ‘maize monsters’ about to be approved for import

The European Food Safety Authority (EFSA) has signalled that it is in favour of approving further controversial genetically engineered maize variants. Recent EFSA opinions published in January 2019, deal with two approval applications for maize developed through cross-breeding to combine several genetically engineered traits. The plants are resistant to up to four groups of herbicides (glyphosate, glufosinate, 2,4-D and AOPP) and produce up to six insecticides. <http://www.testbiotech.org/en/node/2340>

EFSA opinion on maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and subcombinations (Dow): <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5521>

EFSA opinion on maize MON 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations (Dow): <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5522>

Testbiotech comments: www.testbiotech.org/node/2333

EFSA opinion on Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and subcombinations (Syngenta). <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5635>

Testbiotech comments: www.testbiotech.org/node/2369

Assessment of genetically modified soybean A2704-12 for renewal of authorisation (Bayer)

On 14 January, EFSA published an assessment of glufosinate resistant soybean A2704-12 for renewal. <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5523>

Testbiotech comment: www.testbiotech.org/node/2330 According to Testbiotech, EFSA completely ignores the fact that there has been a considerable increase in the number of problems with herbicide-resistant weeds in the past ten years and that, therefore, the agronomic conditions under which herbicide resistant soybeans are cultivated have also changed. This has inevitably led to higher amounts of pesticides being sprayed onto the crops; and new data are required before any decision on the safety of the GE soybean can be made.

EU Parliament against new approvals for the import of genetically engineered plants

The Greens/EFA group recently published an overview on EU Parliament objections to GMO authorisations. The overview shows that since 2015, the Parliament objected to 36 applications for import or cultivation of genetically engineered soybean, maize, oilseed rape, and others.

www.greens-efa.eu/en/article/news/why-we-objected-to-gmos-in-the-eu-36-times/

Scientific news

New scientific publication shows differences between genome editing and conventional breeding

A new peer reviewed publication provides an overview of several differences between genome editing (CRISPR/Cas) and conventional plant breeding on the molecular level. It is the first scientific review specifically exploring this issue, and is the outcome of a German research project in horizon scanning of new methods in genetic engineering from the perspective of the protection of health, the environment and nature (“Fachstelle Gentechnik und Umwelt“). The publication is authored by Dr. Katharina Kawall and was published today in the Journal *Frontiers in Plant Science*. The publication reviews applications of CRISPR/Cas in plants and shows some differences to conventional mutagenesis used in plant breeding and to spontaneous mutations. In conventional breeding and in natural processes some regions of the genome e.g. undergo changes less frequently than others because these regions are protected by repair mechanisms of the cell. CRISPR/Cas applications can bypass these naturally occurring processes.

<https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full>

Can Bt toxins cause allergies? Mexican scientists disagree with EFSA

At the request of the EU Commission, the European Food Safety Authority (EFSA) assessed research published by Mexican scientists. This new research concludes that a Bt toxin (Cry1Ac) that is also produced in several genetically engineered plants authorised for import into the EU can cause allergies. As reported in our last newsletter, EFSA has come to the conclusion that the study does not provide any new information and suffers from methodological flaws. Testbiotech in turn asked the Mexican scientists for their comments. In their reply, the Mexican scientists show that EFSA is not correct on crucial details and their own findings are still valid.

<https://www.testbiotech.org/en/press-release/can-bt-toxins-cause-allergies>

Further news from EFSA

Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post market environmental monitoring reports on GMOs authorised in the EU market

On 10 April, EFSA published an “*Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market*”. The note is intended to clarify the scope and methodology for literature searches and provides detailed recommendations on how to conduct them.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1614>

Annual Report 2018 - EFSA Scientific Network for Risk Assessment of GMOs

On 20 February, EFSA published the annual “Scientific Network for Risk Assessment of GMOs” report.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1577>

Annual Report of preparatory work on toxicological studies and animal feeding studies

On 22 February, EFSA published its “*Annual Report of preparatory work on the toxicological studies and animal feeding studies performed under the EFSA contract OC/EFSA/GMO/2014/01, Lot 2 during the period 1/3/2017 to 27/11/2018*”. The report covers the check for study adherence to relevant EFSA guidance documents and to several OECD guidelines. The work was performed on three 28-day studies on newly expressed proteins and six subchronic 90-day studies.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1586>

Assessment of genetically modified oilseed rape T45 for renewal of authorisation (Bayer)

On 14 February, EFSA published an assessment of glufosinate resistant oilseed rape T45 for renewal. The GMO Panel concludes that there is no evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5597>

Literature review in support of adjuvanticity/immunogenicity assessment of proteins

On 25 January, EFSA published a literature review and critically appraisal on adjuvanticity and immunogenicity of Cry proteins in genetically engineered plants. The report comes to several conclusions. Amongst others:

- there are several factors affecting the propensity of a protein to stimulate immune response (like aggregation, thermal processing, digestion, food matrix);
- adjuvanticity and immunogenicity of Cry proteins in certain experimental conditions seems plausible but due to low dosage, oral route of administration, food and feed processing and digestion, it is unlikely to emerge as a safety issue in food and feed;
- eliciting an immune response is a very complex matter as the body responds to immune offence by inducing many processes.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1551>

Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals

On 25 March, the EFSA Scientific Committee published a guidance regarding methodologies for combined exposure to multiple chemicals. It gives some explanations and definitions, which Testbiotech considers useful for risk assessment of genetically engineered organisms such as the whole mixture approach. However, the guidance does not mention GMOs.

<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5634>

Authorisations

EU Commission authorises new maize events

On 19 December 2018, the EU Commission authorised stacked GE maize for food and feed uses: maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and subcombinations.

http://europa.eu/rapid/press-release_MEX-18-6883_en.htm

Testbiotech filed a request for internal review regarding the authorisation:

www.testbiotech.org/content/technical-background-smartstaxplus

In reaction, EFSA published “Scientific advice on Testbiotech's request for internal review of Commission Implementing Decision (EU) No 2018/2046 on maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and subcombinations” After analysing Testbiotech’s assessment, EFSA concludes that it contains no new information that would invalidate the previous risk assessment conclusions and risk management recommendations made by the the authority.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1603>

Meanwhile Testbiotech received the answer from the Commission, rejecting the request for internal revision. Testbiotech is assessing the answer and then will publish the relevant documents.