



Testbiotech EU Newsletter 1/2020 (February 2020)

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

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Most important topics:

Presentation of RAGES project in Berlin and Brussels / Legal challenge to EU approval of GE plants / Peer-reviewed paper from RAGES project published / EU Commission authorises new GE plants

Current Issues and Activities

- International project RAGES presents its results: risk assessment of genetically engineered plants deemed insufficient
- Start of proceedings in legal challenge to EU approval of genetically engineered maize
- EURACTIV editorial: the EU dilemma with the GMO industry and independent risk research
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Current Issues and Activities

Results of international project RAGES: risk assessment of genetically engineered plants deemed insufficient

The RAGES project (Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland) was carried out between 2016 and 2019. It critically evaluated the risk assessment practice of genetically engineered (GE) food plants at the European Food Safety Authority (EFSA) and its Swiss counterpart. RAGES focused on the risks of transgenic plants intended for food production and also took some new methods of genetic engineering (genome 'editing') into account. ENSSER, its Swiss branch CSS (Critical Scientists Switzerland), GeneWatch UK and Testbiotech all contributed to the consortium of the project, which was funded by the Mercator Foundation Switzerland. Its final results are available online and were presented at the European Parliament in Brussels and the "Grüne Woche" in Berlin.

<https://www.testbiotech.org/en/press-release/risks-genetically-engineered-plants-wake-call>

Summary of RAGES findings: <https://www.testbiotech.org/node/2424>

The reports published by RAGES: <https://www.testbiotech.org/en/content/research-project-rages>

Start of proceedings in legal challenge to EU approval of genetically engineered maize MON87427 x MON89034 x 1507 x MON88017 x 59122

In November, Testbiotech filed a new legal challenge against EU approval for the import of genetically engineered maize. The General Court of the European Union confirmed the start of the proceedings (T-534/19) and asked the EU Commission for a response. The new legal challenge is levelled at the import approval for genetically engineered maize produced by Bayer (Monsanto). The maize is doubly resistant to the herbicides glyphosate and glufosinate. In addition, the plants themselves produce six insecticidal toxins. The combined toxicity of the insecticides and the residues from spraying the herbicides were not tested. Further, no feeding study was made available to test potential health effects of the maize at the stage of consumption. The 'stacked' maize was approved in December 2018.

<https://www.testbiotech.org/en/press-release/start-proceedings-legal-challenge-eu-approval-genetically-engineered-maize>

EURACTIV editorial: The EU dilemma with the GMO industry and independent risk research

In October, Testbiotech published a EURACTIV editorial on the EU regulation of genetically engineered plants. According to the text, the EU Parliament has in recent years adopted around 40 resolutions against further approvals for the import of genetically engineered (GE) plants. One of the criticisms was a lack of adequate and sufficient risk assessment. Experts from several member states raised similar criticisms. Nevertheless, the EU Commission gave the green light to all these imports. One reason for this undemocratic and scientifically questionable situation is a wide bias within the EU research landscape.

<https://www.testbiotech.org/en/news/euractiv-editorial-eu-dilemma-gmo-industry-and-independent-risk-research>

New EU Parliament speaks out against approvals for the import of genetically engineered plants

In October, the EU Parliament adopted three resolutions with a large majority against approvals for the import of genetically engineered maize and soybean. The resolutions were tabled by a cross party group of MEPS initiated by the Greens/EFA group. The resolutions call for higher standards in risk assessment and the strengthening of democratic decision-making. It is the first time that the new EU Parliament has dealt with this issue.

<https://www.testbiotech.org/en/news/new-eu-parliament-speaks-out-against-approvals-genetically-engineered-plants>

Drought-tolerant GE maize: rejected in South Africa but approved in the EU?

In October, the European Food Safety Authority EFSA gave the green light for the import of Bayer (Monsanto) GE maize which produces several insecticides; it has multiple resistance to glyphosate and is said to be drought-tolerant. However, experience with the cultivation of the GE crop plants is disappointing: they do not show any advantages in comparison to conventionally bred maize when grown in drought conditions. Recently, South Africa rejected the application of Bayer for the approval of another variation of the GE maize for cultivation because it “did not provide yield protection in water-limited conditions.” The decision on the EU import has not yet been taken. According to Testbiotech, approval cannot be given because the risks to health and the environment have not been sufficiently investigated.

<https://www.testbiotech.org/en/news/drought-tolerant-maize-rejected-south-africa-approved-eu%3F>

European Court of Justice does not request a more detailed investigation of risks of genetically engineered soybeans

In September, the European Court of Justice published its decision on a legal case filed by Testbiotech together with the European Network of Scientists for Social and Environmental Responsibility (ENSSER) and the environmental organisation Sambucus (C-82/17 P). The organisations are concerned about the risks connected with genetically engineered soybeans produced by Monsanto (Bayer) and sold under the brand name “Intacta”. According to the decision of the Court, the risks of the genetically engineered soybeans were investigated sufficiently before they were allowed for import. The organisations wanted to enforce higher standards for risk assessment of genetically engineered plants.

<https://www.testbiotech.org/en/press-release/european-court-justice-does-not-request-more-detailed-investigation-risks-genetically-engineered-soybeans>

Differences between conventional breeding and genetic engineering: an assessment of the statement made by the Group of Chief Scientific Advisors' (SAM)

Testbiotech commented on a 'Statement by the Group of Chief Scientific Advisors' (SAM), titled: "A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive". Testbiotech concluded that this statement needs to be revised, because many of the arguments used in the statement are insufficiently science-based. SAM also uses an array of arguments that are also repeatedly used by various other stakeholders and proponents of deregulation of GMOs derived from new methods of genetic engineering.

<https://www.testbiotech.org/node/2452>

Testbiotech comment on EFSA assessment of genetically engineered soybean MON87751 x MON87701 x MON87708 x MON89788 by Bayer/Monsanto

In December, Testbiotech commented on stacked soybean MON87751 x MON87701 x MON87708 x MON89788. Testbiotech concluded that the EFSA risk assessment cannot be accepted.

<https://www.testbiotech.org/node/2458>

EFSA opinion (November 2019): <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5847>

Testbiotech comment on EFSA statement complementing the scientific opinion on genetically modified maize 3272 by Syngenta

In December, Testbiotech published a comment regarding an EFSA statement complementing the scientific opinion on genetically modified maize 3272, which produces an artificial enzyme belonging the group of alpha-amylase. This enzyme (thermos-tolerant alpha-amylase AMY797E) is supposed to have a positive effect on the processing of the maize kernels at high temperatures, especially when intended for use in producing agro-fuels. The original EFSA opinion was published in 2013. However, it was found to be non-conclusive due to missing data. According to Testbiotech, the EFSA risk assessment is still not conclusive and no approval for import can be issued.

<https://www.testbiotech.org/node/2457>

EFSA opinion (September 2019): <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5844>

Testbiotech comment on EFSA assessment of maize MIR604 for renewal (Syngenta)

In December, Testbiotech published a comment regarding the EFSA opinion on maize MIR604. The maize expresses genes producing a synthetic, artificial version of Cry3A (mCry3A), which is especially toxic for *Coleoptera* species (such as the Western corn rootworm larvae, *Diabrotica virgifera virgifera*). According to Testbiotech, the EFSA risk assessment cannot be accepted. Beyond that, since MIR604 has to be considered to be a stacked event derived from the crossing two distinct lines of maize, data have to be requested on the parental plants. In the absence of such data, the market authorisation and the renewal application for the maize does not fulfil the standards required by EU law.

<https://www.testbiotech.org/node/2456>

EFSA opinion (November 2019): <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5846>

Testbiotech comment on EFSA assessment of genetically engineered maize MON87427 x MON89034 x MIR162 x MON87411 and subcombinations (Bayer/Monsanto)

In December, Testbiotech published a comment on an EFSA opinion regarding MON87427 x MON89034 x MIR162 x MON87411. The maize contains genes conferring double resistance to glyphosate and produces three insecticides, further it is supposed to render drought tolerance.

According to Testbiotech, the EFSA risk assessment is not conclusive and therefore, no market authorisation can be given.

<https://www.testbiotech.org/node/2455>

EFSA opinion (November 2019): <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5848>

Testbiotech comment on EFSA assessment of genetically engineered maize MON 87427 x MON87460 x MON 89034 x MIR162 x NK603 and subcombinations

Testbiotech published a comment on an EFSA opinion regarding the five-stacked maize MON 87427 x MON87460 x MON 89034 x MIR162 x NK603, which is derived from crossing genetically engineered maize events. The maize contains genes conferring triple resistance to glyphosate and produces three insecticides, further it is supposed to render drought tolerance. Testbiotech identified major gaps in the EFSA assessment.

<https://www.testbiotech.org/node/2411>

Scientific News

EU risk assessment of genetically engineered glyphosate-resistant crops is insufficient

According to a scientific paper published by experts from the RAGES project, there are already 72 types ('events') of genetically engineered plants currently allowed for import and usage in food and feed in the EU; they are also herbicide-resistant, especially glyphosate. The published results show that the amount of herbicide sprayed on the plants during the field trials specifically carried out for the approval process was much lower compared to what might be expected under current agricultural practice. Consequently, the plants assessed by European Food Safety Authority (EFSA) are not representative in real terms of the imported products. Therefore, the results from the risk assessment are not sufficiently reliable. Gaps in risk assessment not only concern the load of residues from spraying, but also overall plant composition and combinatorial effects that may impact health at the stage of consumption.

<https://www.testbiotech.org/en/press-release/new-scientific-publication-eu-risk-assessment-genetically-engineered-glyphosate>

Genetically engineered mosquitoes out of control

According to a new scientific publication, genetically engineered mosquitoes produced by Oxitec (Intrexon) have escaped human control after trials in Brazil. They are now spreading in the environment. The yellow fever mosquitos (*Aedes aegypti*) are genetically engineered to make it impossible for their offspring to survive. After release they were supposed to mate with female mosquitoes of the species which transmit infectious diseases, such as Dengue fever, to diminish the natural populations.

However, the now published research shows that many offspring of the genetically engineered mosquitoes actually survived and are spreading and propagating further.

<https://www.testbiotech.org/en/press-release/genetically-engineered-mosquitoes-out-of-control>

News from EFSA

Assessment of maize MON 89034 for renewal authorisation (Bayer)

On 25 September, EFSA published an opinion on maize MON 89034 for renewal authorisation. EFSA concluded that under the assumption “*that the DNA sequence of the event in maize MON 89034 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-015 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5845>

Authorisations

EU Commission authorises several genetically engineered plants

On 28 November, the EU Commission authorised eight genetically engineered plants. Market approval was given to

- maize MZHG0JG,
- maize MON 89034 x 1507 x NK603 x DAS-40278-9,
- maize MON 89034 x 1507 x MON 88017 x 59122 x DAS-40278-9, and
- maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21.

Further, the authorisations for soybean MON 89788, soybean A2704-12, cotton LLCotton25 and oilseed rape T45 were renewed.

https://ec.europa.eu/luxembourg/news/commission-authorises-eight-genetically-modified-products-food-and-feed-uses_fr