Maize MZHG0JG

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

a. Assessment:
b. Food Safety Assessment:
Toxicology

The GMO Panel concludes that maize MZHG0JG is nutritionally equivalent to and as safe as the conventional counterpart and non-GM maize reference varieties tested, and no post-market monitoring of food/feed is considered necessary. SCIENTIFIC OPINION ADOPTED: 17 October 2018 doi: 10.2903/j.efsa.2018.5469

"…….in 1985, the EPA classified glyphosate as a Class C carcinogen. Six years later, just about the time former Monsanto lawyer Michael Taylor got himself installed in a key position at the U.S. Food & Drug Administration (FDA), the EPA reversed that decision."
http://salsa3.salsalabs.com/o/50865/t/0/blastContent.jsp?email_blast_KEY=1315174

Do GMOs Accumulate Formaldehyde and Disrupt Molecular Systems Equilibria? Systems Biology May Provide Answers V. A. Shiva Ayyadurai*, Prabhakar Deonikar Systems Biology Group, International Center for Integrative Systems, Cambridge, MA, USA Email: *vashiva@integrativesystems.org Received 17 June 2015; accepted 7 July 2015; published 10 July 2015 Copyright © 2015 by authors and Scientific Research Publishing Inc. This work is licensed under the Creative Commons Attribution International License (CC BY). http://creativecommons.org/licenses/by/4.0/ Abstract.

Safety assessment of genetically modified organisms (GMOs) is a contentious topic. Proponents of GMOs assert that GMOs are safe since the FDA's policy of substantial equivalence considers GMOs "equivalent" to their non-GMO counterparts, and argue that genetic modification (GM) is simply an extension of a "natural" process of plant breeding, a form of "genetic modification", though done over longer time scales. Anti-GMO activists counter that GMOs are unsafe since substantial equivalence is unscientific and outdated since it originates in the 1970s to assess safety of medical devices, which are not comparable to the complexity of

biological systems, and contend that targeted GM is not plant breeding. The heart of the debate appears to be on the methodology used to determine criteria for substantial equivalence. Systems biology, which aims to understand complexity of the whole organism, as a system, rather than just studying its parts in a reductionist manner, may provide a framework to determine appropriate criteria, as it recognizes that GM, small or large, may affect emergent properties of the whole system. Herein, a promising computational systems biology method couples known perturbations on five biomolecules caused by the CP4 EPSPS GM of Glycine max L. (soybean), with an integrative model of C1 metabolism and oxidative stress (two molecular systems critical to plant function). The results predict significant accumulation of formaldehyde and concomitant depletion of glutathione in the GMO, suggesting how a "small" and single GM creates "large" and systemic perturbations to molecular systems equilibria. Regulatory agencies, currently reviewing rules for GMO safety, may wish to adopt a systems biology approach using a combination of in silico, computational methods used herein, and subsequent targeted experimental in vitro and in vivo designs, to develop a systems understanding of "equivalence" using biomarkers, such as formaldehyde and glutathione, which predict metabolic disruptions, towards modernizing the safety assessment of GMOs.

Ayyadurai, V.A.S. and Deonikar, P. (2015) Do GMOs Accumulate Formaldehyde and Disrupt Molecular Systems Equilibria? Systems Biology May Provide Answers. Agricultural Sciences, 6, 630-662.
http://dx.doi.org/10.4236/as.2015.67062

"Basis — Inadequate evidence for oncogenicity in animals. Glyphosate was originally classified as C, possible human carcinogen, on the basis of increased incidence of renal tumors in mice."

https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0057_summary.pdf

3.2 Lankas, 1981 Testicular interstitial cell tumors In this 2-year study in Sprague-Dawley rats conducted by Bio/dynamics, EPA reports a significant trend of testicular interstitial cell tumors in males, with pairwise comparison significant even after multiple comparisons adjustment (0.039). It appears that EPA misreported the high-dose incidence rate in Table 4.1 (6/44 = 14%, not 12%).

https://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments--cfs-20161_35863.pdf

https://file.scirp.org/pdf/AS_2015071017323113.pdf

TIME: I Won a Historic Lawsuit, But May Not Live to Get the Money

“Evidence revealed in the trial included internal Monsanto records that included discussions of “ghostwriting” scientific papers that asserted the safety of its products and plans to discredit an international agency that declared the main ingredient in Roundup, a chemical called glyphosate, to be a probable human carcinogen” Quote By CAREY GILLAM 7:48 AM EST http://time.com/5460793/dewayne-lee-johnson-monsanto-lawsuit/?utm_source=twitter.com&utm_medium=social&utm_campaign=social-share-article

Do GMOs Accumulate Formaldehyde and Disrupt Molecular Systems Equilibria?

Systems Biology May Provide Answers

V. A. Shiva Ayyadurai*, Prabhakar Deonikar Systems Biology Group, International Center for Integrative Systems, Cambridge, MA, USA Email: *vashiva@integrativesystems.org Received 17 June 2015; accepted 7 July 2015; published 10 July 2015 7:48 AM EST http://time.com/5460793/dewayne-lee-johnson-monsanto-lawsuit/?utm_source=twitter.com&utm_medium=social&utm_campaign=social-share-article

Articles/reports on GLA. Used with permission.

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

Thomson, C. J. et al.

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

"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 acetylises the glufosinate using not only the added acetyl source, but also acetylised 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 Dysmorphogenic 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 while 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 ontwerpbeschikking 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-ontwerpbeschikking-betreffende-herbicide-resistentie/

See also:

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.PeltzerabAgustínBassóbEduardoLorenzattibc 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. Krimsky 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/index.php/articles/non-gm-successes. Published 2018. https://www.gmwatch.org/en/news/latest-news/18593

HERBICIDES

Norway:

“In the 42-day nutritional study with broilers, feed containing glyphosate and glufosinate-ammonium treated maize MZHG0JG was used in the test group. A range of pesticides and other contaminants in the prepared diets were analysed and reported. However, residual levels of the target herbicides glyphosate and glufosinate-ammonium were not included. VKM suggests that the applicant provides this information.”

The answer:

“Testing for the presence of intended pesticide residues in the diets used in the 90-day feeding study is not a regulatory requirement.”

From: Application EFSA-GMO-DE-2016-133 (maize MZHG0JG) Comments and opinions submitted by Member States during the three-months consultation period.

We agree with the comment from Norway that tests need to be done for “residual levels of the target herbicides glyphosate and glufosinate-ammonium” (see above). We also agree with Germany and other countries that the herbicides glyphosate and glufosinate-ammonium which are used in this genetically modified maize are toxic and compromise 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 read: “The Dutch CA has assessed the dossier with respect to the environmental safety of MZHG0JG maize and has no comments or requests for additional information in relation to the safety of this GM event.” Application EFSA-GMO-DE-2016-133 (maize MZHG0JG) Comments and opinions submitted by Member States during the three-months consultation period.

Our comment: We are ashamed to be Dutch, why has the Dutch CA lost its moral compass? Austria, Belgium, Hungary, France, Germany and Norway asked a lot of questions about this GM maize. It will be high time this important issue will be an important one to address the safety of these GM maize - and other GM products

and the herbicides that have been used! If this is not possible then the EU should change the law!

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 All

4. Bradman A, Quirós-AlcaláL, CastorinaR, et al. Effec tof 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, oktober 2015.

“There are probably many other health effects; we just haven’t studied them”

Quote of Mrs. C. Gillam:

“The problem is that it is not clear to what extent long-term low-level exposure to pesticide residues through food may or may not be health hazards," said Dr. Jorge Chavarro, associate professor of the Departments of Nutrition and Epidemiology at the Harvard T.H. Chan School of Public Health, and one of the study authors.” https://www.ehn.org/when-safe-may-not-really-be-safe-2621578745.amp.html

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substantial equivalence is unscientific and outdated since it originates in the 1970s to assess safety of medical devices, which are not comparable to the complexity of biological systems, and contend that targeted GM is not plant breeding. The heart of the debate appears to be on the methodology used to determine criteria for substantial equivalence. Systems biology, which aims to understand complexity of the whole organism, as a system, rather than just studying its parts in a reductionist manner, may provide a framework to determine appropriate criteria, as it recognizes that GM, small or large, may affect emergent properties of the whole system. Herein, a promising computational systems biology method couples known perturbations on five biomolecules caused by the CP4 EPSPS GM of Glycine max L. (soybean), with an integrative model of C1 metabolism and oxidative stress (two molecular systems critical to plant function). The results predict significant accumulation of formaldehyde and concomitant depletion of glutathione in the GMO, suggesting how a "small" and single GM creates "large" and systemic perturbations to molecular systems equilibria. Regulatory agencies, currently reviewing rules for GMO safety, may wish to adopt a systems biology approach using a combination of in silico, computational methods used herein, and subsequent targeted experimental in vitro and in vivo designs, to develop a systems understanding of "equivalence" using biomarkers, such as formaldehyde and glutathione, which predict metabolic disruptions, towards modernizing the safety assessment of GMOs.

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"Basis — Inadequate evidence for oncogenicity in animals. Glyphosate was originally classified as C, possible human carcinogen, on the basis of increased incidence of renal tumors in mice."

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http://time.com/5460793/dewayne-lee-johnson-monsanto-lawsuit/?utm_source=twitter.com&utm_medium=social&utm_campaign=social-share-article

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Others

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.

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5. Others

The European GMO-free Citizens will not eat these GMOs!
The GM-Free Citizens are supported by Stichting Natuurwetmoeders, Bussum and Stichting Ekopark, Lelystad.

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6. Labelling proposal

No gm maize!

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

Type: Others...

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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

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5. Others

This is a supplement (…)

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

In order to assess the sequences encoding the newly expressed proteins or any other

open reading frames (ORFs) present within the insert and spanning the junction sites, it was assumed that the proteins that might emerge from these DNA sequences would raise no safety issues; no detailed investigations were carried out in this regard.

Furthermore, other gene products, such as miRNA from additional open reading frames, were not assessed. Thus, uncertainties remain about other biologically active substances arising from the method of genetic engineering and the newly introduced gene constructs.

Environmental stress can also cause unexpected patterns of expression in the newly introduced DNA (see, for example, Trtikova et al., 2015). However, the expression of the additional enzymes was only measured under field conditions in the US for one year. According to the data presented, no unusual weather conditions were reported. Therefore, it was not tested to which extent specific environmental conditions, such as those caused by climate change, will influence the overall concentration of the enzymes in the plants. As EFSA states in its answer to the comments from experts from member states (EFSA, 2018b): "It is well documented in the literature that protein levels can vary due to a number of factors including genetic background, environmental conditions and agricultural practices."

Nonetheless, the plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability.

More surprisingly, EFSA and the applicant omitted to assess the maize in regard to its intended purpose. Due to the increased content of EPSPS enzymes that confer resistance to glyphosate, it has to be expected that these plants can and will be exposed to higher and also repeated dosages of glyphosate (see also the comments from experts of member states, EFSA, 2018b).

Higher applications of glyphosate will not only lead to a higher burden of residues in the harvest, but may also influence the expression of the transgenes or other genome activities in the plants. The same aspect is relevant in regard to resistance to glufosinate, which might be applied in higher dosages due to increasing weed pressure. This aspect, which is the most relevant in regard to this specific event, was completely ignored in the risk assessment as performed. Only the so-called 'intended' usage of the complementary herbicide was taken into account, with single sprayings of each of the herbicides. However, the practical conditions under large scale cultivation and increasing weed occurrence were left aside. These missing risk assessment data are the cause of substantial flaws in following risk assessment steps.

EFSA should have requested that Syngenta submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, also including repeated spraying. The material derived from those plants should have been assessed by using Omics techniques to investigate changes in the gene activity of the transgene, as well as the natural genome of the plants.

EFSA GMO Panel (2018b) Comments from the experts of Member States on the scientific opinion on the assessment of genetically modified maize MZHG0JG (application EFSA-GMO-DE-2016-133). Accessed via the register of EFSA, http://registerofquestions.efsa.europa.eu/roqFrontend/login?0

Trtikova, M., Wikmark, O.G., Zemp, N., Widmer, A., Hilbeck, A. (2015) Transgene expression and Bt protein content in transgenic Bt maize (MON810) under optimal and stressful environmental conditions. PloS one, 10(4): e0123011. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011

Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

Field trials for compositional and agronomic assessment of maize MZHG0JG were conducted in the US during one year only (2013) and not in any other relevant maize production areas, such Brazil or Argentina.

Regarding agronomic parameters, only eight agronomic/phenotypic endpoints were submitted to statistical analysis, two of them in each group (with and without the application of the complementary herbicide) were considered to be significantly different, with one of these differences falling in equivalence category IV.

Compositional data revealed many statistically significant differences in regard to 66 constituents that were assessed: • Statistically significant differences between the GE maize (not treated) and the non-GE comparator were identified for 29 endpoints. One was described as being in equivalence category III / IV. • Statistically significant differences between the GE maize (treated) and the non-GE comparator were identified for 34 endpoints. One was described as being in equivalence category IV.

It has to be assumed that this event is essentially different from its comparator in regard to many compositions and biological characteristics. Even if changes taken as isolated data might not directly raise safety concerns, the overall number of effects and their strong significance has to be taken as a starting point for much more detailed investigations. It is not acceptable that EFSA failed to require further studies e.g. • No data from Omics (proteomics, transcriptomics, metabolomics)

were used to assist the compositional analysis and the assessment of the phenotypical changes. • More powerful statistical analysis, such as multidimensional analysis, was not applied to the data. • No field trials were conducted that lasted more than one season. Thus, based on current data, site-specific effects can hardly be assessed. • Further, no data were generated representing more extreme environmental conditions, such as those caused by climate change. Although no application has been filed for cultivation, data on the interaction between the plants and the environment have to be considered as one of the starting points in risk assessment of the plants, and must be made available and assessed in detail. • In addition, more varieties carrying the transgenes should have been included in the field trials to see how the gene constructs interact with the genetic background of the plants.

As mentioned, EFSA and the applicant omitted to assess the GE maize in regard to its intended purpose. Due to the increased content of EPSPS enzymes that confer resistance to glyphosate, it has to be expected that these plants can and will be exposed to higher and also repeated dosages of glyphosate (see also the comments from experts of member states, EFSA, 2018b). Higher applications of glyphosate will not only lead to a higher burden of residues in the harvest, but may also influence the expression of the transgenes or other genome activities in the plants. The same aspect is relevant in regard to resistance to glufosinate, which might be applied in higher dosages due to increasing weed pressure.

This aspect, which is the most relevant in regard to this specific event, was completely ignored in the risk assessment as performed. Only the so-called ‘intended’ usage of the complementary herbicide was taken into account, with single sprayings of each of the herbicides. However, the practical conditions under large scale cultivation and increasing use of the complementary herbicides were left aside. These missing data are the cause of substantial flaws in following risk assessment steps.

EFSA should have requested that Syngenta submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, also including repeated spraying. The material derived from those plants should have been assessed by using Omics techniques to investigate changes in the plants composition or agronomic characteristics

Furthermore, while the GMO panel considers the assessment of the toxicity of the residues from spraying to be outside its remit, it is the duty of the GMO panel to consider and assess the specific metabolism in the plants and the specific metabolites that might occur in the plants after application of the complementary herbicides. These residues might show a specific pattern or accumulation that only occurs in this specific event. The pesticide panel can only assess the toxicity of these metabolites, if the GMO panel request specific data on metabolism and metabolites, also considering the various formulas, mixtures and combination of

the complementary herbicides. So even if it is the case that the pesticide panel only has to assess the toxicity of these metabolites, it is the duty of the GMO panel to request these specific data that are needed to conclude on the safety of these plants.

Based on the available data, no final conclusions can be drawn on the safety of the plants.

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b. Food Safety Assessment:
Toxicology

We agree with EFSA that the data as presented from the 90-day feeding study do not seem to indicate adverse health effects. However, the reliability of the data is questionable:

• The diets should have been composed in way that the results from 10% and 41.5% diets can be compared. • The stability of the test and control materials was not verified in this study. • The material used in the diet seems to be largely different from food and feed that will result from the harvest of commercial large scale cultivation under practical conditions.

EFSA should not accept data from feeding trials that are impacted by these basic uncertainties. Furthermore, chronic feeding studies, including assessing next generation effects, were not conducted.

There are further relevant issues: For example, the potential impact on the intestinal microbiome also has to be considered. Such effects might be caused by the residues from spraying since glyphosate has been shown to have negative effects on the composition of the intestinal flora of cattle (Reuter et al., 2007) and poultry (Shehata et al., 2013). Further, Bremmer and Leist (1997) examined the possible conversion of NAG to glufosinate in rats. Up to 10% deacetylation occurred at a low dose of 3 mg/kg bw as shown by the occurrence of glufosinate in the faeces. The authors concluded, however, that most of the conversion was caused by bacteria in the colon and rectum, although toxicity findings indicate partial bioavailability (Bremmer & Leist, 1997). In general, antibiotic effects and other adverse health effects might occur from exposure to a diet containing these plants; these were not assessed under pesticide regulation.

Further attention should be paid to the specific toxicity of the metabolites of the pesticide active ingredients that might occur specifically in the GE event. For example, glufosinate is classified in the EU as showing reproductive toxicity.1 But there were no detailed investigations into the metabolites arising from spraying glufosinate onto these plants; these metabolites might also differ from those of the

parental plants. Nonetheless, both the EU pesticide regulation and the GMO regulation require a high level of protection for health and the environment. Thus, in regard to herbicide-resistant plants, specific assessment of residues from spraying with complementary herbicides must be considered to be a prerequisite for granting authorisation. In addition, cumulative effects have to be investigated if a plant contains or produces other compounds that are potentially toxic.

In addition, cumulative effects have to be investigated if a plant contains or produces other compounds that are potentially toxic. It should be acknowledged, that no new methodology is needed to assess the health risks emerging from the combinatorial application of the herbicides and their potential interaction with the other plant constituents. Suitable methodology to assess combinatorial effects that emerge from simultaneous exposure to a fixed combination of potential stressors via a defined route of exposure (as it is the case with food and feed products derived from genetically engineered plants that are resistant to several herbicides) is available and widely used. For example, chronic feeding or multigenerational studies are a well-established method to generate the relevant data.

As a result, the toxicological assessment carried out by EFSA is not acceptable.

Bremmer, J.N. and Leist, K.-H. (1997) Disodium-N-acetyl-L-glufosinate; AE F099730 – Hazard evaluation of Lglufosinate produced intestinally from N-acetyl-L-glufosinate. Hoechst Schering AgrEvo GmbH, Safety Evaluation Frankfurt. TOX97/014. A58659. Unpublished.

Reuter, T, Alexander, T.W., Martinez, T.F., McAllister, T.A. (2007) The effect of glyphosate on digestion and horizontal gene transfer during in vitro ruminal fermentation of genetically modified canola. Journal of the Science of Food and Agriculture, 87(15), 2837-2843.
https://onlinelibrary.wiley.com/doi/abs/10.1002/jsfa.3038

Shehata, A.A., Schrödl, W., Aldin, A.A., Hafez, H.M., Krüger, M. (2012) The effect of glyphosate on potential pathogens and beneficial members of poultry microbiota in vitro. Curr Microbiol, 6(4): 350-358.
https://link.springer.com/article/10.1007/s00284-012-0277-2

Allergenicity

No data were presented to show that plant composition is unchanged in regard to allergenic potential.

There might be various reasons why the allergenic potential in the MZHG0JG event is increased: higher applications of glyphosate will not only cause a higher

burden of residues in the harvest, they may also change the composition of the plants in regard to naturally occurring allergens. No data were presented to assess such potential effects.

Consequently, the assessment in regard to allergenicity cannot be regarded as conclusive.

Others

According to Regulation (EU) No 503/2013, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. Thus, the monitoring report should at very least contain detailed information on: i) actual volumes of the GE maize imported into the EU, ii) the ports and silos where shipments of the GE maize were unloaded, iii) the processing plants where the GE maize was transferred to, iv) the amount of the maize used on farms for feed, and v) transport routes of the GE maize.

Environmental monitoring should be run in regions where viable kernels of the GE maize are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of the GE maize, all receiving environments need to be monitored.

Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing MZHG0JG maize during or after the production process, and during or after human or animal consumption should be part of the monitoring procedure (see also EFSA, 2018b).

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3. Environmental risk assessment

Any spillage from the kernels has to be monitored closely. EFSA completely overlooked that populations of teosinte are abundant in Spain and France; these have to be considered to be wild relatives that enable gene flow and potential spread of the transgenes throughout the fields and the environment (Trtikova et al., 2017). Without detailed consideration of the hazards associated with the potential gene flow from maize to teosinte and from teosinte to maize, no conclusion can be drawn on the environmental risks of spillage from the GE maize.

Further, as shown by Pascher (2016), EFSA has also underestimated the risks posed by occurrence of volunteers from maize plants.

Consequently, environmental risk assessment carried out by EFSA is not acceptable.

Pascher, K. (2016) Spread of volunteer and feral maize plants in Central Europe: recent data from Austria. Environmental Sciences Europe, 28(1): 30. https://link.springer.com/article/10.1186/s12302-016-0098-1

Trtikova, M., Lohn, A., Binimelis, R., Chapela, I., Oehen, B., Zemp, N., Widmer, A., Hilbeck, A. (2017) Teosinte in Europe – Searching for the Origin of a Novel Weed. Scientific Reports, 7: 1560. https://www.nature.com/articles/s41598-017-01478-w

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4. Conclusions and recommendations

The EFSA risk assessment should not be accepted.

Organisation: The European GMO-free Citizens
Country: The Netherlands
Type: Others...

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a. Assessment:
Others

CHECK OUT THE RESULTS!

BY SHANNON MCCABE

Traditional corn has 28% more protein than the average GMO food/feed corn in our study,meaning you have to eat 28% more on average to get the same nutrition. Modern GMO food is full of empty carbs and calories, but greatly lacking in real nutrients.

https://www.rareseeds.com/corn-study/

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5. Others

This is a supplement to views which we expressed previously.

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
b. Food Safety Assessment:
Toxicology

With the advent of Genetic modification, corn has been forced into an arranged marriage with pesticides and other harsh chemicals. Much work has been put into creating GMO corn varieties that can tolerate exposure to massive amounts of pesticides. Millions of acres of GMO corn are sprayed with the herbicide roundup each year. Corn has become weaponized in order to wage war on insect pests and weeds. Read all text here, from: https://www.rareseeds.com/corn-study/

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5. Others

Second supplement