



Testbiotech EU Newsletter 1/2021 (January 2021)

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

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Most important topics: EU Parliament votes against further GE plant approvals / New report on Genome Editing / New evidence regarding Bt toxins, teosinte and New GE / EFSA consultations on gene drives and New GE

Current Issues and Activities

- EU Parliament votes against further GE plant approvals - Testbiotech urges the EU Commission to take action
- New report: Why New Genetic Engineering needs to be regulated - frequently asked questions about CRISPR & Co
- Are GE plants with Bt toxins 20 times more toxic than previously known? EFSA has for decades ignored crucial data from Monsanto
- EFSA consultations I: Mutagenic chain reaction cannot be sufficiently controlled - EFSA is disguising real risks of gene drive organisms
- EFSA consultations II: Confusion about risks associated with New GE plants - Opinion of the EU authority insufficient and misleading
- Testbiotech comment on EFSA opinion regarding insect-resistant and herbicide-tolerant soybean DAS-81419-2 × DAS-44406-6

Scientific News

- New problems in GE maize cultivation - Risk of transgenes spreading into the environment higher than expected
- CRISPR: Gene scissors cause chaos in the genome
- CRISPR/Cas gene scissor applications cause changes in gene regulation

News from EFSA

- Evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology

Current Issues and Activities

EU Parliament votes against further approvals of GE plants - Testbiotech urges the EU Commission to take action

On 17 December, the EU Parliament adopted by a large majority several resolutions proposed by the Greens/EFA Group against further EU market approvals of genetically engineered plants. Five applications were filed by Bayer (Monsanto) and Syngenta for maize and soybeans that are resistant to herbicides and/or produce insecticides.

The EU Parliament has adopted more than 50 resolutions since December 2015 against new import approvals for GE plants. However, these votes are not binding for the EU Commission, which approved all of these GE plants for import. According to Testbiotech, the renewed strong evidence for huge gaps in EFSA risk assessment cannot be ignored in upcoming decision-making.

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

The Environmental Committee of the EU parliament had already adopted the resolutions two weeks before the vote: <https://www.testbiotech.org/en/news/eu-close-approving-new-ge-plants>

New report: Why New Genetic Engineering needs to be regulated - frequently asked questions about CRISPR & Co

In October, Testbiotech published a new report on New Genetic Engineering (New GE) that shows why these techniques need to be strictly regulated. New GE - or 'genome editing' - opens up new possibilities which go way beyond conventional breeding and previous methods of genetic engineering. One of the most important tools in this scenario are CRISPR/Cas gene scissors (nuclease). In contrast to chemical or physical mutagens used in conventional breeding, tools such as CRISPR/Cas can directly interact with biological mechanisms in the cells.

<https://www.testbiotech.org/en/news/why-new-genetic-engineering-needs-be-regulated>

Are GE plants with Bt toxins 20 times more toxic than previously known? EFSA has for decades ignored crucial data from Monsanto

Data from Monsanto revealed that Bt proteins expressed in genetically engineered (GE) plants are significantly more toxic than natural Bt toxins. It is more than 30 years since, in 1990, Monsanto data first showed that if mixed with plant material from, e.g. soybeans, cotton and maize, toxicity could be up to 20 times higher. This is due to enzymes naturally present in the tissues of many crop plants. These findings were never taken into account by the European Food Safety Authority (EFSA). It seems as if EFSA simply overlooked the relevant publications. EFSA routinely accepts tests with isolated Bt proteins produced by bacteria to assess the risks of GE plants.

<https://www.testbiotech.org/en/press-release/are-ge-plants-bt-toxins-20-times-more-toxic-previously-known>

EFSA consultations I: Mutagenic chain reaction cannot be sufficiently controlled - EFSA is disguising real risks of gene drive organisms

The European Food Safety Authority (EFSA) has published the results of its public consultation on the risks of so-called gene drive organisms. Testbiotech is accusing the authority of disguising the real dimension of the risks. According to Testbiotech, EFSA refers to publications to describe these problems but fails to present the relevant findings correctly. Rather, EFSA compares gene drives to other methods, such as releases of sterile insects, which are not related to the mechanisms of a mutagenic chain reaction. Such comparisons are misleading and may cause the real risks to be underestimated.

Gene drives are designed to spread artificial genetic constructs throughout populations of wild species much faster than would be expected naturally. Currently, gene drives are being developed with the aid of tools such as the CRISPR/Cas gene scissors. There are plans, e.g. to apply gene drives in insects (flies and mosquitoes) or rodents (rats or mice). The aim is to replace or eradicate natural populations. Once started the process cannot be controlled effectively or reliably. The damage to humans, the environment and nature could be severe.

<https://www.testbiotech.org/en/news/mutagenic-chain-reaction-cannot-be-sufficiently-controlled>

EFSA opinion: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6297>

Outcome of the public consultation: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1939>

EFSA consultations II: Confusion about risks associated with New GE plants - Opinion of the EU authority insufficient and misleading

Testbiotech is extremely critical of a recent European Food Safety Agency (EFSA) opinion on the risks associated with plants derived from new genetic engineering (New GE). It considers the EFSA report on CRISPR & Co to be both inadequate and misleading on the protection of health and the environment.

In its opinion, EFSA claims that applications of gene scissors, such as CRISPR/Cas in plants, do not pose any specific risks as long as no additional genes are inserted. At the same time, EFSA agrees with Testbiotech that New GE opens up the way to new genetic combinations since it makes the whole genome accessible for changes caused, for example, by targeting several genes at once.

The EFSA opinion relates to techniques known as SDN-1 and SDN-2 (site-directed nucleases). These allow the genetic engineering of plants using gene scissors such as CRISPR/Cas without inserting additional genes.

<https://www.testbiotech.org/en/news/efsa-confusion-about-risks-associated-new-ge-plants>

EFSA opinion: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6299>

Outcome of the public consultation: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1972>

Testbiotech comment on EFSA opinion regarding insect-resistant and herbicide-tolerant soybean DAS-81419-2 × DAS-44406-6

In December, Testbiotech published a comment regarding EFSA's opinion on soybean DAS-81419-2 × DAS-44406-6 by Dow Agrosciences. The soybean is resistant to glyphosate, 2,4-D and glufosinate ammonium.

Further, it produces Bt toxins Cry1F and Cry1Ac. According to Testbiotech, the data presented are insufficient to demonstrate safety.

https://www.testbiotech.org/content/testbiotech-comment-efsa-opinion-soybean-DAS-81419-2_DAS-44406-6

New problems in GE maize cultivation - Risk of transgenes spreading into the environment higher than expected

Even though the insecticidal genetically engineered (GE) maize MON810 is controversial in Europe, it has been grown in Spain for about twenty years. However, the cultivation of the transgenic plants is now facing new problems: recent research shows that a weedy plant, teosinte, has changed its biological characteristics in ways that will facilitate further genetic exchange with maize plants. Therefore, the likelihood of hybridisation with the GE maize has strongly increased. As a result, a new super-weed might emerge. 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. Up until now, the risk of these plants crossing with European maize varieties was considered to be moderate. However, as a recent peer-reviewed publication shows, the teosinte plants have already crossed with European maize varieties and acquired biological traits which will facilitate further gene flow from maize. Therefore, the scientists involved have explicitly warned that the risk of the plants becoming invasive should not be underestimated.

<https://www.testbiotech.org/en/news/new-problems-ge-maize-cultivation>

Publication: <https://doi.org/10.1073/pnas.2006633117>

CRISPR: Gene scissors cause chaos in the genome

A new publication has described experiments using CRISPR/Cas9 gene scissors on human embryos. The aim of the experiments conducted in the US was to correct a mutated DNA sequence that causes a genetic disorder. This disorder can result in blindness (*Retinitis pigmentosa*). The gene scissors were supposed to cut the faulty gene sequence – and the expectation was that the fault in the genome would then be corrected via cell repair mechanisms. This aim was not accomplished. Instead, either large parts or the whole of chromosome 6, where the gene is located, were lost. In addition, there were further unintended mutations in the target gene sequence.

<https://www.testbiotech.org/en/news/crispr-gene-scissors-cause-chaos-genome>

Publication: <https://doi.org/10.1016/j.cell.2020.10.025>

CRISPR/Cas gene scissor applications cause changes in gene regulation

A new scientific publication shows that CRISPR/Cas gene scissor applications in animals unintentionally leave traces. The findings are not related to unintended changes in the DNA, which have often been described, but to gene regulation, i.e. epigenetics. The effects are heritable and may, for example, result in disruption of embryonic development. The new scientific publication describes CRISPR/Cas experiments with mice in which their DNA is cut and additional genetic information inserted. Besides intended changes in DNA in the target region, the findings also showed unintended changes in so-called epigenetic markers that control gene regulation. The effects were heritable and could still be identified after ten generations. According to the authors, the effects can also be used to identify CRISPR/Cas gene scissor applications.

<https://www.testbiotech.org/en/news/new-ge-unintentionally-leaves-traces-cells>

Publication: <https://doi.org/10.1186/s12864-020-07233-2>

Evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology

On 28 October, EFSA published an opinion on the public consultation regarding synthetic biology microorganisms (SynBioMs) expected to be deliberately released into the environment. According to EFSA, no “*novel environmental hazards are expected for current and near future SynBioMs. However, the efficacy by which the SynBioMs interact with the environment may differ. This could lead to increased exposure and risk. Novel hazards connected with the development of xenobionts may be expected in the wider future.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6263>

Outcome of the public consultation: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1934>

More EFSA activities are reported in “Current Issues and Activities”.