Testbiotech EU Newsletter 1/2022 (February 2022)

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

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<u>Most important topics:</u> Legal action against the EU Commission; EU Commission shows intention to deregulate New GE; Unintended changes and unexpected patterns of inheritance in CRISPR animals; Research on evolution of plants

Current Issues and Activities

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- EU Commission ignores scientific findings on New GE risks
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Current Issues and Activities

Testbiotech taking legal action against the EU Commission

Testbiotech wants two EU approvals issued for genetically engineered (GE) maize and soybeans to be examined by the General Court of the European Union. The cases against the EU Commission were filed in September 2021 and both cases were accepted by the court in November (T-605/21 and T-606/21). In their analysis, Testbiotech found that the risks associated with the GE plants produced by Bayer had not undergone detailed assessment as foreseen in EU regulation.
https://www.testbiotech.org/en/news/court-proceedings-against-eu-approvals-genetically-engineered-plants
In July, the EU Commission rejected a Testbiotech request for an internal review of the EU approvals.
https://www.testbiotech.org/en/news/eu-commission-treating-risk-assessment-transgenic-plants-formality

EU Commission ignores scientific findings on New GE risks

Testbiotech received a letter in December from the EU Commission in which it set out its views on new publications concerning the risks associated with CRISPR/Cas. In their opinion, any hazard potential arising from unintended genetic changes caused by the processes of New GE, is no different to that of conventional breeding. Existing scientific evidence, however, contradicts this view.
https://www.testbiotech.org/en/news/eu-commission-ignores-scientific-findings-new-ge-risks

Document published by EU Commission shows intention to deregulate New GE

In October, Testbiotech found that, while still officially calling for adequate regulation and high safety standards, the EU Commission seems in reality to be following a different strategy: a document on future GMO regulation published at the end of September indicates a clear intention to widely deregulate plants derived from New Genetic Engineering (New GE). Risks associated with the processes of New GE are either not given sufficient weight or are completely disregarded.
https://www.testbiotech.org/en/news/document-published-eu-commission-shows-intention-deregulate-new-ge

Genetically engineered bacteria put food safety at risk

In November, Testbiotech reported that genetically engineered (GE) bacteria which are used, amongst other things, in the production of enzymes and vitamins, have repeatedly found their way into food and feed production processes. EU member states have discovered more than a dozen such cases in recent years, in more than 20 countries. The GE bacteria carry genes conferring antibiotic resistance which may be transferred to gut bacteria. More detailed examinations have found substantial risks to food safety.
https://www.testbiotech.org/en/news/genetically-engineered-bacteria-put-food-safety-risk

Testbiotech comment on maize NK603 x T25 x DAS-40278-9

In January, Testbiotech commented on an EFSA opinion regarding stacked maize NK603 x T25 x DAS-40278-9 (Pioneer). The maize was made resistant to three herbicides: glufosinate, glyphosate, 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP).
https://www.testbiotech.org/node/2871
EFSA opion: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6942

Testbiotech comment on oilseed rape 73496

Testbiotech commented on an EFSA opinion regarding oilseed rape 73496 (Pioneer). The oilseed rape is engineered to be herbicide-resistant to glyphosate.
https://www.testbiotech.org/node/2864
EFSA opinion: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6610

Testbiotech comment on cotton GHB811

Testbiotech commented on an EFSA opinion regarding cotton GHB811 (BASF). The cotton is engineered to be resistant to glyphosate and a group of herbicides known as HPPD inhibitors, such as isoxaflutole, mesotrionine and tembotrionine.
https://www.testbiotech.org/content/testbiotech-comment-cotton-ghb811
EFSA opinion: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6781

Scientific News

Unintended changes and unexpected patterns of inheritance in CRISPR animals

In experiments with zebrafish, researchers have for the first time shown that unintended effects of CRISPR/Cas applications are inherited in subsequent generations. They also found unusual patterns of inheritance. According to the scientists, the findings show that the effects of CRISPR/Cas applications on subsequent generations need to be examined in much greater detail.
https://www.testbiotech.org/en/news/crisprcas-animals-unintended-changes-and-unexpected-patterns-inheritance
Paper: https://www.nature.com/articles/s41467-022-28244-5

Deficiencies in the risk assessment of Bt cowpea cultivated in Nigeria

A scientific publication found substantial deficiencies in the risk assessment of genetically engineered Bt cowpea approved for cultivation in Nigeria. The transgenic plants produce an insecticidal Bt toxin that is meant to protect the plants from the larvae of *Maruca vitrata*, which feed on the plants and are also known as pod borer. The authors identify several gaps in the risk assessment, e.g. on the safety of the Bt toxins, potential gene flow and uncontrolled spread of the transgenes.

https://www.testbiotech.org/en/news/transgenic-cowpea-may-impact-health-and-environment

Paper: https://www.mdpi.com/2223-7747/11/3/380

Evolution of plants: Research outcomes on the differences between New GE and conventional breeding

A scientific publication in *Nature*, shows that the occurrence of mutations in plant genomes is not purely random, and their frequencies in populations do not only depend on the mechanisms of selection. It is now becoming evident that the genome has natural mechanisms which prevent specific genomic regions from frequent mutations. The published research sheds new light on evolutionary biology and also raises questions in regard to the consequences of genetic engineering in plants.

https://www.testbiotech.org/en/news/new-findings-evolution-plants

Paper: https://www.nature.com/articles/s41586-021-04269-6

Corner stones for environmental risk assessment of genome edited plants

Experts from environmental authorities in Austria, Germany, Italy, Poland and Switzerland published a scientific paper that, for the first time, defines some important initial cornerstones in the environmental risk assessment of plants altered with new genomic techniques (i.e. ‘New GE’ or ‘genome editing’). The authors show that there can be no justification for only risk assessing plants with additionally inserted genes or with extensive genomic changes. Rather, all plants derived from New GE must be subjected to mandatory risk assessment.

https://www.testbiotech.org/en/news/new-ge-how-assess-environmental-risks

Paper: https://www.mdpi.com/2673-6284/10/3/10/htm

“Golden Rice” especially attractive for pest insects?

Recent publications show that genetically engineered (GE) plants fortified with vitamins pose a specific challenge in risk research. A higher content of carotene can be an advantage for insects feeding on the plants. This could be amongst the problems with so-called ‘Golden Rice’, which is to be grown in the Philippines. It will be the first GE plant grown in the fields to produce additional carotene to improve vitamin A intake via consumption.

https://www.testbiotech.org/en/news/golden-rice-especially-attractive-pest-insects

Paper 1: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0246696

Paper 2: https://www.mdpi.com/2075-4450/12/8/718

Position paper on new genomic techniques and their regulation - High risk potential requires case-by-case analysis

The German Federal Agency for Nature Conservation (BfN) published a position paper in October on the

intention of the EU Commission to evaluate new legislative proposals for the regulation of certain new genomic techniques (NGTs) in plants. The paper concludes that these plants have a similar or even greater risk potential than plants obtained from older genetic engineering techniques.
https://www.testbiotech.org/en/news/german-federal-agency-nature-conservation-position-paper-new-genomic-techniques
Position paper: https://www.bfn.de/publikationen/positionspapier/new-developments-and-regulatory-issues-plant-genetic-engineering

Need for a case-specific risk assessment of plants obtained from new genetic engineering
A new study published in the scientific journal *Plants*, presents the specific risks of new genetic engineering techniques and gives an overview of possible gene scissor applications. Inducing even supposedly small alterations in the genome of crop plants can nevertheless generate complex changes. The results of the study highlight the need for plants developed using New Genetic Engineering techniques to undergo case-specific risk assessment, taking both the properties of the end product and risks posed by the applied procedures into account.
https://www.testbiotech.org/en/news/new-scientific-publication-novel-risks-and-applications-gene-scissors
Paper: https://www.mdpi.com/2223-7747/10/11/2259/htm

Uncontrolled spread of GE oilseed rape: a global problem
A Korean publication shows that the uncontrolled spread of genetically engineered (GE) oilseed rape is already happening in 14 countries on 5 continents. These are countries which either allow the cultivation of GE oilseed rape (such as the USA and Canada), or have tested it in experimental releases (such as Germany), or allow the import of kernels (such as Japan). Moreover, it has to be assumed that there is a high number of undetected cases, as many regions do not have systematic monitoring.
https://www.testbiotech.org/en/news/uncontrolled-spread-ge-oilseed-rape-global-problem
Paper: https://www.mdpi.com/2079-7737/10/12/1264

News from EFSA

Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology
In January, EFSA published a scientific opinion on the allergenicity and protein safety assessment of genetically engineered organisms. The agency calls for the modernisation of some key elements of risk assessment. These should include the "*consideration of clinical relevance, route of exposure and potential threshold values of food allergens, the update of in silico tools used with more targeted databases and better integration and standardisation of test materials and in vitro/in vivo protocols.*"
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2022.7044
EFSA also held a workshop on the subject:
https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2021.EN-6826

In vivo and in vitro random mutagenesis techniques in plants

In November, EFSA published an opinion on mutagenesis techniques in plants. The GMO Panel comes to the conclusion that a *"distinction between plants obtained by in vitro or in vivo approaches is [….] not justified. Indeed, the same mutation and the derived trait in a given plant species can be potentially obtained using both in vivo and in vitro random mutagenesis and the resulting mutants would be indistinguishable."*
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6611

Assessment of genetically modified cotton GHB614 for renewal authorisation

In July, EFSA published an opinion on glyphosate tolerant cotton GHB614 for renewal. EFSA concludes that there is *"no evidence in the renewal application [...] for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614."*
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6671

Assessment of the 2019 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in the EU

In July, EFSA published an assessment of the 2019 post-market environmental monitoring report on MON810 cultivation. Again, as in previous years, the GMO Panel identified several shortcomings in the report. *"In particular, the monitoring plan, as implemented in 2019, is not sufficiently sensitive to detect the recommended 3% resistance allele frequency."*
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6683

Authorisations

Ten approvals for the import of genetically engineered crops rushed through

In August, the EU Commission rushed through ten approvals for the import of genetically engineered (GE) plants. The approvals were issued for maize, soybeans, oilseed rape and cotton, which produce insecticidal toxins and/or are engineered to be resistant to herbicides such as glyphosate; the approvals include seven new variants of GE plants and three renewals. The applications were filed by Monsanto (Bayer), Dow AgroSciences (Corteva) and Syngenta (ChemChina).
https://www.testbiotech.org/en/news/ten-approvals-import-genetically-engineered-crops-rushed-through