



Testbiotech EU Newsletter 1/2018 (July 2018)

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

Send a comment or subscribe: info@testbiotech.org

You can also find the newsletter at: www.testbiotech.org/en/eu_news

Unsubscribe: eu_news_en-leave@testbiotech.org

Most important topics:

Genetically engineered soybeans: General Court of the European Union strengthens the precautionary principle / Genome editing: Legal expert criticises opinion of Attorney General of the EuCJ / EFSA strengthens independence rules / Testbiotech Science Blog / Genetically engineered plants give rise to a new dimension in environmental risk

Overview of Topics

Current Issues and Activities

- Health risks of GMOs: General Court of the European Union strengthens the precautionary principle
- Opinion of the Attorney General of the EUCJ regarding genome editing (I): Threat of significant loopholes in EU regulation for genetically engineered organisms
- Opinion of the Attorney General of the EUCJ regarding genome editing (II): Legal expert criticises opinion of the Attorney General
- EFSA and industry united in 'EFSI'
- EFSA strengthens independence rules
- Testbiotech comment on maize 4114 (Pioneer DuPont)
- Testbiotech comment on maize MON 87403 (Monsanto)
- Testbiotech comment on cotton GHB614 x LLCotton25 x MON15985 (Bayer CropScience)
- Testbiotech comment on maize 5307 (Syngenta)
- Testbiotech comment on maize 1507 x 59122 x MON810 x NK603
- Testbiotech comment on oilseed rape MS8, RF3 and MS8×RF3
- Testbiotech publishes report on the amendment of EU Regulation 178/2002

Scientific news

- Experts confirm differences between genome editing and mutation breeding
- New “Science Blog” to analyse publications on the risks of genetically engineered organisms
- Feeding study with genetically engineered maize NK603 does not provide evidence of adverse effects on the health of rats
- Research reveals new dimension in environmental risk brought about by genetically engineered plants
- Data on 'Golden Rice' not sufficient to show health safety and indicate low benefits

News from EFSA

- GMO Panel: New members announced
- Literature review of baseline information on RNAi to support the environmental risk assessment of RNAi-based GM plants
- Annual post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in 2016
- Two EFSA publications on residues in glyphosate-tolerant crops
- Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin
- Assessment of genetically modified maize NK603 x MON810 for renewal of authorisation (Monsanto)

Authorisations:

- EU Commission grants authorisation for imports of genetically engineered soybeans

Current Issues and Activities

Genetically engineered soybeans: General Court of the European Union strengthens the precautionary principle

The General Court of the European Union confirmed the right of civil society organisations to submit legal cases concerning the health risks of genetically engineered plants. The case was prompted by market authorisation being issued for the import of genetically engineered soybeans produced by US companies Monsanto and DuPont/ Pioneer which, according to analysis undertaken by Testbiotech and other experts, have not been adequately investigated for health risks.

www.testbiotech.org/en/press-release/general-court-european-union-strengthens-precautionary-principle

Opinion of the Attorney General of the EUCJ regarding genome editing (I): Threat of significant loopholes in EU regulation of genetically engineered organisms

In January, the Advocate General of the EU Court of Justice publically declared his position on whether new methods of genetic engineering, known as gene editing, should come under EU GMO regulation. In his statement he did not address these new techniques, their applications and risks in detail. Instead, his

reasoning is largely based on very general, and in some cases, outdated categories, likely to lead to considerable legal uncertainty. In particular, the statement lacks a clear distinction between conventional breeding processes and the new techniques of gene editing which, for example, make use of the nuclease CRISPR-Cas. Consequently, Testbiotech is not expecting the forthcoming EU court ruling to put an end to the current debates on the regulation of new methods of genetic engineering.

www.testbiotech.org/en/news/threat-significant-loopholes-eu-regulation-genetically-engineered-organisms

Opinion of the Attorney General of the EUCJ regarding genome editing (II): Legal expert criticises opinion of the Attorney General

The well-known EU legal expert Professor Ludwig Kraemer analysed the position of the Attorney General (C-528/16) on behalf of Testbiotech. In his legal dossier, Professor Kraemer gives several reasons for criticising the position of the Attorney General.

www.testbiotech.org/en/press-release/genome-editing-legal-expert-criticises-opinion-attorney-general-eucj

EFSA and industry united in ‘EFSI’

A new publication discusses the risks of the uncontrolled spread of transgenes from genetically engineered maize grown in Spain. The paper is the result of close and ongoing collaboration between experts of EFSA (European Food Safety Authority) and the biotech industry: The main author, Yann Devos works for EFSA; one of the co-authors, Alan Raybould, works for Syngenta, which wants to sell its genetically engineered seeds for cultivation in Spain. Other EFSA experts were also involved in preparing the paper, including Elisabeth Waigmann, head of the GMO department at EFSA. Testbiotech has suggested naming this collaboration the “European Food Safety Industry” (EFSI) in order to highlight the unacceptable nature of such collusion.

www.testbiotech.org/en/news/efsa-and-industry-united-efsi

EFSA strengthens independence rules

In response to the Testbiotech letter on ‘EFSI’, the Executive Director of the European Food Safety Authority (EFSA), Bernhard Url, announced to “*ensure that in the future EFSA staff members will no longer co-author scientific publications with industry affiliated scientists*”. Now such co-authored publications will no longer be allowed. As EFSA writes in a letter received by Testbiotech, such cases “*may give rise to the perception of inappropriate proximity of staff members from EFSA to industry*”.

www.testbiotech.org/en/node/2236

Testbiotech comment on maize 4114 (Pioneer)

Testbiotech commented on an EFSA opinion on maize 4114 (Pioneer), which expresses Cry1F, Cry34Ab1 and Cry35Ab1 proteins.

www.testbiotech.org/node/2225

Testbiotech comment on maize MON 87403 (Monsanto)

Maize MON87403 is genetically engineered to increase biomass and yield through insertion of a truncated gene sequence derived from another plant species (*Arabidopsis thaliana*).

www.testbiotech.org/en/node/2210

Testbiotech comment on cotton GHB614 x LLCotton25 x MON15985 (Bayer CropScience)

Stacked cotton GHB614 x LL25 x MON15985 was produced by crossing genetically engineered cotton lines to make the stacked event resistant to glyphosate (GHB614) and glufosinate (LL25). Owing to further crossings with MON15985 cotton, the final stacked plants produce two insecticidal proteins (Cry1Ac and Cry2Ab2). In addition, the plants produce proteins that confer resistance to antibiotics (NPTII and AAD) as well as the GUS protein that was used as a histochemical marker during product development. According to Testbiotech, there are indications of substantial risks for animal and human health. Specific concerns were raised regarding the increased content of gossypol.

www.testbiotech.org/en/node/2209

Testbiotech comment on maize 5307 (Syngenta)

Maize 5307 produces a novel insecticidal protein classified as eCry3.1Ab, which is meant to kill corn rootworm effectively.

www.testbiotech.org/en/node/2205

Testbiotech comment on maize 1507 x 59122 x MON810 x NK603 (DowDuPont)

Testbiotech commented on EFSA's opinion on the assessment of DowDuPont genetically modified maize 1507 x 59122 x MON810 x NK603 and subcombinations.

www.testbiotech.org/en/node/2130

Testbiotech comment on oilseed rape MS8, RF3 and MS8×RF3

Oilseed rape MS8, RF3 and MS8×RF3 is resistant to the application of glufosinate. In addition, the plants express Barnase conferring male sterility, while RF3 expresses Barstar, restoring male fertility.

www.testbiotech.org/en/node/2131

Testbiotech publishes report on the amendment of EU Regulation 178/2002

In April 2018, the EU Commission submitted a proposal to amend EU Regulation 178/2002.

https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en

Testbiotech has published a legal opinion assessing the planned changes with regard to the precautionary principle. In addition, it analyses weaknesses and makes suggestions for improvement as well as developing new solutions and requirements.

www.testbiotech.org/node/2248

Scientific news

Experts confirm differences between genome editing and mutation breeding

In a publication jointly prepared by experts from the German regulatory authority (BVL) and US corporation DowDuPont, experts have explicitly confirmed significant differences between new methods of genetic engineering and conventional plant breeding. According to the publication, plants manipulated with methods

known as genome editing can be identified and traced in most cases. This position is in contradiction to previous BVL statements denying such differences.

www.testbiotech.org/en/node/2224

New “Science Blog” to analyse publications on the risks of genetically engineered organisms

Many experts claim there is “consensus” that genetically engineered plants are safe. At the same time, most of the publications on the risks of genetically engineered organisms are prepared for the biotech industry, or authored by experts who lack a certain critical distance to these companies. This is a major problem since any influence of companies with vested interests in the marketing of genetically engineered plants should be avoided when it comes to risk research of the relevant products. To aid informed debate, Testbiotech has therefore started a new science blog.

www.testbiotech.org/en/news/new-science-blog-analyse-publications-risks-genetically-engineered-organisms

Feeding study with genetically engineered maize NK603 does not provide evidence of adverse effects on the health of rats

An EU-funded research project known as G-TwYST conducted a two-year feeding trial with rats using genetically engineered maize resistant to glyphosate (NK603). According to the results which are not yet finally published, the diet fed to the rats did not trigger any clear signs of health effects. The study followed internationally agreed standards. However, it is not fully comparable with a previous rat feeding study using the same maize line: the G-TwYST study used a different rat strain and was designed differently to the original study.

www.testbiotech.org/en/news/feeding-study-genetically-engineered-maize-nk603-does-not-provide-evidence-adverse-effects

Research reveals new dimension in environmental risk posed by genetically engineered plants

Research from China has revealed a new dimension in environmental risk posed by genetically engineered plants: additionally inserted genes can enhance the potential for uncontrolled spread into the environment. There is now evidence to show that this is the case for glyphosate resistant plants. Where there is gene flow from the plants into the natural populations, the offspring will have increased fitness and can spread their transgenic DNA more effectively than assumed.

www.testbiotech.org/en/press-release/research-reveals-new-dimension-environmental-risk-posed-genetically-engineered-plants

Data on 'Golden Rice' not sufficient to show health safety and indicate low benefits

In 2016, the International Rice Research Institute (IRRI) filed an application at the Food Standards Australia New Zealand (FSANZ) for the market approval of food derived from so-called Golden Rice (GR2) for import. The rice is genetically engineered to produce provitamin A carotenoids; and the rice kernels are yellowish in colour. It is intended to be a fortified food with a high content of carotenoids, in particular, beta-carotene in the grains, to help combat vitamin A deficiency (VAD) especially in developing countries. According to a Testbiotech opinion, the risk assessment as performed by FZANZ is not sufficient to demonstrate safety of food derived from GR2.

www.testbiotech.org/en/news/data-golden-rice-not-sufficient-show-health-safety-and-indicate-low-benefits

GMO Panel: New members announced

EFSA announced new GMO Panel members on 15 May.

<https://ess.efsa.europa.eu/doi/doiweb/doisearch/panel/GMO/wg/684410>

Literature review of baseline information on RNAi to support the environmental risk assessment of RNAi-based GM plants

EFSA published a literature review regarding environmental risk assessment of RNAi-based GM plants on 28 May. The review concludes that currently there are major knowledge gaps on many issues, such as “*exposure, specificity, off-target effects, sequence similarities and bioinformatics.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1424>

Annual post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in 2016

EFSA published its annual monitoring report on cultivation of MON810 on 8 May. According to EFSA, “*no new evidence has been reported in the 2016 PMEM report that would invalidate previous EFSA evaluations on the safety of maize MON 810.*”

<https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5287>

Two EFSA publications on residues in glyphosate tolerant crops

EFSA published a “Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005” on 17 May 2018. In this review, the agency confirmed that the current glyphosate MRLs in place for crops, such as maize, sugar beet, oilseed rape and soybean. However, EFSA admits that valid data are missing for several crops species. “*For sugar beet roots, maize and soybeans (EPSPS modification), soybeans (GAT modification) and rapeseeds (GOX modification), the available data were insufficient to derive MRLs and risk assessment values.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5263>

In a second EFSA publication, EFSA evaluated the impact of glyphosate and its residues in feed on animal health. According to the agency, glyphosate (and its metabolite AMPA) “*are not expected to have an impact on the health of cattle and sheep (bovine and ovine species), equine, porcine and selected avian (poultry) species.*” Further, according to EFSA, the absence of adverse effects on the ruminal microflora was demonstrated for cattle and sheep even with high doses. EFSA has given no real data on the residue levels of glyphosate in glyphosate-tolerant crops, such as soybean and oilseed rape. Further, combinatorial effects are completely left aside.

In conclusion, the EFSA reports show substantial gaps in the risk assessment of glyphosate tolerant crops.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5283>

Assessment of genetically modified maize NK603 x MON810 for renewal of authorisation (Monsanto)

On 26 February 2018, EFSA published an opinion on maize NK603 x MON810 for renewal of authorisation. The GMO Panel concluded that there is “*no evidence in the renewal application EFSA-GMO-RX-007 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize NK603 x MON810.*”

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5163>

Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin

On 29 January 2018, EFSA published a note on crop-specific definitions of forage material of GM maize, soybean, sugar beet, rapeseed and cotton suitable for risk assessment, taking into account the specific parts of the plant likely to enter the feed chain and their stage of development at harvesting.

<https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1366>

Authorisation

EU Commission grants authorisation for imports of genetically engineered soybeans

The EU Commission has granted six further authorisations (soybean 305423 x 40-3-2, soybean DAS-44406-6, soybean FG72 x A5547-127, soybean DAS-68416-4, oilseed rape MON88302 x Ms8 x Rf3, renewal of Maize 1507) for genetically engineered plants, including some controversial genetically engineered soybeans with triple herbicide resistance. The decision to grant authorisation was made on the quiet by the EU Commission during the Christmas holiday period. Testbiotech had previously found that the real risks from consumption of these soybeans were not investigated.

www.testbiotech.org/en/press-release/eu-commission-uses-christmas-period-grant-authorisation-imports-genetically-engineered