EFSA GMO Watch – October 2010

Submitted by Anonymous (nicht überprüft) on 3. November 2010 - 21:48

1) News
The Ombudsman has responded to the EFSA's answer concerning the Dr. Suzy Renckens' case. He has asked for more information about Dr. Renckens' tasks, projects, her meetings with industry and the circumstances of her move to industry. In a new time frame, the Ombudsman has now given the EFSA until 30 November to answer questions. The Ombudsman's reaction shows that so far the answers from EFSA do not settle the conflicts of interest involved in this case (for more information see http://www.testbiotech.org/en/node/354 [1]). New problems for EFSA have arisen in the case of Prof. Diana Bánáti, a member of the management board acting in parallel with the ILSI, International Life Science Institute (http://www.gmwatch.org/latest-listing/1-news-items/12527-efsa-chair-in-c... [2]). The ILSI is an international pro industry expert group that publishes studies in cooperation with companies such as Monsanto. Their aim is to achieve lower standards in risk assessment (see for example Glenn, 2008, Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology Case Studies by a Task Force of the ILSI International Food Biotechnology Committee, http://apjcn.nhri.org.tw/server/APJCN/Volume17/vol17suppl.1/229-232S13-1... [3]
ILSI claims that their projects are influencing the work of EFSA – contrary to the statements of Diana Bánáti (http://www.ilsi.org/FoodBioTech/Pages/NutritionalandSafetyAssessments.aspx [4]).

Testbiotech participated in a meeting with stakeholders at EFSA on 29 September to discuss the current draft for the environmental risk assessment of genetically engineered plants. Ten points raised by Testbiotech were discussed at this meeting (http://www.testbiotech.org/en/node/416 [5]). The final guidelines will be published in November. EFSA announced that the Commission and the EU Member States intended to start a process to adopt a final version of the guidelines as an official EU regulation. A similar process is already underway for food and feed risk assessment guidelines. Testbiotech is calling for a much broader and unbiased approach for risk assessment of genetically engineered plants.

Maize 1507 and the Testbiotech dossier (http://www.testbiotech.org/en/node/365 [6]) were discussed in a recent GMO panel meeting. The protocol is now available on EFSA´s website (http://www.efsa.europa.eu/en/events/event/gmo101020-m.pdf [7]). EFSA is eager to defend its previous opinions but fails to address some of the most relevant points such as the adverse effects of the Bt toxin on the greater wax moth (Galleria mellonella) which is an important test organism in ecotoxicology. EFSA overlooked these effects in its previous opinions – and now they are not even mentioned. The EFSA paper also shows that no data is available on the impact the plant´s Bt toxin has on soil organisms. EFSA has announced that it has added some points to its previous opinion. Testbiotech plans to address the deficiencies in the EFSA´s statement in another letter to the EU Commission.

(2) New opinions:
On 27 September, the EFSA GMO panel published opinions on applications for the market approval of two genetically engineered maize hybrids. The biotech companies Monsanto and Dow AgroSciences had handed in both applications jointly and both applications were for so called "stacked events", which contain numerous Bt and herbicide resistance genes.
The applications are for food and feed uses, import and processing but not for cultivation.

Opinion on genetically engineered maize MON 89034 × 1507 × NK603
The opinion looks at the hybrid of three genetically engineered maize lines that already have approval for food and feed uses in the EU. According to EFSA, event MON 89034 × 1507 × NK603 is unlikely to have adverse effects on human and animal health and the environment.
The stacked event MON 89034 × 1507 × NK603 contains three different Bt genes (cry2Ab2, cry1F, cry1A.105). The cry1A.105 gene is a synthetic fusion protein gene comprising parts of Bt toxins Cry1Ab, Cry1F and Cry1Ac. All Bt genes code for proteins that are toxic for certain lepidopteran and

coleopteran pests. The hybrid plants also express three different genes (pat, CP4 epsps and CP4 epsps l214p) that confer tolerance to herbicides with the active ingredients glufosinate-ammonium (brands like Liberty or Basta) and glyphosate (Roundup). The hybrid MON 89034 × 1507 × NK603 was produced from crossing genetically engineered plants by conventional breeding. In the opinion, EFSA relies 100 percent on company data. No independent study on this event has ever been published. According to EFSA, event MON 89034 × 1507 × NK603 is nonetheless unlikely to have adverse effects on human and animal health and the environment.

From the criticisms of several EU member states, it is clearly the case that there is substantial doubt about the safety of maize MON 89034 × 1507 × NK603. For example, the equivalence of the hybrid maize with its conventional counterpart is very questionable. The EFSA opinion reveals that the level of 12 of the 53 analysed components in the genetically engineered maize were significantly different from the level in its conventional counterpart (palmitic acid, stearic acid, oleic acid, linolenic acid, arachidic acid, behenic acid, ferulic acid, calcium, manganese, potassium, folic acid, and vitamin E.). EFSA refused to take into account most of the differences because they did not show up in all of the field trials. The only acknowledged consistent difference through all of the field trials is a higher content of stearic acid. In EFSA's opinion, this is only a statistical difference with no biological relevance. The definition of the term biological relevance remains unclear.

No feeding trial was considered in the safety assessment of MON 89034 × 1507 × NK603. A nutritional study that was provided by the applicants (a 42-day feeding study with broiler chickens) was deviant from Good Agricultural Practice and was rejected by the panel. In the study, many animals died during the first week of the trial. Instead of asking the applicants to repeat the study, EFSA concluded that, based on the outcome of the comparative compositional, phenotypic and agronomic analysis, a feeding trial with maize is not necessary.
According to the EFSA, the security of the parental lines was established in earlier EFSA opinions, so that no tests for toxic or allergenic effects of the genetically engineered maize line MON 89034 × 1507 × NK603 are considered necessary.

EFSA also claims that the parental lines MON 89034, 1507 and NK603 have a history of safe use. As the documentation of the consultation process reveals, the panel stresses two factors for this assumption (http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?que... [8]):
“It is a fact that Bacillus thuringiensis strains expressing various Cry proteins have been used as microbial pesticides for many years without adverse effects having been identified in humans and animals. It is also a fact that large populations have consumed maize expressing the various events in maize MON 89034 x 1507 x NK603 for some years without adverse effects on human and animal health having been reported. These observations might, in a historical perspective, build up to a history of safe use of these GM events.”

It is a well established fact that artificial Bt genes in genetically engineered plants differ from the natural Bt toxin in their mode of action and genetic makeup. Secondly, there are no scientific facts given for the hypothesis that no adverse effects have been reported regarding the consumption of the various events. Since GM products have not been labelled in the USA and Canada, no epidemiological study of potential effects has been conducted. Thus, if GM food were to play a part in the increase of nutrition-related health disturbances such as allergies and food intolerances, such effects could not be clarified.

Opinion on genetically engineered maize MON 89034 x 1507 x MON 88017 x 59122
The second opinion concerns the placing on the market of the hybrid MON 89034 x 1507 x MON 88017 x 59122. This maize is sold with brand name 'SmartStax' in the US and Canada. As in the above mentioned event, the hybrid was produced by crossing genetically engineered plants. An independent study has never been published on this event.
The maize contains six different Bt genes (cry1A.105, cry2Ab2, cry1F, cry34Ab1, cry35Ab1 cry3Bb1), pat,, CP4 epsps, genes conferring resistance to certain lepidopteran and coleopteran target pests and tolerance to glufosinate-ammonium- and glyphosate-based herbicides. The Bt proteins make the plant toxic for a wide range of pests such as the like European corn borer (Ostrinia nubilalis), fall armyworm (Spodoptera ssp), black cutworm (Agrotis ipsilon), corn earworm (Helicoverpa zea) and corn rootworm (Diabrotica spp.).
According to EFSA, the event is unlikely to have adverse effects on human and animal health and the

environment.
As in the above mentioned opinion, there is doubt about EFSA's conclusions. For example, although the applicants had carried out one nutritional study, there were no tests for toxicity and allergenicity. EFSA claims that the safety of maize MON 89034 x 1507 x MON 88017 x 59122 was established by tests undertaken for the market approval of the single events. However, in the feeding trials performed for the single events, all eight proteins used in acute toxicity tests (Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, pat CP4 EPSPS) originated from microbial expression systems and not from plant material. As the microbial proteins differ from the Bt proteins produced in plants, such tests can provide only limited information about the safety of a genetically engineered plant.

Both opinions disregard the fact that a stacked event must be seen as a new event, even if no new modifications have been introduced. For example, unexpected effects (e.g. synergistic effects of the newly introduced proteins) cannot automatically be excluded.
Furthermore there is substantial doubt about the safety of maize 1507, which is included in both maize lines (see Testbiotech Report on maize 1507 http://www.testbiotech.org/en/node/365 [6]). As long as the safety of the single event is not established, there can be no clarity about the safety of the stacked events containing maize 1507.

(3) Others:
Experts from institutions in Austria and Switzerland have carried out work on the risk assessment of genetically engineered insects - “Defining environmental risk assessment criteria for genetically modified insects to be placed on the EU market”
(http://www.efsa.europa.eu/en/scdocs/scdoc/71e.htm [9]), which was published by EFSA. The report gives an overview of the current state of the technologies available and discusses certain case studies. Currently discussions are being held in Malaysia to decide whether to release genetically engineered insects to fight dengue fever.
(http://news.yahoo.com/s/ap/20101011/ap_on_sc/as_malaysia_dengue_fever [10]). There are serious concerns that the genetically engineered insects once released could get out of control.

EFSA has published an update of its opinion on cloning in livestock European Food Safety Authority; Update on the state of play of animal cloning. EFSA Journal 2010:8(9):1784. [21pp.] doi:10.2903/j.efsa.2010.1784. Available online:www.efsa.europa.eu/efsajournal.htm [11]. EFSA does not see any need for amending its previous opinions. EFSA draws a comparison between other techniques for reproduction in cattle and pigs in terms of overall success (around 6-10%). By doing so it sets aside the problem of serious animal welfare problems being reported much more often in context of cloning compared to other technologies such artificial insemination and embryo transfer.

Links
[1] http://www.testbiotech.org/en/node/354 [2] http://www.gmwatch.org/latest-listing/1-news-items/12527-efsa-chair-in-conflict-of-interest-scandal [3] http://apjcn.nhri.org.tw/server/APJCN/Volume17/vol17suppl.1/229-232S13-1.pdf [4] http://www.ilsi.org/FoodBioTech/Pages/NutritionalandSafetyAssessments.aspx [5] http://www.testbiotech.org/en/node/416 [6] http://www.testbiotech.org/en/node/365 [7] http://www.efsa.europa.eu/en/events/event/gmo101020-m.pdf [8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00413 [9] http://www.efsa.europa.eu/en/scdocs/scdoc/71e.htm [10] http://news.yahoo.com/s/ap/20101011/ap_on_sc/as_malaysia_dengue_fever [11] http://www.efsa.europa.eu/efsajournal.htm