Testbiotech EU Newsletter 2/2021 (June 2021)

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

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Current Issues and Activities

Appeal to politicians: Keep gene scissors under control!

In a joint appeal published in May, science-, agricultural-, beekeeping- and environmental protection organisations have criticised a controversial EU Commission report on the regulation of plants and animals derived from new methods of genetic engineering (New GE, genome editing). They are warning that the report does not sufficiently address the risks to health and the environment - and may well lead to political decisions being made which harm the precautionary principle.
https://www.testbiotech.org/en/news/keep-gene-scissors-under-control

What is a 'conventional GMO'? EU Commission embraces new industry-led terminology

Testbiotech published a backgrounder showing how the EU Commission is trying to establish new official terminology which is set to cause 'fundamental confusion' in regulation. Experts with close affiliations to the biotech industry were the first to introduce the new term 'conventional GMO' to imply that the methods used in genetic engineering would have no inherent generic risks. This term was then embraced in an EU Commission report without any explanation or justification.
https://www.testbiotech.org/en/news/what-conventional-gmo

Explainer videos on CRISPR/Cas gene scissors

The *Project Genetic Engineering and the Environment* (FGU) has recently started to publish explainer videos on CRISPR/Cas gene scissors. The basics of the technology, its possibilities and risks are presented in a total of four videos. They explain, in particular, gene scissors applications in plants. The content of the videos is intended to provide the basis for informed public debate. The project is funded by the Federal Agency for Nature Conservation, the project coordinator is Testbiotech.
https://fachstelle-gentechnik-umwelt.de/en/videos-en/

EU Commission wants to reform GMO regulation - Testbiotech points to already existing legal flexibility

In April, the EU Commission published a report on new genomic techniques (New GE, genome editing) in plants and animals – and concluded that the current EU GMO regulation should be reformed. The EU Commission's fundamental goals are to promote New GE applications in agriculture and to foster international trade, technology and product development. The Commission is also demanding that decisions on market approvals should consider the potential benefits and not just risk assessment outcomes. Safety for health and environment should nevertheless be guaranteed.
https://www.testbiotech.org/en/news/eu-commission-wants-reform-gmo-regulation
Commission report: https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en

First application for approval of CRISPR/Cas plants in the EU - maize is resistant to herbicides and produces insecticides

Testbiotech research has shown that the first application for the approval of CRISPR/Cas plants is now in the European Food Safety Authority (EFSA) register. Maize DP915635 is resistant to the herbicide glufosinate and produces an insecticidal toxin found in specific ferns growing on trees. Pioneer (associated with DowDupont/Corteva) has also filed several patent applications for the plants, some of which have already been granted in Europe.
https://www.testbiotech.org/en/press-release/first-application-approval-crisprcas-plants-eu

European Group on Ethics presents report on New Genetic Engineering - Testbiotech criticises lack of balance

In March, the *European Group on Ethics in Science and New Technologies* (EGE), which advises the EU Commission, published its report on New Genetic Engineering (New GE or Genome Editing). The report focusses on New GE applications in humans, animals and plants. A Testbiotech analysis of the report found that the section on plants lacks the necessary balance and scientific accuracy. Testbiotech has therefore criticised the EGE for presenting conclusions on risks associated with genetically engineered plants without sufficient scientific backing.
https://www.testbiotech.org/en/news/european-group-ethics-presents-report-new-genetic-engineering

EU Parliament has again voted against further market approvals for genetically engineered plants

In March, the EU Parliament again voted with a huge majority against further market approvals for genetically engineered plants. The risk assessment carried out by the European Food Safety Authority (EFSA) was found to have substantial gaps. EU member states also voted overwhelmingly against market

approvals in earlier votes. Consequently, there is growing pressure on the EU Commission for much closer scrutiny of EFSA findings and applications for market approval.
https://www.testbiotech.org/en/news/risk-assessment-standards-pressure-growing-eu-commission-and-efsa

EFSA report: Risk assessment of New GE plants necessary even if no additional genes are inserted
In February, EFSA published another report on the risk assessment of plants developed with new genetic engineering (New GE). The report includes plants generated using CRISPR/Cas applications where no new additional genes are inserted (so-called SDN-1 applications). The EFSA report shows that detailed risk assessment must be carried out even if no additional genes are inserted. The report is the outcome of a consultation which included Testbiotech.
https://www.testbiotech.org/en/press-release/efsa-risk-assessment-new-ge-plants-necessary-even-if-no-additional-genes-are-inserted
EFSA report: https://www.efsa.europa.eu/en/efsajournal/pub/6301

Testbiotech report provides evidence that EFSA systematically ignores specific risks
In January, Testbiotech published a report providing evidence that the European Food Safety Authority (EFSA) is intentionally keeping significant risks related to genetically engineered (GE) plants 'in the dark'. While EFSA is aware that the data compiled by industry are insufficient to demonstrate the safety of the plants, it has nevertheless failed to take action to solve the problems.
https://www.testbiotech.org/en/press-release/risk-assessment-ge-plants-eu-taking-look-dark-side-moon

Testbiotech comment on maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122
In March, Testbiotech commented on an EFSA opinion regarding stacked maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 (Bayer/Monsanto).
https://www.testbiotech.org/node/2716
EFSA-Stellungnahme: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6351

Testbiotech comment on soybean GMB151
In May, Testbiotech commented on an EFSA opinion on soybean GMB151 (BASF). The soybean contains genes conferring resistance to a group of herbicides known as HPPD-inhibitors, such as isoxaflutole, mesotrionine and tembotrionine. The soybean also expresses the insecticidal protein Cry14Ab-1.
https://www.testbiotech.org/node/2753
EFSA opinion: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6424

Testbiotech comment on maize 1507 × MIR162 × MON810 × NK603
Testbiotech commented on an EFSA opinion regarding stacked maize 1507 × MIR162 × MON810 × NK603. The maize expresses Cry1Ab, Cry1F, Vip3Aa20, PMI, two versions of EPSPS and PAT proteins.
https://www.testbiotech.org/content/testbiotech-comment-maize-1507-mir162-mon810-nk603
EFSA opinion: https://www.efsa.europa.eu/en/efsajournal/pub/6348

Scientific News

Transgenic plants failing in the fields - increased environmental impact of toxic pesticides

Expectations that the cultivation of transgenic plants would lower the impact of pesticides on the environment have failed to materialise. This failure was confirmed in a recent study published in the academic magazine, Science, and is based on official data from the US. The experts compared volume and toxicity of pesticides applied in fields with genetically engineered (GE) plants to fields with conventional agriculture. The conclusion: in recent years there has been a strong increase in pesticides impacting the environment, with and without transgenic plants.

https://www.testbiotech.org/en/news/transgenic-plants-failing-fields

Publication: https://science.sciencemag.org/content/372/6537/81

Genome-edited plants: Negative effects on ecosystems are possible

A scientific paper in the *Environmental Sciences Europe* journal provides an overview of the unwanted effects that the release of genome-edited plants can have on ecosystems. These result from the intended properties induced by genome editing and can contribute to various metabolic processes. The paper is based on Project Genetic Engineering and the Environment (FGU) findings, and is one of the first worldwide to focus on ecological risks associated with specific CRISPR/Cas applications in plants.

https://www.testbiotech.org/en/news/genome-edited-plants-negative-effects-ecosystems-are-possible

Publication: https://enveurope.springeropen.com/articles/10.1186/s12302-021-00482-2

Adverse environmental effects found in insecticidal Bt plant cultivation

Recent Chinese and Brazilian studies strongly indicate that the cultivation of transgenic insecticidal plants can speed up the spread of specific plant pests. Unexpected and complex environmental interactions play a crucial role in this context. The research was carried out with genetically engineered (GE) cotton and soybeans that produce so-called Bt toxins. In China, cotton bollworm is spreading rapidly in fields where Bt cotton is grown. In Brazil, so-called white flies are becoming increasingly problematic in Bt soybean fields.

https://www.testbiotech.org/en/news/how-do-genetically-engineered-crops-speed-spread-plant-pests

Publication Brazil: https://academic.oup.com/jee/advance-article-abstract/doi/10.1093/jee/toab008/6149198

Publication China: https://www.biorxiv.org/content/10.1101/2021.02.08.430243v1

Disturbance in interactions between GE cotton and the environment

It is known that genetically engineered (GE) cotton is spreading within populations of wild cotton species in Mexico. Resulting offspring are often transgenic and, consequently, produce insecticides or are resistant to the herbicide, glyphosate. A recently published paper has now shown that there are disturbances in interactions between the transgenic offspring and their environment. This finding has serious implications for the protection of wild cotton species because Mexico is one of the centres of origin for cotton.

https://www.testbiotech.org/en/news/disturbance-interactions-between-ge-cotton-and-environment

Publication: https://www.nature.com/articles/s41598-021-81567-z

News from EFSA

Statement complementing the EFSA Scientific Opinion on genetically modified soybean MON 87769 × MON 89788

In May, EFSA published an additional statement on this soybean considering additional information on the human nutritional assessment of refined bleached deodorised oil (RBD GM oil). EFSA comes to the conclusion that the oil does not represent a nutritional concern in humans.
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6589

Scientific assistance on requests for internal review filed by Testbiotech

In May, EFSA published an assessment of Testbiotech's requests for internal review of authorisations regarding soybean MON 87751 x MON 87701 × MON 87708 x MON 89788, maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and subcombinations and maize MON 87427 × MON 89034 × MIR162 × MON 87411 and subcombinations.
https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2021.EN-6590

Overview of sixteen scientific opinions on genetically modified plants obtained by new genomic techniques

In April, EFSA published an external report summarising 16 scientific opinions published by European competent authorities and national institutions since 2012 on plants obtained by new genomic techniques (NGTs), such as CRISPR/Cas or zinc finger nucleases.
https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2021.EN-1973

Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques

In April, EFSA published an overview of the risk assessment of plants developed using new genomic techniques (NGTs), taking into account "previous scientific opinions, its ongoing work on the topic as well as opinions published by competent authorities and national institutions since 2012."
https://www.efsa.europa.eu/en/efsajournal/pub/6314

Extension of the spatially and temporally explicit "briskaR NTL" model to assess potential adverse effects of Bt maize pollen on non target Lepidoptera at landscape level

In April, EFSA published a revised model for the assessment of effects of Bt toxins on non-target butterflies. Several aspects were improved in comparison to an earlier model ('Perry-model'). EFSA acknowledges in this publication that it does not see the old model, which had drawn heavy criticism from scientists and NGOs, as fit for purpose.
https://www.efsa.europa.eu/en/supporting/pub/en-6443
Additional information: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.e190301

Renewal assessments regarding maize Bt11 and MON 88017 × MON 810

EFSA published renewal assessments regarding Bt11 and MON 88017 × MON 810. In both cases the authority comes 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 assessments.

Statement on in vitro protein digestibility tests in allergenicity and protein safety assessment of genetically modified plants

On 12 January, EFSA published a statement on allergenicity testing of GE plants. It analyses weaknesses of the current tests and considers new testing strategies. An updated guidance will be published in 2021.
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6350

Authorisations

EU Commission approves eight applications for import of transgenic crops

In January, the EU Commission approved eight applications for the import of genetically engineered plants. The approvals were issued for maize and soybeans which produce insecticidal toxins and are engineered to be resistant to herbicides such as glyphosate; the approvals include five new variants of GE plants and three renewals. The harvest of these plants is now allowed for import and usage in food and feed. Testbiotech filed three requests for internal review regarding the authorisations of soybean MON 87751 x MON 87701 × MON 87708 x MON 89788, maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and maize MON 87427 × MON 89034 × MIR162 × MON 87411.
https://www.testbiotech.org/en/press-release/eu-commission-approves-eight-applications-import-transgenic-crops