



Testbiotech EU Newsletter 3/2017 (December 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:

Activities regarding triple herbicide resistant soybeans / EFSA gives details of Monsanto sponsoring / New papers on herbicide resistance genes and combinatorial effects / EU Member States agree on glyphosate renewal

Overview of Topics

Current Issues and Activities

- “Toxic soybeans” I: EU member states fail to stop authorisation of new genetically engineered 'toxic soybeans'
- “Toxic soybeans” II: EU Parliament against granting approval for genetically engineered soybeans resistant to three herbicides
- “Toxic soybeans” III: Testbiotech accuses companies of manipulating risk assessment
- Monsanto Sponsoring: EFSA gives details
- Testbiotech comment on maize MON 87427 × MON 89034 × NK603
- Testbiotech comment on MON 87427 x MON 89034 x 1507 x MON 88017 x 59122

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- Critical review of EFSA assessments of combinatorial effects
- Review study on environmental and health effects of glyphosate
- New information regarding herbicide resistant gene bar

News from EFSA

- Assessment of genetically modified maize 1507 × 59122 × MON810 × NK603 and subcombinations for food and feed use
- Assessment of genetically modified oilseed rape MS8, RF3 and MS8×RF3 for renewal of authorisation
- Guidance for the risk assessment of the presence at low levels of genetically modified plant material in imported food and feed
- Assessment of genetically modified sugar beet H7-1 for renewal of authorisation
- Assessment of genetically modified maize GA21 for renewal of authorisation

Other

- EU Member States agree on glyphosate renewal – Resistance growing in EU Parliament

Current Issues and Activities

“Toxic soybeans” I: EU member states fail to stop authorisation of new genetically engineered 'toxic soybeans'

In votes taken in September and October by EU member states, no qualified majority was reached to stop the authorisation of new genetically engineered soybeans produced by Bayer and Dow AgroSciences. These companies want the EU to approve two new genetically engineered soybeans for import and usage in food and feed. Both these new soybean plants have been engineered to be resistant to three herbicides known to leave residues in the harvest.

www.testbiotech.org/en/node/2070

Testbiotech video clip on this subject: www.testbiotech.org/en/limits-to-biotech/toxic-soy

“Toxic soybeans” II: EU Parliament against granting approval for genetically engineered soybeans resistant to three herbicides

The EU Parliament is calling for the rejection of approval for import and use in food and feed for genetically engineered soybeans resistant to three herbicides. The resolution was passed by the European Parliament in October.

www.testbiotech.org/en/node/2098

“Toxic soybeans” III: Testbiotech accuses companies of manipulating risk assessment

According to a Testbiotech analysis, there are clear indications that the companies Dow and Bayer manipulated the data for risk assessment of their genetically engineered soybeans. The claim is based on analysis of the data presented by the companies for risk assessment in the EU. Analysis showed that Dow used a special sample of the genetically engineered soybeans in their feeding studies with rats, which was sprayed with much lower amount of herbicides than usual. In their field trials, Bayer only applied a fraction of the amounts of the herbicides that would normally be used in agricultural practice. The European Food Safety Authority EFSA only just this week and after a long delay made relevant documents on risk

assessment available. Testbiotech is demanding that EU approval is stopped.

www.testbiotech.org/en/node/2124

Most recent version of the background on the risks of genetically engineered soybeans:

www.testbiotech.org/node/2066

Monsanto Sponsoring: EFSA gives details

In a letter to Testbiotech, the European Food Safety Authority (EFSA) has confirmed that there was an offer to sponsor a trip for a leading expert at the authority. According to present knowledge, the US company Monsanto made this offer via a straw man. It was meant to cover the travel costs of a trip to a conference in the USA where there was to be a discussion on the risks of glyphosate. According to the chair of the EFSA management board, Jaana Husu-Kallio, the authority sent one of their employees to the conference, but the offer of sponsorship was rejected.

www.testbiotech.org/en/node/2103

Previously EFSA had rejected any suggestion that the participation of any of its experts in a conference was indirectly funded by Monsanto. In a letter sent to Testbiotech, EFSA did not answer any of the crucial questions contained in a letter sent to them by Testbiotech.

www.testbiotech.org/en/node/2061

Testbiotech comment on maize MON 87427 × MON 89034 × NK603

Testbiotech commented on an EFSA opinion on maize MON 87427 × MON 89034 × NK603 and subcombinations produced by Monsanto. Testbiotech found that EFSA's opinion should be rejected. For example, EFSA did not request any data regarding possible toxicity and impact on the immune system. For several subcombinations, no data were requested at all.

www.testbiotech.org/node/2095

Testbiotech comment on MON 87427 x MON 89034 x 1507 x MON 88017 x 59122

Testbiotech commented on an EFSA opinion on maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 and subcombinations produced by Monsanto. According to Testbiotech's assessment, EFSA did not request any empirical data regarding toxicity and impact on the immune system, and did not name the knowledge gaps or uncertainties. Combinatorial effects were ignored as well as the consequences of higher dosage of glyphosate applications.

www.testbiotech.org/node/2116

Scientific news

Critical review of EFSA assessments of combinatorial effects

In a newly published paper ("Criticism of EFSA's scientific opinion on combinatorial effects of 'stacked' GM plants"), author Thomas Bøhn reviewed the risk assessment of so-called stacked events carried out by EFSA. Bøhn and other scientists had earlier found that combinatorial effects of Bt toxins and glyphosate in

Daphnia magna had not been adequately addressed by the EFSA GMO Panel. However, EFSA dismissed these peer-reviewed results. In his reply to EFSA, Bøhn argues that EFSA does not carry out proper assessments of combinatorial effects of different Cry-toxins or Cry-toxins together with one or more herbicides.

www.sciencedirect.com/science/article/pii/S0278691517306907

Review study on environmental and health effects of glyphosate

A new review, “*Environmental and health effects of the herbicide glyphosate*” was published in the journal *Science of The Total Environment*. The authors review the scientific literature on the movement and residues of glyphosate and its breakdown product aminomethyl phosphonic acid (AMPA) in soil and water, their toxicity to macro- and microorganisms, their effects on microbial compositions and potential indirect effects on plant, animal and human health. Whereas direct health effects for humans are still disputed (as reflected in the dispute between IARC, EFSA and others), the paper concentrates on less prominently discussed effects like shifts in microbial community composition in soil, plants and animals. For example, they claim a connection between glyphosate usage and antibiotic resistance. In conclusion, the authors suggest that the problems associated with the large scale and intensive use of glyphosate are not properly reflected in the risk assessments of regulatory agencies.

www.sciencedirect.com/science/article/pii/S0048969717330279

New information regarding herbicide resistant gene bar

A recent study published in *Nature Plants* (“*Non-specific activities of the major herbicide resistance gene BAR*”) sheds light on unintended effects caused by the usage of herbicide resistance genes in genetically engineered plants. Researchers from USA and Switzerland found that the widely used herbicide resistance gene bar, which produces a protein that renders plants tolerant towards glufosinate-ammonium, also produces two new enzymes, acetyl-aminoadipate and acetyl-tryptophan. These findings came as a surprise, as the bar gene has been used in transgenic plants for decades without any hint that it may interfere with plant metabolism. Tests also revealed that accumulation of the newly produced enzymes can be found in all plant species that were created in the experiments, such as soybean, canola, mustard and wheat. According to the authors, acetyl-tryptophan is a naturally occurring metabolite in different plant species. However, acetyl-aminoadipate has never been reported as a plant metabolite before. As several transgenic crops containing the bar gene are authorised in the EU, the results of the study should lead to further investigations regarding possible risks and a re-evaluation of EFSA’s risk assessment of the events in question.

www.nature.com/articles/s41477-017-0061-1

News from EFSA

Assessment of genetically modified maize 1507 × 59122 × MON810 × NK603 and subcombinations, for food and feed uses

On 28 November, the GMO Panel published an opinion on insecticidal and herbicide tolerant maize 1507 × 59122 × MON810 × NK603. EFSA comes to the conclusion that “*the four-event stack maize is as safe and*

as nutritious as its non-GM comparator”.

www.efsa.europa.eu/en/efsajournal/pub/5000

Assessment of genetically modified oilseed rape MS8, RF3 and MS8×RF3 for renewal of authorisation

On 28 November 2017, EFSA published an assessment regarding the application for renewal of authorisation of glufosinate tolerant oilseed rape MS8, RF3 and MS8×RF3. The GMO Panel concluded *“that there is no evidence in the context of this renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape MS8, RF3 and MS8×RF3.”*

www.efsa.europa.eu/en/efsajournal/pub/5067

Guidance for the risk assessment of the presence at low levels of genetically modified plant material in imported food and feed

On 20 November 2017, EFSA published new guidance regarding risk assessment of low level presence of genetically engineered plants in imported food and feed (www.efsa.europa.eu/en/efsajournal/pub/5048). The guidance is intended to indicate some basic scientific requirements considered necessary for risk assessment. The main points recommended by EFSA are:

- Characterisation of the transformation event and of its intended effects;
- On a case-by-case basis, a targeted compositional analysis should be requested;
- The possible cumulative contribution to an ingredient from various genetically modified plants and derived products present at low level and showing similar traits should be considered.
- Comparative analysis studies of the genetically engineered plant and 90-day toxicity studies in rodents on the whole food and feed are not considered as necessary by EFSA.

A technical report, *“Outcome of the European Member States and Public consultations on the draft guidance”*, can be found here:

www.efsa.europa.eu/en/supporting/pub/1329e

Assessment of genetically modified sugar beet H7-1 for renewal of authorisation

On 16 November, EFSA published an opinion regarding the renewal of authorisation of glyphosate-tolerant sugar beet. The GMO Panel concluded that *“there is no evidence in the context of this renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on sugar beet H7-1.”*

www.efsa.europa.eu/en/efsajournal/pub/5065

Assessment of genetically modified maize GA21 for renewal of authorisation

On 24 October, EFSA published an assessment regarding the renewal of authorisation of glyphosate tolerant maize GA21. The GMO Panel concluded that *“there is no evidence in the renewal application EFSA-GMO-RX-005 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize GA21.”*

www.efsa.europa.eu/en/efsajournal/pub/5006

Other

EU Member States agree on glyphosate renewal – Resistance growing in EU Parliament

On 27 November, the Standing Committee voted on the renewal of authorisation of glyphosate. A qualified majority of Member States agreed on a 5 year extension. On 12 December, the EU Commission decided to prolong the authorisation for another 5 years.

However, resistance against this decision is growing in the EU Parliament. A new report commissioned by the Green party at the European Parliament and drawn up by former UN Special Rapporteur on the right to food, Oliver De Schutter, questions the rightfulness of the Commission's Implementing Regulation regarding the authorisation.

According to the report, the Commission's Implementing Regulation is unlawful and should be annulled by the European Court of Justice.

<http://extranet.greens-efa-service.eu/public/media/file/1/5422>