



Testbiotech EU Newsletter 2/2016 (July 2016)

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. It is supported by the Software AG Foundation.

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Current Issues and Activities

Court Case 1: Case against the authorisation of Monsanto genetically engineered Intacta soybeans at the EU Court of Justice

On 12 May, a hearing on legal action brought against the import of the genetically engineered Monsanto soybeans (T-77/13) was held at the Court of Justice of the EU (CJEU). MON87701 x MON89788 soybeans were authorised in the EU for use in food and feed. They are grown predominantly in Brazil and sold under the brand name Intacta. These plants have a unique combination of two genetically engineered traits: They express a so-called insecticidal Bt toxin and are resistant to the herbicide glyphosate, commonly known under trade names such as Roundup. According to the complainants, the European Food Safety Authority (EFSA) has failed to carry out the legally required risk assessments for these genetically engineered soybeans: Amongst others, the combinatorial effects between the residues from spraying with glyphosate and the insecticide were not investigated. Further, there are indications that these soybeans pose risks to the immune system. Therefore, the EU Commission should not have given permission for the marketing of derived products (www.testbiotech.org/en/node/1639).

Court Case 2: Testbiotech takes EU Commission to court over genetically engineered soybeans which have not been adequately tested

The EU Commission wants to prevent Testbiotech from initiating a legal revision of a decision to allow the import of genetically engineered soybeans. This move by the Commission is in contradiction to previous decisions and Testbiotech has now initiated a precedent case at the Court of Justice of the EU (CJEU) to gain access to justice (T-33/16). This action 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 as far as health risks are concerned (www.testbiotech.org/en/node/1603).

Patent case 1: Opposition against a patent on genetically engineered primates

Testbiotech has filed an opposition against Patent EP2328918 issued to the Max Planck Society, based in Munich. This patent claims genetically engineered animals, even including primates as “inventions”. Testbiotech believes the patent constitutes an unacceptable violation of ethical boundaries. In a letter to the president of the Max Planck Society, Testbiotech is now arguing that the publicly funded German research institution should take a leading role in protecting the interests of civil society, and initiate changes to the patent of its own accord (www.testbiotech.org/en/node/1635).

Patent case 2: Appeal against patents on genetically engineered chimpanzees

The next round in the legal battle against patents held by a US company on genetically engineered chimpanzees has now started. After the European Patent Office (EPO) rejected joint oppositions against patents EP1572862 and EP1456346, the opponents are appealing the decision. Intrexon has claimed genetically engineered mice, rats, rabbits, cats, dogs, cattle, pigs, horses, sheep and even chimpanzees as its invention. The animals are supposedly manipulated with some kind of 'gene switch' that targets gene activity in the mammals. The crucial concern of the appellants: Patents on genetically engineered animals provide incentives to perform unnecessary animal experiments for commercial purposes.

Conflicts of interest played down by the European Food Safety Authority (EFSA)

In an open letter to the EFSA Management Board, Testbiotech and GeneWatch UK are urging them to take measures to safeguard the independence of the European Food Safety Authority (EFSA) and restore its credibility. The reasons for this are recent cases of conflicts of interest. The cases were brought to the attention of EFSA's executive Director Bernhard Url in March. However, the response from Mr Url does not

express much interest in sorting these problems out. For example, he believes the involvement of EFSA experts in the International Society for Biosafety Research (ISBR) is accidental and within the “normal range of activities performed by a scientist”. The work of ISBR is funded by Bayer, ILSI, CropLife, DuPont/Pioneer, Dow, Monsanto and Syngenta. One of the staff members of EFSA, involved in risk assessment of genetically engineered plants, is even member of the Board of Directors at ISBR (www.testbiotech.org/en/node/1666).

Glyphosate assessment: Testbiotech requests that experts with strong affiliations to industry are removed from the FAO/WHO panel

In a letter to the World Health Organisation (WHO), Testbiotech has requested that experts with strong affiliations to industry are removed from the Joint Meeting on Pesticide Residues (JMPR). Furthermore, the standards for avoiding conflict of interests within this body need to be raised substantially. The letter was written and sent in response to a recent assessment of the herbicide glyphosate carried out by the JMPR. As evidenced by the Testbiotech letter, the chair of the task group of the JMPR, Alan Boobis, and the rapporteur Angelo Moretto, are both well-known for their close affiliations with industry (www.testbiotech.org/en/node/1651).

In a meeting of the EU Member States on glyphosate, which was held on June 24, no qualified majority could be reached by voting. In reaction, the EU Commission decided to extend the authorisation for 18 months. Within this period of time, the EU Chemicals Agency ECHA is supposed to come up with its assessment.

Transgenic maize in Spain could spread uncontrollably / Spanish government does not respond to contamination risk

In a letter to civil society organisations (CSOs), the Spanish government states that they have, as yet, not taken any measures to prevent genetically engineered maize MON810 from spreading into wild populations of teosinte (www.testbiotech.org/en/node/1676). Teosinte is an alien species that has been found growing in Spain in recent years. It is a wild relative of maize and native to Mexico. Crossings between teosinte and maize can enable transgenes from genetically engineered maize to spread and persist in the environment. Maize MON810 produces an insecticide and is grown on more than 100.000 hectares in Spain. The civil society organisations informed the EU Commission several months ago about the outbreak of teosinte. Only now has the EU Commission said it is aware of the problem and that the data should be assessed by the European Food Safety Authority (EFSA) (www.testbiotech.org/en/node/1676). As the organisations had discovered earlier, neither Monsanto nor the EFSA have made any mention of the spread of teosinte and its possible implications (www.testbiotech.org/en/node/1623).

In another letter, civil society organisations are raising gaps in risk assessment as further reasons to stop cultivation of Bt maize in the EU (www.testbiotech.org/node/1682).

Testbiotech comment on transgenic cotton 281-24-236 × 3006-210-23 × MON 88913

Testbiotech commented on an EFSA scientific opinion on an application for the placing on the market of food, feed and other products containing or consisting of genetically modified herbicide tolerant and insect resistant cotton 281-24-236 × 3006-210-23 × MON 88913. This cotton was developed to confer resistance to lepidopteran target pests and tolerance to glyphosate-based herbicides. In its comment, Testbiotech states that the EFSA risk assessment is based to a large extent on assumptions instead of valid data. Testbiotech comes to the conclusion that risks cannot be assessed properly and market authorisation for import and usage in food and feed cannot be given (www.testbiotech.org/node/1641).

New report on flaws of risk assessment of EFSA's risk assessment of genetically engineered plants used for food & feed production

At present, there is a controversy in the EU as to whether feeding trials with genetically engineered plants have to be conducted before the plants are granted market authorisation. Both the biotech industry and EFSA experts are pushing for these feeding trials not to be mandatory. They are demanding the withdrawal of a regulation requesting 90-day feeding trials that was only very recently introduced by the EU Commission. This is the background against which Testbiotech is publishing its new report providing an overview of the risks of genetically engineered plants for humans and animals, and showing that current regulations are completely inadequate (www.testbiotech.org/node/1668).

Scientific News

Combinatorial effects of Bt toxins and glyphosate on non-target organisms

A new study exposed waterflea (*Daphnia magna*), an important organism in aquatic ecosystems, to different Bt toxins. Animals exposed to high doses of Cry1Ab and Cry2Aa and the combination of both showed higher mortality, smaller body size and very low juvenile production compared to controls. Moreover, exposure to two Cry toxins gave stronger effects in combination. When the herbicide Roundup was added, toads showed stronger early reproductive output, but rapid mortality later on. The study thus raises concern of combinatorial effects of different Bt toxins in genetically engineered plants, as present in stacked events. It further shows further studies are warranted regarding combinatorial effects of multiple Cry-toxins and herbicides that co-occur in the environment (www.sciencedirect.com/science/article/pii/S0278691516300722).

Combinatorial effects of dicamba and glyphosate on amphibians

A new study by Argentine researchers shows that dicamba and glyphosate herbicide formulations cause genetic damage in the larvae of a toad species (*Rhinella arenarum*), when used separately. The study also found that dicamba and glyphosate formulations applied together have a synergistic effect in causing DNA breaks in blood cells of the toad larvae. Glyphosate and dicamba may be used together on Monsanto's Roundup Ready Xtend GM soybeans (MON87708 x MON89788) (<https://link.springer.com/article/10.1007/s11356-016-6992-7>).

News from EFSA

EFSA opinion on oilseed rape MS8 × RF3 × GT73

On 20 May, EFSA published a scientific opinion on an application by Bayer CropScience and Monsanto for placing on the market of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MS8 × RF3 × GT73 (www.efsa.europa.eu/en/efsajournal/pub/4466). Because of the absence of data, EFSA could not complete the risk assessment for products rich in protein, such as rapeseed protein isolates. According to EFSA, the authority is therefore not in a position to complete the food and feed safety assessment of subcombinations within the scope of this application (i.e. MS8 × GT73 and RF3 × GT73).

EFSA opinion on prohibition of oilseed rape GT73 in Austria

On 12 April, EFSA published scientific opinions regarding the "Prolongation of the market prohibition of GM oilseed rape GT73 in Austria" (www.efsa.europa.eu/en/supporting/pub/1022e) and the "Prolongation of the market prohibition of GM oilseed rape Ms8, Rf3 and Ms8×Rf3 in Austria". (www.efsa.europa.eu/en/supporting/pub/1021e). In both cases, the GMO Panel concluded that Austria presented no specific scientific evidence in terms of risk to the environment that would support the prohibition of oilseed rape GT73.

EFSA opinion on 2014 monitoring report on Monsanto's maize MON 810

On 12 April, the GMO Panel also published its opinion on the annual 2014 post-marketing environmental monitoring (PMEM) report on Monsanto's maize MON 810 (www.efsa.europa.eu/en/efsajournal/pub/4446). For details see above.

EFSA opinion on cotton 281-24-236 × 3006-210-23 × MON 88913

On 8 April, EFSA published a scientific opinion on GM cotton 281-24-236 × 3006-210-23 × MON 88913 (www.efsa.europa.eu/en/efsajournal/pub/4430). For details see above.

EFSA opinion on carnation FLO-40685-2 cut flowers

On 7 April, EFSA published an opinion on “Carnation FLO-40685-2 cut flowers for import in the EU for ornamental use” (www.efsa.europa.eu/en/efsajournal/pub/4431). The panel comes to the conclusion that the import, distribution and retailing of the GM carnation will not cause adverse effects on human health or in the environment.

EFSA working on risk assessment of chemical mixtures

EFSA and the Dutch Competent Authority hosted a conference on the effects of chemical mixtures (e.g. pesticides) on health and ecosystems. EFSA now has set up a working group to develop guidance aimed at harmonising methodologies for assessing the human and ecological risks posed by exposure to multiple chemicals (www.efsa.europa.eu/en/press/news/160608b).

EFSA to trial uncertainty toolbox

EFSA's Scientific Committee developed guidance on how to characterise, document and explain uncertainties in risk assessment. This should cover uncertainties at the various steps of risk assessment, i.e. hazard identification and characterisation, exposure assessment and risk characterisation (www.efsa.europa.eu/en/press/news/160321). According to EFSA, the new guidance will now be tested in some of the authority's opinions.

Report on ‘the identification of food safety priorities using the Delphi technique’

A study commissioned by EFSA to prioritise future work in the area of food safety has identified 28 key topics which will be essential for future risk assessment in the EU. Amongst the 28 topics, Ribonucleic acid interference (RNAi) applied to food producing organisms as pesticide, or newly expressed trait in genetically modified crops, as well as cumulative exposure assessment (e.g. for pesticide residues) were named as urgent topics that need better assessment (www.efsa.europa.eu/en/press/news/160331).

Other

EU Parliament: MacIntyre report

The European Parliament adopted a report calling for technology-based agriculture. An earlier draft of this report had also contained passages on new genetic techniques such as CRISPR. MacIntyre had proposed to classify such techniques not as genetic engineering but as a "smart breeding". That argument was not followed by the Parliament (www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2016-0251+0+DOC+XML+V0//DE).