



Testbiotech EU Newsletter 2/2022 (August 2022)

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

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Most important topics: EU Commission consultation on New GE / EFSA consultation on cisgenic plants / No new GMO applications for import into the EU in 2021 / Eggs from CRISPR/Cas hens / Changes in single genes may threaten whole ecosystems / More pest insects due to transgenic soybeans / Transgenic maize is contaminating traditional varieties in Brazil

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Current Issues and Activities

EU Commission consultation: Prospective technology assessment essential for New GE in agriculture

Testbiotech is demanding that applications of New GE (new genomic techniques, NGTs) in agriculture should undergo a comprehensive prospective technology assessment. The demand is being made against the backdrop of a public consultation organised by the EU Commission on the future regulation of genetically engineered plants. The consultation was closed in July. Testbiotech is warning that the Commission is aiming to lower standards in the approval processes to an extent which is equivalent to deregulation. In addition, it is planning targeted measures to promote the introduction of New GE in agricultural plant breeding. In starting this new initiative, the Commission is mostly ignoring the potentially negative impacts.

<https://www.testbiotech.org/en/news/prospective-technology-assessment-essential-new-ge-agriculture>

Biased questions and flawed assumptions - how the EU Commission and EFSA are paving the way for deregulation of New GE

In June, Testbiotech participated in a European Food Safety Authority (EFSA) consultation on guidelines for the risk assessment of 'cisgenic' plants. The 'cisgenic' plants are genetically engineered, but, in contrast to transgenic plants, contain no genetic material from other species. EFSA suggests that most CRISPR/Cas applications can be put into this category. The consultation is, therefore, generally relevant to the risk assessment of plants derived from New GE (also called new genomic techniques, NGT). However, the way in which EFSA is dealing with this issue appears to be completely inadequate.

<https://www.testbiotech.org/en/news/biased-questions-and-flawed-assumptions>

New letter from the EU Commission on CRISPR applications reveals impact of trade interests and CETA

In a letter written in April 2022, the EU Commission states that CRISPR/Cas applications do not create any new or specific risks due to unintended effects. This letter came in response to a joint letter sent by the German Union of Peasant Farmers (AbL) and Testbiotech. In their letter, Testbiotech and the AbL argued that the statement made by the Commission is not based on scientific facts and is largely driven by trade interests, such as those included in the CETA free trade agreement (The Comprehensive Economic and Trade Agreement) between the EU and Canada.

<https://www.testbiotech.org/en/news/eu-commission-political-statements-instead-scientific-evidence>

No new applications for the import of transgenic plants into the EU in 2021

In April, Testbiotech reported that no new applications were registered in 2021 for the import of transgenic plants into the EU – the first time this has happened. The European Food Safety Authority EFSA was initially set up in 2004, and has since then received more than 150 applications for the market approval of transgenic plants. It appears that new applications were still being registered each year up until the end of 2020, although in noticeably fewer numbers.

<https://www.testbiotech.org/en/news/future-transgenic-plants-thing-past>

The risks of New GE techniques: Warning against the deregulation of genetically engineered organisms

A new document released by Testbiotech and the Canadian Biotechnology Action Network (CBAN) discusses the basic differences between plant breeding and genetic engineering, and argues that these differences need to be considered in regulation.

<https://www.testbiotech.org/en/news/risks-new-ge-techniques>

Regulatory clearance in the US: EU could be affected by imports of CRISPR cattle

In March, the US FDA (Food and Drug Administration) decided in favour of allowing CRISPR/Cas cattle with short, slick coats for agricultural purposes. The shorter hair is said to let the cattle more easily withstand hot weather, and thus gain weight faster. However, the supposed advantages of the gene scissors application are questionable – and the desired characteristics can also be achieved using conventional breeding.

<https://www.testbiotech.org/en/news/crispr-cattle-given-regulatory-clearance-us>

EU Commission: Eggs from CRISPR/Cas laying hens will not be risk assessed or labelled

Eggs and laying hens originating from transgenic hens could be marketed in the EU without these having to undergo an approval process, and without being labelled. This is the conclusion that can be drawn from a letter sent by the EU Commission to the German Federal Office of Consumer Protection and Food Safety (BVL) in July 2021. The letter was made public after a request from the German Union of Peasant Farmers (AbL).

<https://www.testbiotech.org/en/news/new-ge-deregulated-through-backdoor>

EU Parliament votes against import approvals for transgenic plants

In February, the EU parliament voted against two resolutions for import approval of transgenic soybean (GMB151) and cotton (GHB614) produced by BASF. The plants are resistant to herbicides, such as glyphosate and isoxaflutole, soybean GMB151 also produces an insecticidal toxin. Reasons for rejection are, for example, the damage that cultivation of the plants can cause in countries like Brazil. The parliament also criticised the insufficient European Food Safety Authority (EFSA) risk assessment.

<https://www.testbiotech.org/en/news/eu-parliament-votes-against-import-approvals-transgenic-plants>

Testbiotech comment on maize DP4114 x MON810 x MIR604 x NK603

In April, Testbiotech commented on an EFSA opinion on maize DP4114 x MON810 x MIR604 x NK603 (Pioneer). The maize expresses several Bt toxins (Cry1F, Cry34Ab1, Cry35Ab1, Cry1Ab, mCry3A) and was made tolerant to herbicides containing glufosinate and glyphosate.

<https://www.testbiotech.org/en/node/2911>

EFSA opinion: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7134>

Testbiotech comment on oilseed rape MON94100

Testbiotech commented on an EFSA opinion on oilseed rape MON94100 which was developed to confer tolerance to dicamba herbicide.

<https://www.testbiotech.org/content/testbiotech-comment-efsa-oilseed-rape-mon-94100>

EFSA opinion: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7411>

Scientific News

CRISPR tomatoes genetically engineered to produce vitamin D

According to recent UK and South Korean publications, new genetic engineering techniques (New GE) have been used to produce tomatoes with a higher concentration of vitamin D. The researchers used CRISPR/Cas technology to 'knock-out' gene functions which are important for the plants' response to stress conditions. The tomatoes have a higher concentration of vitamin D3, but at the same time, they may, e.g. be more susceptible to plant pests.

<https://www.testbiotech.org/en/news/crispr-tomatoes-created-produce-vitamin-d>

UK paper: <https://www.nature.com/articles/s41477-022-01154-6>

South Korean paper (preprint): <https://www.researchsquare.com/article/rs-1403571/v1>

More pest insects due to transgenic soybeans

In a recent publication, scientists from Argentina and Brazil show how the spread of black armyworm (*Spodoptera cosmioides*) is being promoted by the cultivation of transgenic soybean plants. Black armyworm are the larvae of a butterfly and considered to be a pest insect. Transgenic “Intacta” soybeans, which were originally produced by Monsanto, are resistant to glyphosate and produce an insecticidal protein. The combination of these traits contributes to the spread of the larvae which can then cause substantial damage in the fields.

<https://www.testbiotech.org/en/news/more-pest-insects-due-transgenic-soybeans>

Paper: <https://onlinelibrary.wiley.com/doi/10.1002/ps.6882>

Changes in single genes may threaten whole ecosystems: study sheds new light on the risks of New GE

A recent study highlighted how changes in single genes can impact food webs and ecosystems. In the study, the researchers separated out and planted different genetic variants (alleles) of the genetic model organism *Arabidopsis thaliana* - which would all exist together in natural populations. The outcome was surprising: even a reduction in the diversity of a single gene caused species interacting with the plants to become extinct. The researchers therefore refer to such genes as ‘keystone genes’.

<https://www.testbiotech.org/en/news/changes-single-genes-may-threaten-whole-ecosystems>

Paper: <https://www.science.org/doi/10.1126/science.abf2232>

Transgenic maize is contaminating traditional varieties in Brazil

Researchers at the Brazilian agricultural research agency, Embrapa, have found large-scale transgenic contamination of traditional maize varieties. According to the study that has been published in the journal *Plants*, transgenes were found in one third (34 percent) of around 1,000 samples taken in 2018/19 and 2020/21 in states in the east and northeast of the country.

<https://www.testbiotech.org/en/news/transgenic-maize-contaminating-traditional-varieties-brazil>

Paper: <https://www.mdpi.com/2223-7747/11/5/603/htm>

News from EFSA

Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of microorganisms obtained through synthetic biology

On 16 August, EFSA published an evaluation of the current guidelines for the risk assessment of Synbio organisms. EFSA is recommending updated guidance in different areas:

- organism classes (bacteriophages, protists/microalgae),
- exposure to plant protection products and biostimulants,
- xenobionts and
- feed additives for insects as target species.

Moreover, the development of risk assessment tools is recommended “for assessing nutritional value of biomasses, influence of microorganisms on the gut microbiome and the gut function, allergenic potential of new-to-nature proteins, impact of horizontal gene transfer and potential risks of living cell intake.”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7479>

Assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9

On 12 August, EFSA published an opinion regarding the five-event stacked maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9. The maize produces Bt toxins Cry1A.105, Cry2Ab2, Cry1F Vip3Aa20 and is tolerant to glyphosate, glufosinate, 2,4-D and aryloxyphenoxypropionate (AOPP) containing herbicides. EFSA comes to the conclusion that the “five-event stack maize and its subcombinations are as safe as its non-GM comparator and the tested non-GM maize varieties with respect to potential effects on human and animal health and the environment.”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7451>

Risk assessment of a new bioinformatics evaluation of the insertion sites in genetically modified soybean event 40-3-2

On 22 July, EFSA published an assessment of new sequence data on RoundupReady soybean 40-3-2. The new data show genomic deletions at the insertion sites. EFSA found that

- a) “comparing data only to the reference genome does not allow to conclude that the transformation event resulted in gene loss”;
- b) “transcriptomic analysis did not show major differences in gene expression when comparing the soybean 40-3-2 with the most closely related conventional variety, indicating that the genetic redundancy may compensate for the potential gene loss”;
- c) “composition, phenotypic and agronomic analyses already assessed by the GMO Panel in previous opinions did not show differences between soybean 40-3-2 and its comparators suggesting that the potential gene loss may not have a significant phenotypic effect”:

EFSA therefore concluded that the new information does not alter the agency’s previous conclusions.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7412>

Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology

On 20 July, EFSA published an assessment on the adequacy of its guidelines for plants obtained through synthetic biology. EFSA did not identify any novel potential hazards or risks but found that the guidelines may need an update in some areas.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7410>

Testbiotech contributed to the consultation on the draft opinion. While the final outcome only partially represents the findings presented by Testbiotech, it is interesting to note that EFSA, for the first time, comes to the conclusion that the current guidelines may in some cases not be sufficient to assess the risks of plants derived from New Genetic Engineering. The need to further develop the guidelines was also identified for cases where no additional genes are inserted (SDN-1).

Assessment of the 2020 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in the EU

On 6 July, EFSA published an assessment of the monitoring report on the cultivation of MON810 maize in

the EU. As in previous years, EFSA identified several shortcomings in the report and demanded the revision of resistance monitoring in the future. EFSA also recommended the revision of the farmers' questionnaires.
<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7406>

Assessment of new sequencing information for genetically modified cotton DAS-24236-5 × DAS-21Ø23-5

On 27 June, EFSA published a report on new sequence data for cotton DAS-24236-5 × DAS-21Ø23-5. The cotton event produces two Bt toxins (Cry1F and Cry1Ac) and is tolerant to herbicides containing glufosinate ammonium. EFSA found that the new data, which showed one amino acid substitution in Cry1F and a change in one nucleotide in the flanking region of DAS-21Ø23-5 do “not give rise to any safety concerns”.
<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7345>

Assessment of genetically modified soybean A5547-127 for renewal authorisation

On 20 June, EFSA published an opinion on the glufosinate-tolerant soybean A5547-127 for renewal of authorisation. The GMO Panel found no evidence “for new hazards, modified exposure or scientific uncertainties” that would change its original risk assessment.”
<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7340>

Concept Papers

On 31 May, EFSA published a range of concept papers on several aspects of future risk assessment methodologies. Some of the ideas and recommendations may also become relevant for GMO risk assessment:

- Risk Assessment of Combined Exposure to Multiple Chemicals (RACEMiC):
<https://www.efsa.europa.eu/en/supporting/pub/e200504>
- New Approach Methodologies, <https://www.efsa.europa.eu/en/supporting/pub/e200502>
- Application of OMICS and BIOINFORMATICS Approaches,
<https://www.efsa.europa.eu/en/supporting/pub/e200506>

Risk assessment of new sequencing information for genetically modified sugar beet H7-1

In June, EFSA published a report on new molecular data for sugar beet H7-1. The applicant had found several nucleotide differences in comparison to the sequence originally provided in earlier applications. EFSA found that the sequence differences are “most likely attributed to sequencing errors in the originally reported event sequence” and came to the conclusion that “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.2022.7354>

Update of environmental risk assessment conclusions and risk management recommendations of EFSA (2016) on EU teosinte

In April, EFSA published an updated environmental risk assessment (ERA) on teosinte. Teosinte originated in Latin America and is the wild ancestor of maize; for several years it has been found growing in maize fields in Spain and France. Following a request from the European Commission, EFSA evaluated whether

its earlier conclusions remained valid. EFSA concluded that its earlier assessment from 2016 remains valid, except for recommendations regarding the use of glyphosate-based herbicides on maize GA21.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7228>

Statement complementing the EFSA Scientific Opinion on the assessment of genetically modified oilseed rape MS11 (application EFSA-GMO-BE-2016-138)

In March, EFSA published a statement complementing an earlier opinion on oilseed rape MS11. The earlier assessment could not be completed due to the lack of an appropriate compositional data set. The additional data provided by the applicant was considered to be unsuitable, and therefore the EFSA GMO Panel is “still not in the position to conclude on either the compositional analysis or the toxicological, allergenicity or nutritional assessment of OSR MS11.”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7190>

Authorisations

On 31 March, the EU Commission announced it was issuing authorisations for cotton GHB811, soybean GMB151 and oilseed rape 73496 for import, in addition to renewed authorisation for cotton GHB614.

https://ec.europa.eu/commission/presscorner/detail/en/mex_22_2204

Decision documents for the new events:

Cotton GHB811: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D0530>

Soybean GMB151: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D0531>

Oilseed rape 73496: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D0529>