



Testbiotech EU Newsletter 1/2016 (March 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

New call to “Stop the toxic soybeans”

Testbiotech renewed its call to stop the approval process for market authorisation of herbicide resistant genetically engineered soybeans produced by Bayer (FG72) and Monsanto (MON87708 x MON89788) (www.testbiotech.org/en/node/1548). These soybean varieties can all be sprayed with a combination of herbicides, such as glyphosate together with dicamba or isoxaflutole. According to a recent toxicological dossier (www.testbiotech.org/node/1532), the mixtures of these residues are thought to cause adverse effects on health, such as genotoxicity, liver toxicity and tumours. EU authorities have never assessed the combined toxicity of the herbicides. In a letter to Testbiotech from January 2016, the Commission admits that “it is true that the legislation requires cumulative and synergistic effects of pesticide residues to be considered”. It also states that methods to assess these health effects are not yet available. In February 2016, EFSA published its peer review of the pesticide risk assessment of the active substance isoxaflutole (www.efsa.europa.eu/en/efsajournal/pub/4416). This has only served to heighten previous concerns since:

- Carcinogenicity and developmental toxicity were confirmed for the active substance.
- In soybean seeds three different metabolites of isoxaflutole were found, most of them at higher levels compared to uses in other crops.
- Risk assessment for food and feed could not be concluded, and no maximum residue level (MRL) could be determined due to lack of data.
- There were further data gaps concerning the method for the determining residues in food and feed of plant origin.

Online petition: www.testbiotech.org/en/campaign_toxic_soy

On 3 February, the European Parliament also called for a stop to the authorisation of herbicide resistant soybeans citing concerns regarding the possible carcinogenicity of glyphosate (www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2016-0039&language=EN&ring=B8-2016-0134, www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2016-0040&language=EN&ring=B8-2016-0135, www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2016-0038&language=EN&ring=B8-2016-0133)

Teosinte found spreading in Spain

Testbiotech, together with other civil society organisations have alerted the European Commission that the wild ancestor of cultivated maize, teosinte, has appeared in Spain and is spreading widely in maize growing areas as an invasive species. Teosinte and maize have the potential to interbreed and form hybrids. This applies equally to genetically engineered maize MON810, produced by Monsanto and grown on more than 100,000 hectares in Spain. Due to the risks of appearance of an invasive, transgenic teosinte species, the organisations have asked the Commission and the Spanish government to ban the cultivation of MON810 in 2016.

Biotech industry has massive influence on EU research projects investigating the risks of genetically engineered plants

A Testbiotech report shows that the biotech industry has not only systematically influenced the EU funded GRACE research project, which has conducted feeding trials with genetically engineered plants on rats and reviewed existing publications on risk research, but four other similar EU research projects. All of the coordinators of these projects are part of a close network of institutions that are funded by industry. In June 2016, the EU Commission wants to take a decision on further standards of risk assessment for genetically engineered plants. The Commission will be referring to the outcome of the GRACE project. Testbiotech is warning that there is a substantial risk that the EU Commission will come to false conclusions, and could fail to set sufficiently robust standards to maintain the precautionary approach as required by EU regulations (www.testbiotech.org/en/node/1438).

German authorities biased in their assessment of new methods of genetic engineering

In 2015 Testbiotech together with other organisations started a petition against the cultivation of the herbicide resistant oilseed rape produced by the US company CIBUS. The plants were produced using methods that are commonly known as gene editing. The German Federal Office of Consumer Protection and Food Safety (BVL) had already given the go-ahead to the cultivation of these plants, which were not classified as genetically engineered. This assessment was later contradicted by two legal dossiers. Now the EU Commission wants to decide upon these regulatory questions. In this context, Testbiotech published a background on the BVL decision-making process and the underlying legal questions (www.testbiotech.org/en/node/1449).

Testbiotech in hearings at the European Parliament on genome-editing in plants and animals

There has been much debate for several years now on new methods of genetic engineering that can be collectively termed 'gene editing' and used for plants and animals in food production. As two recently published legal dossiers show, these techniques are definitely covered by EU Directive 2001/18. If the new techniques were to be exempted from regulation, all plants and animals derived from them could enter the market without risk assessment and labelling, thus undermining the protection goals of EU regulation. Testbiotech gave input on this subject at hearings at the European Parliament and published further background informations (testbiotech.org/en/node/1453, www.testbiotech.org/en/node/1570).

Last exit before the Frankenstein-Zoo? Report on genetically engineered animals

A new Testbiotech report on genetically engineered animals, commissioned by the Green Group in the German Bundestag, provides a comprehensive overview of planned applications, the risks for human health and the environment and the consequences for agriculture. According to the report, most of the planned applications such as increasing the amount of milk or changing its composition in dairy cattle, increasing the amount of meat in other livestock or the release of genetically engineered insects are highly questionable from a technical point of view (testbiotech.org/en/node/1537).

Testbiotech comment on EFSA opinion on Syngenta herbicide tolerant and insect resistant maize Bt11 × MIR162 × MIR604 × GA21

Testbiotech published a comment on EFSA's opinion on Syngenta maize Bt11 × MIR162 × MIR604 × GA21. Testbiotech came to the conclusion that no final risk assessment is possible based on the data presented. Consequently, the application should be rejected (www.testbiotech.org/en/node/1551).

Scientific News

New publication on glyphosate use

A new study on glyphosate use in the USA and worldwide was recently published in the peer reviewed journal *Environmental Science Europe* (<http://enveurope.springeropen.com/articles/10.1186/s12302-016-0070-0>). The paper by agricultural scientist Charles Benbrook shows a massive rise in glyphosate use over the last few decades. The data also shows the impact of glyphosate tolerant crops. According to the study, 56% of current glyphosate use can be attributed to genetically engineered crops such as maize, soybeans, cotton or oilseed rape that have been engineered to be resistant to glyphosate.

Toxicological dossier on the combinatorial effects of pesticides

A toxicology dossier published today assessing herbicides sprayed onto genetically engineered soybeans has revealed some alarming results. Residues originating from a combination of glyphosate with dicamba or isoxaflutole show a higher risk of serious detrimental health effects such as genotoxicity, liver toxicity and tumours than each of the single substances. Combinations of these herbicides are regularly applied to new genetically engineered soybean varieties produced by Monsanto and Bayer (www.testbiotech.org/node/1532).

Diseased animals - but genetically engineered plants are safe?

Several new publications on the outcomes of feeding genetically engineered plants to cattle and goats have triggered a new controversial debate about the impact on the health of animals. One new publication documents the case of a German farm where dairy cows died after being fed with genetically engineered plants. Although this happened about 15 years ago, the real causes are still cause for controversy. Publications documenting the health impact on the offspring of goats fed with genetically engineered soybeans are currently gaining international attention, after some doubts were raised about the quality of the publications. Apparently some of the figures used in the publications were used several times (www.testbiotech.org/en/node/1554).

News from EFSA

Conclusion on the peer review of the pesticide risk assessment of glyphosate

On 12 November, EFSA published the long awaited „Peer review of the pesticide risk assessment of the active substance glyphosate“ (www.efsa.europa.eu/en/efsajournal/pub/4302). In its report, EFSA concludes that „glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential.“ However, in April 2015, the International Agency for Research on Cancer (IARC) classified glyphosate as a possible human carcinogen. EFSA rejection of the IARC position has led to intense scientific disagreement. Shortly after the rejection, members of IARC and other prominent scientists published an open letter to the EU Commission urging them to “disregard the flawed EFSA finding” and calling for a “transparent, open and credible review of the scientific literature” (<https://drive.google.com/a/greenpeace.org/file/d/0B9F6ub8wD7gqS3luaGFVM2YxY2c/view?pli=1>). EFSA in turn accused the scientists of being involved as lobbyists and the open letter as “facebook science“ (<http://guests.blogactiv.eu/2015/12/07/efsa-accuses-world-class-cancer-experts-of-engaging-in-facebook-science/>). EFSA also published a report attempting to settle several points that were criticised by IARC (www.efsa.europa.eu/en/press/news/160113). The latest development in the controversy: Dr. Wild, the head of IARC, has insisted in a letter that EFSA retracts false claims regarding IARC work on glyphosate on the EFSA website and threatened to boycott a joint

meeting of IARC and EFSA regarding the different outcomes of the risk assessments (www.efsa.europa.eu/en/press/news/160113).

If glyphosate will be authorised as announced by the EU Commission remains a matter of doubt after several EU governments raised opposition (www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicense-weedkiller-glyphosate).

Toxicological assessment of the co-formulant POE-tallowamine

With regard to glyphosate, EFSA also published a statement on the highly controversial co-formulant POE-tallowamine (www.efsa.europa.eu/en/efsajournal/pub/4303). The authority states there is a lack of data regarding the toxicity of tallowamine and that information on the residues in plants and livestock is missing.

Cumulative risks assessment

In February, the European Food Safety Agency EFSA also published guidance on cumulative risk assessment (CRA). Whereas this can be seen as the first step towards methodology to assess risks that may arise from mixtures of pesticides, the underlying risk assessment tool called Monte Carlo Risk Assessment has attracted a great deal of detailed criticism (www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-a-poisonous-injection.pdf).

Risk assessment of new maize sequencing data

On 12 November, EFSA published a statement on new Syngenta GM maize GA21 sequencing data (www.efsa.europa.eu/en/efsajournal/pub/4296). Syngenta had presented new nucleic acid sequencing data on event GA21 as well as updated bioinformatic analyses of the data. The new data „indicated a one-base pair addition in a non-coding region of the insert, a three-base pair deletion in the 3' flanking region of the insert, and a difference in the number of functional copies of the mepsps expression cassette.“ According to EFSA, the new information does not give rise to safety issues.

Revised annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2013

On 17 November, EFSA published a revised annual 2013 Post Market Environmental Monitoring (PMEM) report on maize MON 810 (www.efsa.europa.eu/en/efsajournal/pub/4295). The revision was necessary because EFSA rejected a first report provided by Monsanto because it failed to comply with monitoring obligations (see Testbiotech analysis from April 2015, www.testbiotech.org/en/node/1225). As shown by findings of Teosinte in Spain (see above), the monitoring reports of Monsanto lack crucial data concerning potential persistence and spread of its transgene in the environment.

Opinion on import, distribution and retailing of carnation SHD-27531-4 cut flowers with modified petal colour

On 15 December, EFSA published an opinion on carnation SHD-27531-4 cut flowers for import in the EU for ornamental use (www.efsa.europa.eu/en/efsajournal/pub/4358). The carnations are modified to have purple petals. The altered colour is due to an altered expression level of anthocyanins. According to EFSA, there is no reason to be concerned about the safety of carnation SHD-27531-4 for humans. Further, the GMO panel did not identify any environmental safety concerns.

Update and expansion of the database of bio-ecological information on non-target arthropod species established to support the environmental risk assessment of genetically modified crops in the EU

On 13 January, EFSA published the external report „Update and expansion of the database of bio-ecological information on non-target arthropod species established to support the environmental risk assessment of genetically modified crops in the EU“ (www.efsa.europa.eu/en/supporting/pub/956e).

Other

New conflict of interest case at EFSA

At the end of January, EFSA announced Barbara Gallani as its new communications director (www.efsa.europa.eu/en/press/news/160126). Barbara Gallani will take up her post at EFSA in May 2016. She is currently serving as chief scientist at the UK food industry lobby group Food and Drink Federation, and will take up her position at EFSA without any cooling-off period (www.foodnavigator.com/Policy/EFSA-comes-under-fire-for-latest-revolving-door-industry-recruitment). According to Food Navigator, Gallani defended industry positions on issues such as PCBs, dioxins and organic contaminants during her time at Food and Drink Federation.

Monsanto withdraws maize MON863 from the EU market

According to EU sources, the US company Monsanto has announced the withdrawal of genetically engineered maize MON863 and several stacked events containing this event from the European market (http://ec.europa.eu/food/plant/docs/sc_modif-genet_20151214_sum.pdf). The withdrawal therefore also includes maize events MON863 x NK603, MON863 x MON810 and MON863 x MON810 x NK603.

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