

LLCotton25

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)

Country: The Netherlands

Type: Others...

a. Assessment:

b. Food Safety Assessment:

Toxicology

Considerations from the EFSA: Quote: "Food and feed from cotton GHB614 × LLCotton25 × MON 15985 are expected to have the same nutritional impact as those derived from the non-GM comparator."

"Are expected to have" is not science.

We agree with the comment from Belgium and Germany that the herbicide glufosinate-ammonium used in this GM cotton is toxic and compromises food safety. We therefore request an internal review. We dispute the claim that the GMO Panel is not competent to conduct such a review, partly in the light of the following:

"85 It is plain, as was stated in paragraphs 49 and 62 above, that the request for internal review is admissible, in this case, only to the extent that it claims that the authorisation decisions contravened provisions of environmental law within the meaning of Regulation No 1367/2006. Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003 provide that the food and feed concerned must not be placed on the market if they cause adverse effects on human health, animal health or the environment. The 305423, MON 87769 and MON 87705 soybeans constituted, when being cultivated, elements modified by human intervention that were in interaction with the natural environment. Accordingly, genetic modifications of those elements of the environment were liable to have consequences for their nutritional value or to represent a risk for food safety and constituted therefore matters within the scope of environmental law within the meaning of Regulation No 1367/2006."

Source: InfoCuria – Case-law of the Court of Justice. JUDGMENT OF THE GENERAL COURT (Seventh Chamber) 14 March 2018 (*) Environment - Genetically modified products – Regulation (EC) No 1367/2006 – Regulation (EC) No 1829/2003 – Genetically modified soybeans MON 87769, MON 87705 and 305423 — Rejection of an application for internal review of market authorisation decisions – Concept of ‘environmental law’ – Article 10 of Regulation No 1367/2006”. Case T-33/16, Applicant: TestBioTech eV (Munich, Germany) (represented by: R. Stein, Solicitor, K. Smith QC, and J. Stevenson, Barrister); Defendant: European Commission (represented by: J. Tomkin, L. Pignataro-Nolin and C. Valero, acting as Agents). Please regard the entire judgment as an integral part of the present document. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62016TJ0033&from=NL>

We agree with this comment from Germany.

“In this context, the current paper by Christ et al. (published end of November 2017) should also be included in the evaluation of new scientific literature. Combining metabolomics, plant genetics and biochemical approaches, Christ et al. (2017) have demonstrated non-specific activities of the PAT/bar enzyme in various genetically modified recipient plants (Arabidopsis, soybean, canola, mustard and wheat). In addition to the actual substrate glufosinate-ammonium, PAT/bar was shown to also acetylate two endogenous amino acids (tryptophan and amino adipate) at low velocity. This results in an ectopic accumulation of acetyltryptophan and acetyl-amino adipate in the genetically modified plant. While acetyl tryptophan is a naturally occurring metabolite found in many plant species, acetyl-amino adipate has not yet been described as an endogenous plant metabolite. In general, it is not unexpected that an acetyltransferase also acetylates other than the actual substrate at low velocity. However, the occurrence of the two above-mentioned acetylated amino acids was not explicitly considered in the previous risk assessment. Therefore, the applicant should discuss the paper with regard to safety aspects in the context of the renewal application.” Christ B, Hochstrasser R, Guyer L, Francisco R, Aubry S, Hörtensteiner S, Weng JK. (2017) Non-specific activities of the major herbicide-resistance gene BAR. *Nat Plants* 3(12):937-945. doi: 10.1038/s41477-017-0061-1.

Application EFSA-GMO-RX-010 (LLCotton25) Comments and opinions submitted by Member States during the three-months consultation period.

Mutation Research/Genetic Toxicology and Environmental Mutagenesis Volume 769, 15 July 2014, Pages 7-12

Induction of micronuclei and nuclear abnormalities in tadpoles of the common toad (*Rhinella arenarum*) treated with the herbicides Liberty® and glufosinate-ammonium

Author links open overlay panelRafael C.LajmanovichabMariana C.Cabagna-ZenklusenbAndrés M.AttademoabCelina M.JungesabPaola M.PeltzerabAgustínBassó bEduardoLorenzattibc a National Council for Scientific and Technical Research (CONICET), Buenos Aires, Argentina b Faculty of Biochemistry and Biological Sciences, (FBCB-UNL), Ciudad Universitaria, Paraje el Pozo s/n, 3000 Santa Fe, Argentina c Institute of Technological Development for the Chemical Industry (INTEC-UNL-CONICET), Güemes 3450, 3000 Santa Fe, Argentina Received 1 June 2013, Revised 12 December 2013, Accepted 15 January 2014, Available online 24 April 2014. Quote of abstract: “Our study demonstrates that the commercial formulation of a GLA-based herbicide induces micronucleus formation in *R. arenarum* tadpoles, in contrast to the active ingredient. According to these results, the inert ingredients of the commercial formulation played an important role in the production of genotoxic damage in erythrocytes of amphibian tadpoles.” Bound to fail: The flawed scientific foundations of agricultural genetic engineering (part 2) <https://www.gmwatch.org/en/news/latest-news/18593> This quote is from a second commentary on the same theme by the London-based molecular geneticist Dr Michael Antoniou, this time from the standpoint of molecular biology. Part 1 of this series of two articles is here: <https://www.gmwatch.org/en/news/latest-news/18582>

Quote: “However, in-depth molecular profiling analysis of transgenic plants shows that transgenic procedures invariably result in a spectrum of unpredicted alterations, not only in the function of the inserted foreign transgene but also of the plant's host genes. This in turn results in unintended changes in the plant's biochemistry”.

10. Krinsky S. An illusory consensus behind GMO health assessment. *Sci Technol Hum Values*. August 2015;0162243915598381. doi:10.1177/0162243915598381 11. Robinson C, Antoniou M, Fagan J. *GMO Myths and Truths (4th Edition): A Citizen's Guide to the Evidence on the Safety and Efficacy of Genetically Modified Crops and Foods*, 4th Edition. Chelsea Green; 2018. https://www.amazon.com/GMO-Myths-Truths-Citizens-Genetically/dp/0993436722/ref=dp_ob_title_bk. 12. Gilbert N. Cross-bred crops get fit faster. *Nat News*. 2014;513(7518):292. doi:10.1038/513292a 14. Francia E, Tacconi G, Crosatti C, et al. Marker assisted selection in crop plants. *Plant Cell Tissue Organ Cult*. 2005;82(3):317-342. doi:10.1007/s11240-005-2387-z 15. GMWatch. Non-GM successes. [gmwatch.org](http://www.gmwatch.org). <http://www.gmwatch.org/index.php/articles/non-gm-successes>. Published 2018. <https://www.gmwatch.org/en/news/latest-news/18593>

A team of Harvard scientists : “Crossover trials have shown that switching from consuming conventionally grown foods to organic foods decreases urinary concentrations of pesticide metabolites, suggesting reduced exposure to pesticides.⁴

Organic Foods for Cancer Prevention—Worth the Investment?

Elena C. Hemler et al

4. Bradman A, Quirós-Alcalál, Castorina R, et al. Effect of organic diet intervention on pesticide exposures in young children living in low-income urban and agricultural communities. *Environ Health Perspect.* 2015;123(10):1086-1093.doi:10.1289/ehp.1408660, October 2015.

“There are probably many other health effects; we just haven’t studied them.” “A team of Harvard scientists published a commentary in October stating that more research about potential links between disease and consumption of pesticide residues is "urgently needed" as more than 90 percent of the U.S. population has pesticide residues in their urine and blood.” The primary route of exposure to these pesticides is through the food people eat, the Harvard research team said. Several additional Harvard-affiliated scientists published a study earlier this year of women who were trying to get pregnant. The findings suggested that dietary pesticide exposure within a "typical" range was associated both with problems women had getting pregnant and delivering live babies, the scientists said. <https://www.ehn.org/when-safe-may-not-really-be-safe-2621578745.amp.html> Commentary: <http://www.ask-force.org/web/Organic/Hemler-Organic-Foods-for-Cancer-Preventio-Worth-the-Investment-2018.pdf>

“The Dutch CA has assessed the renewal dossier with respect to the environmental, food and feed safety of LLCotton25 cotton and has no comments or requests for additional information in relation to the safety of this GM event.”

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Our comment: We are ashamed to be Dutch, why has the Dutch CA lost its moral compass? Hungary and Italy asked questions about this GM cotton and Germany asked questions because of health issues of humans and animals. It will be high time this important issue will be an important one to address the safety of these GM cotton - and other GM products and the herbicide used! If this is not possible the EU should change the law!

Allergenicity

Articles/reports on GLA. Used with permission.

The following article by Thomson, C.J. et al. appeared in 1987:

"Characterisation of the herbicide-resistance gene bar from *S. hygroscopicus*" The EMBO Journal Vol. 6 no.9, pag. 2519-23.

The article states that phosphinothricin-acetyl also has a glutamine acid substrate (by adding the two substances together and demonstrating the reaction product.) Hoechst disputes this in one of its reports (93-01):

Dr. Arno Schulz

"L-phosphinothricin N acetyltransferase Biochemical Characterisation"

This article describes how glufosinate was exposed to the effects of the acetyltransferase (with an acetyl source) TOGETHER WITH a large surplus of glutamine acid (and other amino acids). Schulz was UNABLE to demonstrate a reaction product with glutamine acid, and his sole conclusion at the time was that glutamine acid was not a substrate. THIS IS INCORRECT AND HIGHLY MISLEADING because:

* in situations where the acetyltransferase (present in the modified plant) could have toxic effects, as in the human gastrointestinal tract, there is no simultaneous presence of glufosinate (see Thomson). Incredible!

* it is logical, given the test conditions applied by Schulz, that the acetyltransferase acetylates the glufosinate using not only the added acetyl source, but also acetylated glutamine acid as a source of acetyl (because the transferase has a greater affinity with glufosinate). In a MIXTURE, a reaction product will only be formed with the substrate with which the transferase has the greater affinity.

AN EXTREMELY MISLEADING REPORT.

We object to the development of a GMO in which this GM product is present.

1. According to Hoechst, it is not teratogenic: E. Ebert et al.: 'Summary of safety evaluation toxicity studies of glufosinate ammonium'. 1989/1990. Hoechst swept deviations found in the offspring of rabbits under the carpet and attributed them to "maternal toxicity"!! It was claimed that the toxicity of the mother animal prevented her from having healthy babies! We think that this is a shabby game of semantics.

Furthermore, we submit the research data obtained by Tomoko Fujii et al., 1996

"Alterations in the Response to Kainic Acid in Rats Exposed to Glufosinate Ammonium, a Herbicide, during Infantile Period" (study sponsored by the Japanese

Ministry of Education, Science, Sports and Culture). Exposure to GLA, even in low doses (1 mg/kg) during Infantile Period in the rat, induces alterations in the kainic receptor in the brain.

https://www.researchgate.net/publication/244754595_Alterations_in_the_Response_to_Kainic_Acid_in_Rats_Exposed_to_Glufosinate_Ammonium_a_Herbicide_during_Infantile_Period

T. Watanabe. 1996

"Apoptose induced by GLA in the neuroepithelium of developing mouse embryos in culture. Programmed cell death caused by the release of substances which destroy the cell from inside; this cell suicide is regulated by a suicide gene which is obviously switched on by GLA. T. Watanabe et al. 1997.

"Developmental and Dymorphogenic Effects of GLA in mouse Embryos in culture". Deformities.

2. Hoechst claims that GLA does not have sensitising properties.

Ms Eijsten has personally experienced the very opposite of GLA's "non-sensitizing properties". She has reported this on an earlier occasion. She was sensitized in 1992. (somebody from the local Parks Department walked past, spraying the grass verges with Finale SL 14 when she was sitting on a bench reading while out with her dog.) Seemingly innocuous at the time. But the next year, she was walking her dog on grass verges which had just been sprayed with this herbicide, and just seven hours later her legs were covered in eczema.

The next day she took the same route, only this time wearing a sleeveless blouse, and soon afterwards her arms and face were also covered in eczema. (Her dog also had red patches on its tummy.) She has reported this on numerous occasions. The most serious thing, however, is the attempt to sweep the facts under the carpet, for example, by arguing that Ms Eijsten was suffering from a food allergy (letter from VWS, Mr Top/ Ms Terpstra, 10 June 1996: a really scientific communication).

It was clear from the photograph which was submitted that the eczema occurred on unprotected parts of the body! There was no trace of eczema on the back of her hands, which is only logical, as she washed her hands after contact. An examination by her dermatologist consisted of tests using patches with Vaseline to which the herbicide had been added, i.e. a hydrophilic substance was tested using a hydrophobic one. Unsurprisingly, the test did not produce a visible effect. The dermatologist performed the same test three times, despite Ms Eijsten's request that he perform the test using a hydrophile such as lanoline or use unadulterated herbicide on her skin.

His argument was: "I always do it this way", which speaks volumes about his level of competence.

He had previously informed her that he was not familiar with this herbicide, and asked her to bring him a sample. This is strange, because Finale had already been in use for 20 years or so.

That was also the reason why she collected a range of literature on Finale, including an American publication which discussed methods of demonstrating sensitisation. The relevant EU LEGISLATION prescribes numerous methods of doing so. She is constantly asking herself why he did not want to do any other test. She found the whole thing utterly reprehensible. If dermatologists in the Netherlands treat all their patients in the way that "her" dermatologist treated her, cases of eczema as a result of GLA will never come to light!

What was the reason for not performing the correct tests?

We rather feel that everything possible is being done to cover up the harmful effect of GLA.

The *Consument en Biotechnologie (C&B)* annual report for 1996/1997 states that the 1996 report by Fujii claimed that brain damage was demonstrated when large doses were used. Ms Eijsten had, it should be noted, actually sent C&B the 1996 Fujii report at their request. The whole thrust of the report was that very small doses had been used (1 mg/kg).

In response to her complaint, she was promised that this would be corrected. She was recently informed, without any reason being given, that no corrections would be made. This distortion of the truth is the result of dishonest lobbying.

We think it is necessary to communicate the above information about sensitization again, in the light of the dangers associated with the spraying of herbicides and the drift associated with the small- or large-scale cultivation of herbicide-resistant crops. Murphy's Law! Fragment from: 'Bezwaarschrift bij een ontwerpbesikking betreffende herbicide-resistentie' ('Objection to a draft decision concerning herbicide resistance') by J. van der Meulen, L. Eijsten.

<https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/bezwaarschrift-bij-een-ontwerpbesikking-betreffende-herbicide-resistentie/>

4. Conclusions and recommendations

The GMO-free citizens have been contributing their views in writing as part of the open consultations for a number of years now. They never receive a reply, and nor do they even know if there is really any point in writing if their views are 'noted' but no action is taken. So, can you tell us the purpose of these open consultations? Surely you agree that consumers, who are expected to buy these GM products, can have opinions about what they put on their families' plates? Or are they expected to swallow everything? For this reason they now only eat organic food. Steps need to be taken to ensure that they can continue to do so.

6. Labelling proposal

Don't authorise GM cotton on the EU market! And withdraw existing authorisations for GM cotton. We have never seen food labels which state the authorised GM cotton (seed oil). Why is this? The same is true of GM cotton clothing and other applications, such as cotton wool, for which the GM cotton in question should not be used. Surely we have the right to know what's in our food, don't we?

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)

Country: The Netherlands

Type: Others...

a. Assessment:

Others

Press release

11.12.2018 Parliament calls for more transparency on the authorisation of pesticides and additives in the food chain Food law

Today, Members of the European Parliament have just voted in favour of greater transparency around the authorisation of pesticides, GMOs and additives in the food chain. Following the call of over 1.4 million people in the largest ever European Citizens' Initiative (ECI "Stop Glyphosate") for more transparency in the authorisation of pesticides, in April 2018 the European Commission proposed a new regulation: "Transparency and sustainability of EU risk assessment in the food chain". The regulation will have an impact on the General EU Food Law and other legislation, for example on the authorisation of genetic engineering, pesticides and food additives. Fragment of <https://www.greens-efa.eu/en/article/press/parliament-calls-for-more-transparency-on-the-authorisation-of-pesticides-and-additives-in-the-food-chain/#lang-es>

5. Others

This is a supplement (...)
