



Testbiotech EU Newsletter 2/2018 (November 2018)

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

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Most important topics:

Genetically engineered bacteria in animal feed products / EU Court decides in favour of clear regulation for genome edited plants / Advocate General of the EU Court does not request a more detailed risk assessment / European Ombudsman starts investigation into transgenic crop approvals / EU might allow the import of new 'Baysanto maize monster' / First GE maize with RNAi insecticidal mechanisms

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Current Issues and Activities

Genetically engineered bacteria in animal feed products are spreading resistance to antibiotics

Currently, the EU is facing the biggest case of uncontrolled spread of non-approved genetically engineered organisms in its history: viable bacteria with a four-fold resistance to antibiotics, of which three are due to genetic engineering, have been found in animal feed products. The resistance is to antibiotics that are therapeutically important. According to the European Food Safety Authority (EFSA), the animal feed products pose a risk for “consumers, users and the environment”.

<https://www.testbiotech.org/en/press-release/genetically-engineered-bacteria-animal-feed-products-are-spreading-resistance>

EU votes on more transparency in food safety

On 11 December, the European Parliament will vote on more transparency in the area of food safety. This could lead to improvements in the risk assessment of herbicides. However, in the area of genetic engineering there is even a threat of deterioration: in order to enable independent controls of the uncontrolled spread of GMOs, it is imperative that accurate data on the genetic modification in the respective organisms is published.

However, according to the European Commission this information should be kept secret in the future. The Commission has introduced corresponding provisions in a recast of Regulation 178/2002 on food safety, which will also be voted on in the European Parliament in December. These and other questions are highlighted in a legal opinion commissioned by Testbiotech.

Legal analysis by Prof Ludwig Kraemer: <https://www.testbiotech.org/node/2248>

Inadequate procedure led to transgenic crop approvals: European Ombudsman starts investigation

The office of the European Ombudsman has confirmed it will investigate a complaint by GeneWatch UK, supported by Testbiotech, regarding the authorisation for import of three transgenic crops with altered oil

content for use as food and feed.

The three transgenic soybeans, produced by Monsanto (Bayer) and Pioneer (DowDuPont / Corteva), were approved for import by the European Commission in 2015. The organisations objected to the authorisations at the time, but the Commission refused to review the substance of their complaint until this year, after losing a legal case brought by Testbiotech. In their complaint to the ombudsman, the organisations state that a letter sent to them by the Commission in July 2018 is still inadequate to address their concerns and to protect the environment and human health.

<https://www.testbiotech.org/en/press-release/inadequate-procedure-led-transgenic-crop-approvals-european-ombudsman-starts>

Will EU Commission allow the import of new Baysanto 'maize monster'?

On 22 October, EU Member States voted on whether a new genetically engineered (GE) maize that is super-resistant to the herbicides glyphosate and glufosinate and produces six insecticides can be imported. The maize is produced by crossing five different GE plants. Bayer wants approval for import and usage in food and feed. According to Testbiotech, the health impacts resulting from the specific combination of potential toxic substances were not investigated.

<https://www.testbiotech.org/en/press-release/will-eu-commission-allow-import-new-baysanto-maize-monster>

Advocate General of the European Court of Justice does not request a more detailed investigation into the risks of genetically engineered soybeans

On 17 October, the Advocate General of the European Court of Justice published his findings on a legal case filed by Testbiotech together with the European Network of Scientists for Social and Environmental Responsibility (ENSSER) and the environmental organisation Sambucus (C-82/17 P). The organisations are concerned about the risks connected with genetically engineered soybeans produced by Monsanto and sold under the brand name “Intacta”. The plants inherit a specific combination of two genetically engineered traits: they express a so-called insecticidal Bt toxin and are resistant to glyphosate-based herbicides. These soybean plants are the first with a combination of such traits. According to the opinion of the Advocate General of the European Court of Justice, it is not necessary to investigate the risks of the genetically engineered soybeans in more detail. The court will make its final decision in the coming months.

<https://www.testbiotech.org/en/news/advocate-general-european-court-justice-does-not-request-more-detailed-investigation-risks>

The Court of Justice of the European Union decides in favour of clear regulation

On 25 July, the European Court of Justice ruled on the regulation of new methods of genetic engineering. According to the ruling, plants that are changed in their genetic condition through application of new genetic engineering methods cannot be exempted from existing EU GMO regulation. Testbiotech welcomes this decision. <https://www.testbiotech.org/en/node/2252>

The Court ruling followed a similar legal interpretation provided in a Testbiotech dossier.

<https://www.testbiotech.org/node/2161>

Testbiotech comment on EFSA opinion regarding maize Bt11 x MIR162 x 1507 x GA21 and three subcombinations (Syngenta)

Testbiotech criticised EFSA for declaring three subcombinations of the plants to be safe without requesting experimental data. This concern is shared by one member of the GMO panel who also voiced reservations about the assessment of the subcombinations without any specific data.

<https://www.testbiotech.org/node/2256>

Testbiotech comment on EFSA assessment regarding maize MON 87411 (Monsanto)

Testbiotech published an opinion on maize MON87411. This maize produces Bt toxin Cry3Bb1 as well as an insecticidal dsRNA targeting the corn rootworm. The dsRNA produced in the genetically engineered maize is meant to be taken up by pest insect larvae while feeding on the maize. In the larvae, the dsRNA is taken up from the intestinal gut into the cells of the insects where it interacts with gene regulation. The dsRNA is meant to kill the larvae by down-regulating the Snf7 gene transcript via RNA interference (RNAi).

Testbiotech is highly critical of EFSA's assessment as many open questions regarding the technology were not considered by the authority.

<https://www.testbiotech.org/node/2257>

Testbiotech comment regarding EFSA's opinion on soybean MON 87751 (Monsanto)

Testbiotech published an opinion on soybean MON 87751. Soybean MON 87751 produces two insecticidal toxins: Cry1A.105 and Cry2Ab2.

<https://www.testbiotech.org/node/2263>

Testbiotech comment regarding EFSA opinion on cotton GHB614 x T304-40 x GHB119 (Bayer)

Testbiotech published an opinion on stacked cotton GHB614 x T304-40 x GHB119. This cotton has a double resistance to glufosinate as well as being resistant to glyphosate and producing the insecticidal proteins Cry1Ab and Cry2Ae.

<https://www.testbiotech.org/node/2264>

Scientific news

Bt toxin and glyphosate effects on stingless bees

The possible effects of different Bt toxins on honey bees has been examined several times during the last decade. In most cases, no or only minor effects were found in these studies. The effects of Bt proteins on other bee species was of limited scientific interest. Recently, however, scientists in Brazil tested for the first time whether Bt toxins Cry1F and Cry2Aa were harmful to the stingless bee *Melipona quadrifasciata* at immature stages of development. Further, the Brazilian scientists tested whether glyphosate was harmful to this bee species (*Seide al. (2018), Glyphosate is lethal and Cry toxins alter the development of the stingless bee Melipona quadrifasciata*).

The study came to several interesting conclusions. First, glyphosate proved to be highly toxic for *Melipona quadrifasciata* bees; it proved to be even more toxic to the bees than the neonicotinoid imidacloprid, which was used as control. The results in respect to Bt were mixed. Whereas treatment with both Cry2Aa and

Cry1F led to delayed development in the bee larvae, bees treated with Cry2Aa had a higher survival rate. According to the authors, the mixed results warrant more research in this area.

<https://www.sciencedirect.com/science/article/pii/S0269749118325478>

RNA profiling suggested for risk assessment

A paper published by scientists from Norway, Brazil and Germany (*Agapito-Tenfen et al., Systematic miRNome profiling reveals differential microRNAs in transgenic maize metabolism*), explores possible changes in transgenic plant metabolism. The scientists wanted to know whether genetically engineered maize events show signs of dysregulated miRNA. MiRNA is noncoding RNA relevant for gene expression and plays an important role in gene silencing. As miRNA data is not currently requested by EFSA, an assessment is not part of the standard EU risk assessment of genetically engineered plants. The following maize events were investigated:

- MON89304, expressing the Bt toxins Cry2Ab2 and Cry1A.105,
- NK603, expressing EPSPS enzyme for glyphosate resistance,
- stacked event MON89304 x NK603.

According to the study, thirteen different conserved miRNAs were found to be dysregulated in GM samples, with Bt leading to the most distinct changes. However, interpretation of the results is difficult because e.g. a new approach was developed for the study. However, Agapito-Tenfen et al. claim that the production of RNA molecules in GM crops is a “*legitimate concern due to their potential off-target effects on silencing genes other than those intended*”. Also other new so-called “omics” methods such as proteomics, transcriptomics and metabolomics have proven to be valuable tools for risk assessment.

<https://enveurope.springeropen.com/articles/10.1186/s12302-018-0168-7>

News from EFSA

New sequencing information regarding soybean A2704-12

On 26 November, EFSA published an assessment of new sequencing information regarding soybean A2704-12. According to new data provided by the applicant, several changes in nucleotide sequences were discovered that give rise to new open reading frames. However, according to EFSA, the “*new sequencing data and the bioinformatic analyses performed on the new sequence did not give rise to safety issues.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5496>

Relevance of new scientific information (Santos-Vigil et al., 2018*) in relation to the risk assessment of genetically modified crops with Cry1Ac

On 14 November, EFSA published an assessment of a new scientific study (Santos-Vigil et al., 2018) relevant for the risk assessment of allergenicity of genetically engineered plants. Santos-Vigil et al. investigated the allergenic potential and immunological effects of Cry1Ac protein that is present in nine transgenic plants currently authorised in the EU. According to EFSA, the study “*does not bring new elements that would lead the EFSA GMO Panel to reconsider the outcome of its previous scientific opinions on genetically modified crops with Cry1Ac. Therefore, EFSA considers that the previous risk assessment conclusions on GM crops with Cry1Ac remain valid and applicable.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1504>

Assessment of genetically modified soybean MON 89788 for renewal of authorisation

On 16 November, EFSA published an assessment of soybean MON 89788 (marketed by Monsanto) for renewal of authorisation. MON 89788 is engineered to be resistant towards glyphosate. The GMO Panel concluded that *“there is no evidence [...] for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788.”*

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5468>

Assessment of genetically modified LLCotton25 for renewal of authorisation

On 14 November, EFSA published an assessment of glufosinate resistant LLCotton25 (marketed by Bayer) for renewal of authorisation. The GMO Panel came to the conclusion that *“there is no evidence [...] for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on LLCotton25.”*

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5473>

Assessment of genetically modified maize MZHG0JG

On 14 November, EFSA published an assessment of glufosinate and glyphosate resistant maize MZHG0JG, marketed by Syngenta. In its assessment, the GMO Panel comes to the conclusion that maize MZHG0JG *“is as safe as its conventional counterpart and the tested non-GM maize 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.2018.5469>

Assessment of genetically modified maize MON 87411 (Monsanto)

On 28 June, EFSA published an opinion on genetically modified maize MON 87411 produced by Monsanto. 87411 expresses the cry3Bb1 gene to confer resistance to corn rootworms and a DvSnf7 dsRNA expression cassette. Further, the maize was made tolerant towards glyphosate. EFSA concluded that MON87411 is *“as safe as its conventional counterpart and the tested non-GM maize 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.2018.5310>

Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants

On 11 July, EFSA published a technical note on data requirements for applicants. The Technical Note *“puts together requirements and recommendations for when DNA sequencing is part of the molecular characterisation of GM plants, in particular for the characterisation of the inserted genetic material at each insertion site and flanking regions, the determination of the copy number of all detectable inserts, and the analysis of the genetic stability of the inserts”*

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5345>

Assessment of maize Bt11 x MIR162 x 1507 x GA21 and three subcombinations (Syngenta)

On 11 July, EFSA published an opinion on maize Bt11 × MIR162 × 1507 × GA21 and three subcombinations (Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507).

It produces three insecticidal toxins (Cry1F, Vip3Aa20 and Cry1Ab) is tolerant to applications of glyphosate and glufosinate.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5309>

Authorisations

EU Commission authorises two new maize events

On 3 August, the EU Commission authorised two new GMO events (maize MON 87427 x MON 89034 x NK603, maize 1507 x 59122 x MON 810 x NK603). Further, the Commission approved the renewal of three existing authorisations (maize DAS-59122-7, maize GA21, sugar beet H7-1).

http://europa.eu/rapid/press-release_MEX-18-4834_en.htm