Testbiotech EU Newsletter 1/2015

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: 13 genetically engineered plants waiting for approval for import / / EU Project GRACE under criticism

Overview of Topics

Current Issues and Activities

- Free trade agreements CETA and TTIP and the consequences for GM crops in the EU
- GRACE feeding study
- Glyphosate Review
- Controversy over Chief Scientific Adviser to the European Commission
- EU opt-out rules

Recent comments from Testbiotech on the work of the European Food Safety Authority:

- Import approval for 13 GM plants pending
- GMO cotton 15985
- EFSA guidance (Guidance) to evaluate agronomic / phenotypic characteristics of genetically modified plants
- EFSA Guidance on the examination of applications for renewal of approval for GM crops.

Votes on EU registrations

- oilseed rape MON88302
- cotton Llcotton25xGHB614
- cotton MON89913
- soybean MON87769

New EFSA opinions

Cultivation bans in France and Bulgaria, import of carnations and feeding studies

Current issues and activities

- CETA and TTIP and the consequences for GM crops in the EU

On behalf of the Green Party in the German Bundestag, Testbiotech prepared a report on the possible impact of the planned EU free trade agreement with the United States (TTIP) and Canada (CETA) in the field of biotechnology. According to the report, even the negotiations will considerably restrict the manoeuverability of EU Member states. Among other things, implementation of the labelling of products from cloned animals or animals fed with GM crops as foreseen by the German Federal Government, has already been made almost impossible (http://www.testbiotech.de/en/node/1135).

- GRACE feeding study

Testbiotech published several reports on a 90-day feeding study with genetically engineered maize MON810. The study was conducted by the EU funded GRACE consortium and the results were published in the journal Archives of Toxicology in October 2014. According to the EU Commission, the outcomes of the GRACE project will be important for future EU risk assessment of transgenic crops.
However, according to a Testbiotech analysis, the conclusions of the study are not based on a sufficiently thorough assessment of the data. In addition, there are serious problems regarding conflicts of interest and the credibility of editors at the Archives of Toxicology. For these reasons, Testbiotech is requesting that this publication be withdrawn and subjected to independent scrutiny. We have asked EU Commissioner Vytenis Andriukaitis to look into the matter and resolve the problems.
Further information: http://www.testbiotech.org/en/node/1123

- Testbiotech criticisism the glyphosate report published by the German authorities

In October 2014, Testbiotech published a report on the inadequacies in the risk assessment of glyphosate. At the beginning of 2014, German authorities had published a Renewal Assessment Report (RAR) as part of an EU re-evaluation process for the most widely used weed killer. Testbiotech analysis showed that the German assessment report, which claimed there were no risks to health, is untenable in light of new scientific evidence, and concluded that risks associated with glyphosate must be examined much more closely than has been the case so far.
Further information: http://www.testbiotech.org/en/node/1101
In December, the Pesticide Action Network (PAN) also published a report on this subject (www.pan-germany.org/download/Glyphosat-Broschuere_2014.pdf)

- EU Chief Scientific Adviser controversy

From August 2014, there was a lot of controversy centred on Anne Glover, Chief Scientific Adviser (CSA) to the European Commission. Several NGOs, amongst them Testbiotech, demanded that the new EU Commission scrap the post, claiming that that the position of CSA was fundamentally problematic as it concentrated too much influence in one person. Further, the NGOs criticised Anne Glover's unbalanced claims on the subject of genetically engineered crops. In the past, she had several times spoken out publically in favour of genetically engineered plants for food production, calling opposition against the technology “madness”. In November, the new Commission decided not to prolong the position of Anne Glover. If there will be any Chief Scientific Adviser in the future seems not be decided yet. Further information: http://www.testbiotech.org/en/node/1091).

- Decision on opt-out rules

The EU has adopted rules to facilitate national bans on the cultivation of GM crops. Unfortunately, the rules are not based on EU environmental law (Article 192 of the Treaty on the Functioning of the European Union, TFEU), which would have ensured greater legal certainty. In the coming weeks, the new rules will be integrated into the EU Directive 2001/18. Whether there will be further changes in EU regulation and how the policies will be implemented remains to be seen. So far, only Monsanto's Bt maize MON810 has been approved for cultivation. In 2015, further approvals might follow, for example for maize 1507.

Testbiotech comments on the work of the European Food Safety Authority (EFSA)

- After the feed industry had demanded the swift approval of eight genetically modified crops in July, Testbiotech summarised the criticism of the risk assessment of these crops in an overview and sent a letter to the European Commission (http://www.testbiotech.de/en/node/1105). Meanwhile the feed industry requests market authorisation for twelve genetically engineered crops within next months (www.coceral.com/data/1423152634COCERAL_FEDIOL_FEFAC_PR_EU%20missing_GM_import%20authorizations_ticking_bomb.pdf). In February, the number of pending authorisations increased to 13. The events concerned are: Maize MON 87460, Rapeseed GT 73 (renewal), Soybean 305423, Soybean MON87708, Soybean MON87705, Soybean BPS-CV127-9, Maize T25 (renewal), Cotton T304-40, Maize NK603 (renewal), Rapeseed MON88302, Cotton LL25xGHB614, Cotton MON 88913 and Soybean MON87769. In addition there pending authorisations for cultivation 1507 and MON810 (renewal). For further informations also see our database: www.testbiotech.org/database

- In September Testbiotech commented on an EFSA opinion regarding the import of the GM cotton event MON15985 manufactured by Monsanto. Amongst others, Testbiotech criticised that the plants contain a gene for antibiotic resistance. Further, the differences between the transgenic cotton plants and conventionally bred plants were not adequately studied (http://www.testbiotech.org/en/node/1097).

- Testbiotech commented on an EFSA draft guidance for the evaluation of agronomic / phenotypic characteristics of genetically engineered plants. Amongst others, Testbiotech proposed the introduction of a stress test to examine how the transgenic plants react to different environmental conditions. (http://www.testbiotech.org/node/1149).

- Testbiotech also commented on an EFSA draft guidance regarding applications for renewal of approval for GM crops that need to be made ten years after the first registration. Among other requirements, Testbiotech thinks it is necessary to provide accurate information on herbicide loads.

Votes on EU authorisations

On 24 October and 28 November, EU committees voted on import authorisations for several genetically engineered crops:

- herbicide tolerant oilseed rape MON88302 (http://www.testbiotech.org/node/1079),
- herbicide tolerant cotton LLcotton25xGHB614 (www.testbiotech.org/node/1063), and

- herbicide tolerant cotton MON88913 (http://www.efsa.europa.eu/en/efsajournal/pub/3311.htm).

Although only a minority of Member States voted in favour of the authorisations, the number of votes was not sufficient for a rejection of the applications. Now the EU Commission must decide on the applications.
In particular, Testbiotech criticised the proposed approval of Monsanto's genetically engineered oilseed rape MON88302. If authorised, the glyphosate-resistant plants will be imported as viable seeds and processed into feed. However, it is assumed that there will be spillage from transportation of the seeds, which could lead to the uncontrolled spread of the genetically engineered plants into the environment. Consequently, non-authorised feral plants might contaminate fields which might also lead to gene flow into native populations. The German Federal Government abstained from the vote (http://www.testbiotech.org/en/node/1119).

On 9 December, the Standing Committee voted on the authorisation of genetically engineered soybean MON87769 for import. When fed to farm animals, this soybean should lead to a higher proportion of health-promoting fatty acids. However, EFSA didn't investigate the actual health effects (see http://www.testbiotech.org/node/1062). Here, too, there was no sufficient majority for or against authorisation.

New EFSA opinions
On 1 August, the GMO Panel published a statement related to the prohibition of the cultivation of genetically engineered maize MON 810 in France. EFSA rejected the reasons given by France (http://www.efsa.europa.eu/en/efsajournal/pub/3809.htm).

On 9 October, EFSA published an explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment. In these studies, the GMO percentage is mostly at a maximum of 33 percent. In future, a percentage of 50 percent has been advised to gain more knowledge of possible health effects (http://www.efsa.europa.eu/en/efsajournal/pub/3871.htm).

On 10 November, the GMO Panel published a scientific opinion on objections put forward by Cyprus regarding the import market of genetically modified carnations. EFSA rejected the Cyprian objections. However, EFSA cannot rule out the uncontrolled spread of the plants, for example by vegetative propagation (http://www.efsa.europa.eu/en/efsajournal/pub/3878.htm).

On 14 November, the GMO Panel published a scientific opinion regarding the post-market environmental monitoring of genetically modified plants. The aim of the opinion is to make the outcomes of monitoring more significant (http://www.efsa.europa.eu/en/efsajournal/pub/3883.htm).

On 12 December, EFSA published scientific opinions on GM carnation lines IFD-25958-3 (http://www.efsa.europa.eu/en/efsajournal/pub/3934.htm) and IFD-26407-2 (http://www.efsa.europa.eu/en/efsajournal/pub/3935.htm) for import of cut flowers into the EU.

On 16 December, the GMO Panel published a statement on the emergency measure implemented by Bulgaria for GM maize MON 810. EFSA rejected the reasons given by Bulgaria (http://www.efsa.europa.eu/en/efsajournal/pub/3962.htm).