



## **Testbiotech EU Newsletter 2/2020 (May 2020)**

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

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### **Most important topics:**

**Comments on EFSA consultations regarding gene drives and new methods of genetic engineering / Testbiotech report on regulation of new genomic techniques / Legal proceedings started against patents / New scientific papers on persistence of genetically engineered plants and gene drives**

### **Current Issues and Activities**

- Will Bayer GE soybeans be allowed for use in food production without safety being demonstrated?
- EFSA holding public consultation on new methods of genetic engineering
- Comment on EFSA gene drive consultation and new scientific paper - Testbiotech demands 'cut-off' criteria are applied
- Testbiotech report: strict regulation of new genomic techniques is scientifically necessary
- Will there be GMO fast track approvals in the EU? Testbiotech warns about planned trade deal with the US
- Follow-up: Trade deal with US: EU Commission is keeping the doors wide open
- Import approval for genetically engineered maize: Did Monsanto benefit from unlawful exploitation of transitional provisions?
- Legal proceedings started against patents on human embryonic stem cells and interventions in the human germ line
- Testbiotech comment regarding EFSA opinion on maize MON88017 for renewal
- Testbiotech comment regarding EFSA opinion on soybean SYHT0H2

### **Scientific News**

- Spreading the risks: when genetically engineered organisms go wild
- GeneTip project results published in full - New publication on technology assessment of gene drives

## News from EFSA

- Scientific advice on Testbiotech requests for internal review of Commission Implementing Decisions on soybean MON 89788 and soybean A2704-12
- Public consultation on the GMO Panel draft scientific opinion on genetically modified plants obtained through synthetic biology
- Public consultation on the draft EFSA Scientific Committee opinion “Evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of micro-organisms obtained through synthetic biology”
- EFSA assessment of mixtures of multiple pesticides
- Stakeholder workshop “Problem formulation for the environmental risk assessment of gene drive modified insects” (15 May 2019, Brussels)

## Current Issues and Activities

### **Will Bayer GE soybeans be allowed for use in food production without safety being demonstrated?**

In May, the EU Parliament voted with a huge majority against the import of genetically engineered (GE) soybeans (MON 87708 x MON 89788 x A5547-127) resistant to three herbicides produced by Bayer. The European Food Safety Authority (EFSA) considered the soybeans which inherit several transgenes, to be safe for human consumption. However, according to the EU Parliament, the risk assessment was not sufficient. One reason: the soybeans have not been tested for combinatorial effects arising from the genetic interventions and the residues from spraying with herbicides glyphosate, dicamba and glufosinate.

<https://www.testbiotech.org/en/news/bayer-ge-soybeans-allowed-without-safety-being-demonstrated>

### **EFSA holding public consultation on new methods of genetic engineering**

The European Food Safety Authority (EFSA) is holding a public consultation on plants developed with new methods of genetic engineering (genome editing). The EFSA draft document looks at changes made to the genome using tools such as CRISPR/Cas, but without the insertion of additional gene sequences. Testbiotech has concluded that the published draft suffers extensively from not taking numerous relevant publications and important scientific findings into account. Comments can be submitted until 27 May.

<https://www.testbiotech.org/en/news/efsa-holding-public-consultation-new-methods-genetic-engineering>

Link to the consultation: <http://www.efsa.europa.eu/en/consultations/call/public-consultation-applicability-efsa-opinion-site-directed>

### **Comment on EFSA gene drive consultation and new scientific paper - Testbiotech demands that ‘cut-off’ criteria are applied**

The European Food Safety Authority (EFSA) carried out a public consultation on guidance for the risk assessment of so-called gene drives at the request of the EU Commission. At the same time, a new Testbiotech scientific paper was accepted after peer review. The paper shows that the EFSA concept is insufficient. To control the risks of gene drives, ‘cut-off criteria’ need to be defined to prevent the uncontrolled spread of genetically engineered organisms.

Link: <https://www.testbiotech.org/en/news/EFSA-discusses-risk-assessment-of-gene-drives>

The EFSA consultation: <http://www.efsa.europa.eu/en/consultations/call/public-consultation-gmo-panel-scientific-opinion-evaluation>

### **Testbiotech report: strict regulation of new genomic techniques is scientifically necessary**

In a new report published in March, Testbiotech provides an overview of the latest research developments in environmental risk assessment and new methods of genetic engineering. The authors come to the conclusion that there are imperative scientific reasons for all organisms derived from these new techniques to undergo mandatory risk assessment before they can be released or marketed. Therefore, regulation requirements foreseen by current GMO law in the EU must be mandatory whether or not additional DNA sequences are inserted. In addition, a broad range of ethical and social issues must be taken into account by the regulatory decision-makers.

<https://www.testbiotech.org/en/news/new-report-strict-regulation-new-genomic-techniques-scientifically-necessary>

The report: <https://www.testbiotech.org/node/2569>

### **Will there be GMO fast track approvals in the EU? Testbiotech warns about planned trade deal with the US**

Testbiotech has warned in a letter to the EU Commission against a planned trade agreement between the EU and the Trump administration. The deal might allow fast track approvals for genetically engineered plants. Such plans were reported by the media in Brussels. They would be contrary to the views of many experts in EU member states and independent scientists, who have repeatedly drawn attention to substantial insufficiencies and gaps in current EU risk assessment. Current standards in risk assessment should be substantially tightened rather than weakened as demanded by the US government and industry.

<https://www.testbiotech.org/en/news/will-there-be-gmo-fast-track-approvals-eu>

### **Follow-up: Trade deal with US: EU Commission is keeping the doors wide open**

In an answer to Testbiotech, the EU Commission rejected the concerns regarding a new trade deal with the US. According to the letter from the EU Commission, there are no plans to change the legal standards. However, *“on the other hand, the EU and the US are engaged in regular dialogues on biotechnology policies in both parties, with a view to exchange information and foster cooperation in innovative biotechnology fields.”*

<https://www.testbiotech.org/en/news/trade-deal-us-eu-commission-keeping-doors-wide-open>

### **Import approval for genetically engineered maize: Did Monsanto benefit from unlawful exploitation of transitional provisions?**

Testbiotech is concerned that Monsanto (Bayer) unlawfully obtained an import authorisation for genetically engineered maize without a proper risk assessment as required by EU regulations. The reason: officially, Monsanto filed its application for market approval just before a more rigorous EU regulatory framework for risk assessment came into force. However, there are doubts that the application was actually filed in time.

<https://www.testbiotech.org/en/news/dubious-import-approval-genetically-engineered-maize>

## **Legal proceedings started against patents on human embryonic stem cells and interventions in the human germ line**

Testbiotech started legal proceedings in two cases against patents. The cases were initiated to clarify fundamental ethical questions in patent law, especially in regard to the protection of human dignity. A case was filed at the German Federal patent court (Bundespategericht) in a bid to nullify the German patent (DE102004062184), which claims uses of human embryos to obtain stem cells. In addition, Testbiotech has filed an opposition to a European patent on uses of the so-called CRISPR/Cas gene scissors; the well-known scientists Jennifer Doudna and Emmanuelle Charpentier are named as the inventors in this patent (EP3401400). The human germ line and the commercial use of human embryos are not definitively excluded in this patent as required in law. In addition, the patent claims the application of CRISPR/Cas on plants and animals.

<https://www.testbiotech.org/en/press-release/legal-proceedings-patents-human-embryonic-stem-cells-germ-line>

## **Testbiotech comment regarding EFSA opinion on maize MON88017 for renewal**

Testbiotech published an analysis of EFSA's opinion regarding maize MON88017. This maize produces Cry3Bb1 protein toxic to the larvae of *Coleoptera* (beetles) that feed below the ground and a CP4 EPSPS protein for tolerance to glyphosate-containing herbicides.

<https://www.testbiotech.org/content/testbiotech-comment-efsa-maize-mon88017-renewal>

EFSA opinion: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6008>

## **Testbiotech comment regarding EFSA opinion on soybean SYHT0H2**

Testbiotech published an analysis of EFSA's opinion on soybean SYHT0H2. The soybean contains genes conferring resistance to two groups of herbicides, glufosinate and mesotrione, as well as other HPPD inhibitors (such as isoxaflutole).

<https://www.testbiotech.org/en/node/2562>

EFSA opinion: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.5946>

## **Scientific News**

### **Spreading the risks: When genetically engineered organisms go wild**

A new peer-reviewed paper was published in the international *Environmental Sciences Europe* journal. The paper addresses specific environmental risks associated with genetically engineered (GE) plants that can spread and propagate in the environment. It is the first publication with a focus on the risk assessment of so-called next generation effects. The review addresses unintended effects that were observed in spontaneous hybrid offspring but absent in the original plants. Some of the risks include a higher invasive potential of the GE plants and/or disruption of the associated ecosystems.

<https://enveurope.springeropen.com/articles/10.1186/s12302-020-00301-0>

### **GeneTip project results published - New publication on technology assessment of gene drives**

The GeneTip research project was a joint enterprise carried out from 2017 until 2019 by the Universities of

Bremen and Vechta, the University of Natural Resources and Life Sciences, Vienna and Testbiotech, Munich. The researchers focused on risks associated with the spread of newly designed genetically engineered organisms into the environment. In particular, the project examined plants and animals with a so-called gene drive. The results have now been published in full by the Springer Publishing Company in a book titled “Gene Drives at Tipping Points”.

<https://www.testbiotech.org/en/news/genetip-project-results-published>

Springer Book “Gene Dives at Tipping Points” (open access):

<https://link.springer.com/book/10.1007/978-3-030-38934-5>

## News from EFSA

### **Scientific advice on Testbiotech requests for internal review of Commission Implementing Decisions (EU) No 2019/2083 and 2019/2084 on soybean MON 89788 and soybean A2704-12**

In February, EFSA published an assessment of requests Testbiotech had filed regarding soybean MON 89788 and soybean A2704-12. EFSA rejected Testbiotech’s claims regarding the necessity of new field trials reflecting the different management practices and meteorological and agronomic conditions under which soybean A2704-12 and soybean MON 89788 are expected to be grown, as well as new feeding studies with whole feed and food from these GM soybeans.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1805>

### **Public consultation on the GMO Panel draft scientific opinion on the evaluation of existing guidelines for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology**

EFSA has launched an open consultation on its draft scientific opinion on the evaluation of existing guidelines for the molecular characterisation and environmental risk assessment of genetically modified plants (GMPs) obtained through synthetic biology (SynBio). Comments can be submitted until 26 May.

<http://www.efsa.europa.eu/en/consultations/call/public-consultation-gmo-panel-draft-scientific-opinion-evaluation>

An external report regarding this subject was also published:

<http://www.efsa.europa.eu/en/supporting/pub/en-1687>

### **Public consultation on the draft EFSA Scientific Committee opinion “Evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of micro-organisms obtained through synthetic biology”**

EFSA’s Scientific Committee launched an open consultation on its draft opinion “*Evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of micro-organisms obtained through synthetic biology*”. Comments can be submitted until 26 May.

<http://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-efsa-scientific-committee-opinion>

An external report regarding this subject was also published:

<https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2020.EN-1664>

### **EFSA assessment of mixtures of multiple pesticides**

In April, EFSA published the results of two pilot assessments (regarding chronic effects on the thyroid and the acute effects on the nervous system) of risks posed by residues of multiple pesticides in food. The assessments are the first outputs regarding EFSA's new framework for the evaluation of "combined effects" of chemical mixtures in food and feed.

<https://www.efsa.europa.eu/en/news/pesticides-first-cumulative-risk-reports-published>

<https://www.efsa.europa.eu/en/press/news/190325>

### **Stakeholder workshop “Problem formulation for the environmental risk assessment of gene drive modified insects” (15 May 2019, Brussels)**

In March, EFSA published the outcomes of a workshop regarding risk assessment of gene drive modified insects. According to EFSA: *“Points raised by the workshop participants reveal different often contrasting opinions/perspectives toward gene drive and their risk assessment. Overall, there was agreement that the problem formulation process is fit-for-purpose for the environmental risk assessment of gene drive modified insects, but it was acknowledged that practical challenges may be encountered. Points raised by the workshop participants, on defining protection goals, formulating specific pathways to harm and on structuring risks, have been considered by EFSA's Panel on genetically modified organisms during its deliberations.”*

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1819>