



Testbiotech EU Newsletter 2/2017 (August 2017)

This newsletter provides an overview of current developments in the EU and related Testbiotech activities. The newsletter is published every three months and more often where appropriate.

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Most important topics:

Leading expert of EFSA – sponsored by Monsanto? / Activities regarding “Toxic soybeans” / 'Aliens' in Spain: Teosinte-maize hybrids are out in the fields / EU authorises five genetically engineered crops / EU Parliament against the approval of new genetically engineered soybeans

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- EU Parliament against the approval of new genetically engineered soybeans

Current Issues and Activities

Leading expert of EFSA – sponsored by Monsanto?

A number of emails published by US consumer attorneys show how Monsanto is secretly influencing European scientists behind the scenes in order to have their herbicide glyphosate declared as being non-carcinogenic. It seems that payments by Monsanto can be traced to a leading expert at the European Food Safety Authority (EFSA).

<http://www.testbiotech.org/en/node/2051>

Update: <http://www.testbiotech.org/en/node/2053>

Activities regarding “Toxic soybeans” (I): EU to decide on the import of new genetically engineered soybeans

In important votes on 12 and 17 July, EU Member States did not reach qualified majorities regarding the authorisation of new genetically engineered soybeans. The soybean plants produced by Bayer and Dow AgroSciences are engineered to be resistant to the application of three herbicides each. Consequently, the harvest will be burdened with the respective residues. Nonetheless, the European Food Safety Authority

EFSA has only partially assessed the residues of the herbicides and did not take combinatorial effects into account. According to the data available, consumption of the soybeans are likely to pose health risks.

<http://www.testbiotech.org/en/node/2031>

Activities regarding “Toxic soybeans” (II): Germany abstained in vote on import of new genetically engineered soybeans

In the vote on import approval for a new variety of genetically engineered soybeans in Brussels on 12 July, Germany was the only country which abstained.

<http://www.testbiotech.org/en/node/2037>

Activities regarding “Toxic soybeans” (III): Testbiotech files legal case against the EU authorisation of 'toxic soybeans' produced by Bayer & Monsanto

Testbiotech has filed a case at the General Court of the EU against authorisation for the import of genetically soybeans produced by Bayer and Monsanto. The soybeans sold under brand names, such as 'Balance GT' or 'Roundup Ready 2 Xtend Soybeans', can be sprayed with the herbicide glyphosate in combination with other herbicides e.g. isoxaflutole and dicamba. The combination of these herbicides and their residues from spraying were not assessed in respect to health risks. The case is registered under case number T-173/17.

<http://www.testbiotech.org/en/node/1957>

'Aliens' in Spain: Teosinte-maize hybrids are out in the fields

Analysis carried out by researchers at the ETH Zürich revealed that teosinte plants found in Spain cannot be grouped with any of the currently recognised teosinte taxa. Instead, these plants seem to be of mixed origin, most likely with teosinte and maize as parental plants. Experimental crosses indicate that there is ongoing hybridisation between teosinte growing in Spain and maize cultivated there.

<http://www.testbiotech.org/en/node/1961>

Glyphosate: Industry blackmailing the EU

The EU Commission has announced that it is planning to extend authorisation for glyphosate for a further ten years. The decision is based on the latest evaluation published by the European Chemicals Agency (ECHA) in March 2017, declaring glyphosate to be safe. However, it appears that banning the herbicide was never seriously considered. In fact, the EU Commission approved 14 new import authorisations for genetically engineered plants resistant to herbicides even while official discussions on the evaluation of glyphosate were still in progress.

<http://www.testbiotech.org/en/node/1995>

Testbiotech comment on EFSA opinion regarding herbicide-tolerant soybean DAS-44406-6 by Dow AgroSciences

Testbiotech published a comment on EFSA's opinion regarding soybean DAS-44406-6, which is made resistant to three herbicides, glyphosate, glufosinate and 2,4-D.

<http://www.testbiotech.org/en/node/1946>

Testbiotech comment on EFSA opinion on herbicide-tolerant soybean DAS-68416-4

Testbiotech published a comment on EFSA's opinion regarding soybean DAS-68416-4. This herbicide tolerant soybean expresses the AAD-12 protein, which confers tolerance to 2,4-D and other related phenoxy herbicides, and the PAT protein which confers tolerance to glufosinate ammonium based herbicides.

<http://www.testbiotech.org/en/node/1943>

Testbiotech comment on EFSA opinion on herbicide-tolerant soybean FG72 x A5547-127

Testbiotech published a comment on EFSA's opinion regarding soybean FG72 x A5547-127. The soybean was developed by Bayer and was made resistant to three herbicides: glyphosate, isoxaflutole and glufosinate.

<http://www.testbiotech.org/en/node/1975>

Testbiotech also published a short backgrounder on the general problems with risk assessment of herbicide resistant plants: http://www.testbiotech.org/sites/default/files/Testbiotech_Factsheet-Glyphosate_and_herbicide_resistant_plants-July_2017.pdf

Testbiotech comment on EFSA opinion on herbicide-tolerant oilseed rape MON 88302 x MS8 x RF3

Testbiotech published a comment on EFSA's opinion regarding oilseed rape MON 88302 x MS8 x RF3. This oilseed rape is genetically engineered to be resistant to the combined application of glyphosate and glufosinate and designed to withstand even higher dosages and even more frequent applications of herbicides. <http://www.testbiotech.org/en/node/1996>

New decisions on EU authorisations

EU authorises five genetically engineered crops

On 4 July, the EU Commission authorised the import of four new GE crops: cotton 281-24-236 x 3006-210-23 x MON 88913, cotton GHB 119, maize Bt11 x 59122 x MIR604 x 1507 x GA21 and maize DAS-40278-9. Authorisation for maize MON 810 was also renewed.

http://europa.eu/rapid/press-release_MEX-17-1908_en.htm

Vote on the import of genetically engineered soybean DAS-68416-4: no qualified majority

On 12 June, the Standing Committee on Plants, Animals, Food and Feed voted on the authorisation of soybean DAS-68416-4. No qualified majority was reached. On 12 July, the Appeal Committee voted on the soybean. Again, no qualified majority was reached. It is now up to the Commission to decide on the authorisation.

Vote on the import of genetically engineered soybean DAS-44406-6 and FG72 x A5547-127: no qualified majority

On 17 July, the Standing Committee on Plants, Animals, Food and Feed voted on the authorisation of soybean DAS-44406-6 and FG72 x A5547-127. No qualified majority was reached.

News from EFSA

Risk assessment of new sequencing information on genetically modified soybean event 40-3-2

On 7 August, EFSA published a report on new nucleic acid sequencing and updated bioinformatics data for soybean event 40-3-2 provided by the applicant. According to Monsanto, the sequence of soybean event 40-3-2 as present in the stacked soybean 305423 × 40-3-2 contains an additional nucleotide in the 5' flanking region of a 72 bp additional insert of CP4 EPSPS. According to EFSA, the new information does not give rise to safety issues.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4968/full>

Risk assessment of new sequencing information on genetically modified soybean event 305423

On 7 August, EFSA published a report on new nucleic acid sequencing data and updated bioinformatics data for soybean event 305423. The new data provided by Monsanto indicated a four base pair (bp) difference compared to the sequencing data originally provided: one bp located in the genomic 3' flanking region, two bp located in a gene silencing cassette and one bp in a partial promoter. According to EFSA, the new sequencing data and analyses performed on the new sequence did not give rise to safety issues

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4967/full>

Scientific Opinion on maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and sub-combinations by Monsanto

On 1 August, EFSA published an opinion regarding the authorisation of maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.

The five-event stack was made resistant to glyphosate, glufosinate and produces six Bt toxins Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1.

The GMO Panel concluded *“that the five-event stack maize is as safe and as nutritious as the non-GM comparator and tested non-GM reference varieties in the context of the scope of this application.”*

No experimental data were provided for 14 sub-combinations.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4921/full>

Contrary to the usual practice, no deadline has yet been published for public comments.

Scientific Opinion on maize MON 87427 × MON 89034 × NK603 and sub-combinations by Monsanto

On 1 August, EFSA published an opinion regarding the authorisation of the three-event stack maize MON 87427 × MON 89034 × NK603. The maize contains two genes for glyphosate resistance. Further, it produces the Bt toxins Cry1A.105 and Cry2Ab2. The GMO Panel concluded that *“the three-event stack maize is as safe and as nutritious as the non-GM comparator and the tested non-GM reference varieties”*.

However, no experimental data were provided for the two sub-combinations MON 87427 × MON 89034 and MON 87427 × NK603.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4922/full>

Comments can be posted here - the deadline for comments is 5 September:

https://ec.europa.eu/food/plant/gmo/public_consultations

Scientific opinion on maize 59122 by Pioneer and Dow AgroSciences

On 29 June, EFSA published an opinion regarding the renewal of authorisation for maize 59122. The GMO Panel concluded that “no new hazards or modified exposure and no new scientific uncertainties were identified that would change the conclusions of the original risk assessment on maize 59122.”

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4861/full>

New guidance for securing EFSA independence

The European Food Safety Authority (EFSA) published new guidance for securing its independence. Testbiotech is demanding substantial improvements: EFSA should prioritise more independence specifically in regard to curbing the influence of the agrifood industries. In this respect, the EFSA position should be to give preference to the interests of the general public and, more particularly, the protection of health and the environment.

<http://www.testbiotech.org/en/node/2009>

Guidance on allergenicity assessment of genetically modified plants

On 18 May, EFSA published new guidance regarding the allergenicity of genetically engineered plants.

Main findings are:

- For non-IgE-mediated adverse immune reactions to food: “detailed risk assessment considerations are provided to determine the safety profile of the protein or peptide under assessment with regard to its potential to cause celiac disease.”
- For in vitro protein digestibility tests: “the EFSA GMO Panel considers that additional investigations are needed before any additional recommendation in the form of guidance for applicants can be provided.”
- For assessing endogenous allergenicity of GM plants and to support the practical implementation of mandatory requirements in Implementing Regulation EU (No) 503/2013: “the guidance provides further information on: (i) relevant crops subjected to such analysis; (ii) relevant allergens that should be quantified; (iii) methodology to be used for quantification; and (iv) principles to be followed for data interpretation and risk assessment considerations.”

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4862/full>

A technical report was published on the “Outcome of the public consultation on the draft guidance on allergenicity assessment of genetically modified plants”.

<http://www.efsa.europa.eu/en/supporting/pub/1259e>

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

On 9 June, EFSA published an external review of information regarding risk assessment of RNAi plants.

Amongst others, main findings of the report are:

- “Mobile RNA silencing exists in plants and some animals.
- RNA silencing, and RNAi in particular, operates with unique (though not absolute) selectivity and is being explored in many different ways in biomedicine and biotechnology.
- In some cases, RNA silencing can spread across cellular boundaries, which can extend into systemic silencing. Systemic silencing is restricted to specific taxons and RNA silencing pathways. While the framework for understanding the molecular basis of systemic silencing in different model systems

was established, the knowledge is still fragmented and far from complete.

- Even less clear is the horizontal transmission of RNA silencing, especially into species, where primarily cell-autonomous silencing is expected.”

<http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN-1246/abstract>

Annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2015 from Monsanto

On 8 May, EFSA published its annual report regarding the post-market environmental monitoring of maize MON810. EFSA found similar “methodological shortcomings to those observed in previous annual PMEM reports on maize MON 810”.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4805/full>

EFSA opinion on application regarding glufosinate-ammonium and glyphosate-tolerant oilseed rape MON 88302 × MS8 × RF3 by Monsanto

On 10 April, the GMO Panel published an opinion regarding oilseed rape MON 88302 × MS8 × RF3. The GMO Panel concluded “*that the three-event stack OSR is as safe and as nutritious as its conventional counterpart and the tested non-GM reference varieties.*”

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4767/full>

Other

EU Parliament against the approval of new genetically engineered soybeans

The committee for the environment at the EU Parliament demanded that the import and use of a new variety of genetically engineered soybeans in food and feed was rejected. They maintain that residues left after spraying with specific herbicides to which the plants were resistant needed further and more detailed investigation before approval was given. The soybeans (DAS-68416-4) developed by the US company Dow can be sprayed with a combination of 2,4-D and glufosinate.

<http://www.testbiotech.org/en/node/2035>

The Parliament made clear that risk assessment of genetically herbicide resistant plants (in resolution HT GMHP) cannot be separated from the risk assessment of the complementary herbicide and called “on the Commission to fully integrate the risk assessment of the application of the complementary herbicides and their residues into the risk assessment of HT GMP, regardless of whether the genetically modified plant is for cultivation in the Union or for import for food and feed.”

<http://www.testbiotech.org/sites/default/files/ENVI%20resolution%20objecting%20to%20GM%20soybean%20DAS-68416-4%20July%202017.pdf>