Soybean A2704-12

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

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a. Assessment:
Allergenicity

Statements by mothers in the USA, where GMOs are not labelled

"When my son was born he fussed a lot, the whole day, wouldn't nap. I breast fed until he was three months old. And because his gut was not right, he fussed and I could never console him. I tried all the gassy meds, not sure they are considered meds. Once on formula the fussy continued, we switched to different formulas, but not until we switched to Parent's Choice Organic (Walmart), his fussy stopped, he began taking naps. As a toddler, I fed him Cheerios, a main staple in our house. The tantrums began; two hours at a time, a couple times a day. This is with head banging or slamming his head into the wall repeatedly. He wouldn't let me hold him, not even touch him. Can you imagine not cuddling your baby? I cried every day. I had watched the movie Food Inc. It touched on a subject I wasn't familiar with. After watching Genetic Roulette, I cleaned out the cupboards. After doing this, within two weeks my son's tantrums stopped completely, he started smiling, crawling into my lap for cuddles. I had no idea that was the issue. Even now when he gets something conventionally/GMO poison, he'll have another tantrum like his past. So if there's a question as to where it's from - what kind of seed, I don't take it. So for me and my family, we bow out from being a guinea pig." - Stephanie Vanderyacht

"My husband was in hospital 5 times last year. Doctors wanted to remove part of his intestine because it was so infected. Instead, doctors pumped him full of antibiotics for a week when he got out of hospital I changed his diet and all our family food choices to NON- GMO foods WOW, what a difference! He’s doing great and food never tasted so good! I will march sign petitions anything to reclaim our healthy labeled food choices. Godspeed! JUST SAY NO TO GMOs ….MAAM! " Rhonda Bryne, MAA

My 7 year old son was diagnosed with asthma and needed glasses inside of two weeks. I started learning about asthma and natural ways to control it. Then I found out about GMO. I removed my family from GMO foods/drinks. My 7 year old

went from needing a nebulizer 3x's a day to not at all. His asthma disappeared. He also no longer had the stigmatism that required glasses. The eye Dr. said he must have had 'some sort of inflammation' that is now gone for whatever reason. The reason was removing GMO from our diets. He was recommended for retention last year. This year, he is at the top of his class. Karen L.~Moms Across America The above testimonials are a sampling of the hundreds of testimonials which Moms have sent to us. More see:
http://www.momsacrossamerica.com/zenhoneycutt/mom_s_testimonials

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Others

Angela Browning, on behalf of the UK Department of Agriculture, Fisheries and Food, gave the go-ahead to it in 1995, whereupon it was brought onto the market throughout the EU.

This is the first GM soy to have been approved in the UK (by Angela Browning on behalf of the British Ministry of Agriculture, Fisheries and Food), whereupon it was placed on the market throughout the EU. Name: Event Code: MON-Ø4Ø32-6 Trade Name: Roundup Ready™ soybean. In 2000, the Health Council of the Netherlands wrote to the Minister for Public Health, Welfare and Sport as follows: Subject: Recommendation concerning the safety of herbicide-resistant soy GTS 40-3-2. Your ref.: GZB/VVB 2077665 Our ref.: 2000/03VNV, U1599/JW/cb/622-AB Annexes: 2 Date: 14 July 2000 "This is probably true of other crops which have been genetically modified using the charged particle method. It does not appear possible, given current molecular biological technology, to establish with certainty that no additional unknown protein is formed in this type of GM crop. It can only be assumed to be the case…." (See the report for more.) The only evidence which was examined was reports released by Monsanto in May and June 2000. Feed tests were carried out which took only between one and four weeks, and the percentage of soymeal (not the entire plant) in the feed was only 25%! The Health Council insisted on food trials in humans, but they were not done in the laboratory: rather, citizens were used as human guinea pigs. Because this GM soy, which had been made resistant to Roundup, was authorised in the United Kingdom in 1995 for use in feed and food, the authorisation was valid throughout the EU. The authorisation for this GM-RR soy was renewed in 2012 and will be again in 2022 at the request of Monsanto (now Bayer). This is because: (2) "Foodstuffs produced using genetically modified soy, including food additives, animal feed and additives for animal feed produced using genetically modified soy 40-3-2, were placed on the market prior to the entry into force of Regulation (EU) No 1829/2003. (3) Pursuant to Articles 8(1) and 20(1) of Regulation (EC) No 1829/2003, products which were lawfully placed on the market before the date of application of the Regulation may continue to be placed on the market provided that the Commission is notified accordingly." This is scandalous!!!!!

4. Conclusions and recommendations

GMO-free Citizens do not want GMOs on their plates, nor do they want them in medicines, biologicals, vaccines or crops on the fields. We eat organic food.

5. Others

"The fact that the consumer has excellent objective arguments (adverse health effects) for rejecting GMOs is not apparent from this article, i.e. no upsides, no one has asked about the downsides, the health risks have not been investigated (see the court case against Monsanto conducted by the lawyers Cohn *et al.*), government policy failing in the face of the growing power of the multinationals. Consumers, don't let yourselves be manipulated! As we have already said, there are no advantages for the consumer, and the downsides are not mentioned, even though they are many. So far, there have only been drawbacks for the consumer, such as adverse health effects: asthma, sensitisation/eczema, the allergies which have been reported, brain damage, neural cell death (apoptosis), reduced sperm quality, deformations: health problems which are the subject of validated scientific reports. And yet the consumer gets to hear none of this. Environmental organisations are not concerned with human health problems caused by GM foods, because “they're none of our business” (whereas environmental problems ARE). Nor does it appear to be the business of the Ministry of Health, Spatial Planning and the Environment or the Netherlands Commission on Genetic Modification (COGEM). Not even the Environmental Yardstick takes account of health effects (no available data, or at best, data which are difficult to get hold of!). The Minister has his own area of responsibility. We are gently being led, like sheep, to the final destination: acceptance. That is also the purpose of the motion brought before the Lower House of Parliament by Ms Agnes van Ardenne (CDA) in the summer of 1999. And so, without any reliable information, the consumer is being corralled into giving informed approval of the measures which the Government intends to adopt – as a result of which the GOVERNMENT'S RESPONSIBILITY for preventing disasters is shifted to the consumer. (See the White Paper on Food Safety, 12 January 2000, and the report by Berenschot dated 8 October 1999: 'Voedselveiligheid: Waar borgen en waar zorgen – Onderzoek naar het waarborgen van Voedselveiligheid' ('Food Safety: Guaranteed or not? An Investigation into Food Safety Guarantees'). Keeping citizens informed is not the Government's priority." J. van der Meulen, L. Eijsten.

Our comment: This is still going on. When are these people going to own up?

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

a. Assessment:
b. Food Safety Assessment:
Toxicology

Supplement: New research confirms GM causes massive off-target damage to plant genomes Details Published: 28 January 2019 A new open-access paper (see link) by researchers at the Salk Institute in the US confirms that the GM transformation process in plants is extraordinarily damaging at a genetic and epigenetic level. The researchers found that inserting new genes into a plant using the bacterium Agrobacterium tumefaciens as a shuttle creates major unintended effects in the genome. The authors studied four different GM lines of the standard laboratory model plant Arabidopsis. https://www.gmwatch.org/en/news/latest-news/18730

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

EFSA should have requested data that took the increasing problems with herbicide-resistant weeds in fields where the soybean is grown into consideration; these weeds very often show multiple resistances that can lead to crops being treated with higher amounts of glufonsinate and other pesticide applications. In fact, the USDA data base shows that there has been a strong increase in overall pesticide applications in soybean cultivation within last ten years, with substantial dosages of glufosinate being applied (https://www.nass.usda.gov/Quick_Stats/Lite/result.php?84BEAC98-E84C-3AC0-9EAE-E6885717C3F2). According to USDA, the average applications of glufosinate (a.i.) were 0,66 kg/(a.i.) ha in 2017, with an application rate of 1,3. Bayer in its own recommendations suggests up to 1,6 kg (a.i.)/ha. This is in line with Monsanto, in its patent application WO2008051633, recommends that up to 1.6 kg (a.i.)/ha of glufosinate is used on the soybean crops. It has to be assumed that similar dosages are also applied in regions with high weed pressure. Higher numbers of pesticide applications will not only lead to a higher burden of residues in the harvest, but may also influence the expression of the transgenes or other genomic activities in the plants due to interaction with the additionally inserted gene constructs.

This aspect, which is the most relevant in regard to the re-assessment of this event, was completely ignored in the EFSA risk assessment. EFSA should have requested that Bayer submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying. The material derived from those plants should also 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.

Further, in the original application, several open reading frames were identified, but not assessed in regard to all relevant biological active compounds such as miRNA. Therefore, EFSA should have requested more detailed analysis of the relevant gene products.

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

In the past ten years, agricultural practice in the cultivation of herbicide-resistant soybeans has changed considerably; there has also been a substantial increase in the number of regions where these soybeans are grown and, therefore, new field trials should have been requested from the applicant for all relevant regions. It has to be assumed that the plants will be exposed to higher dosages and sprayed more frequently with the complementary herbicide in comparison to agronomic practice 10 years ago. A higher number of applications will not only lead to a higher burden of residues in the harvest, but may also influence plant composition and agronomic characteristics. The USDA data base shows a strong increase in overall pesticide applications in soybean cultivation within last ten years, with substantial dosages of glufosinate being applied (www.nass.usda.gov/Quick_Stats/Lite/result.php?84BEAC98-E84C-3AC0-9EAE-E6885717C3F2). According to USDA, the average applications of glufosinate (a.i.) were 0.66 kg/ (a.i.)/ha in 2017, with an application rate of 1,3. Bayer in its own recommendations suggests up to 1,6 kg (a.i.)/ha. This in line with Monsanto, in its patent application WO2008051633 recommends up to 1.6 kg (a.i.) / ha of glufosinate to be sprayed in the soybean cultivation. It has to be assumed that similar dosages are also applied in regions with high weed pressure. A higher number of pesticide applications will not only lead to a higher burden of residues in the harvest, but may also influence plant composition and agronomic performance due to the additionally inserted gene constructs.

This aspect, which is the most relevant in regard to this specific event, was completely ignored in the risk assessment. Both the practical conditions in large scale cultivation in specific regions and increasing weed occurrence were left aside.

EFSA should have requested that Bayer 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 plant composition and agronomic characteristics.

Further, data representing more regions and more extreme environmental conditions, such as those caused by climate change, would have been necessary.

New field trials should have also been requested because the EU has introduced new standards for conducting trials and assessment of the data. (see Regulation 503/2013).

b. Food Safety Assessment:
Toxicology

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. There is very little data available on which degradation products in which concentrations can to be expected from the application of glufosinate on herbicide-resistant soybeans. Since glufosinate is classified as showing reproductive toxicity (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN) EFSA should have requested data on the levels of residues from spraying within last ten years. Even if this is not within the remit of the GMO panel, the risk assessor and the risk manager have to make sure that these data are provided before any decision is made on the renewal of the authorisation.

Further, while the GMO panel considers the assessment of the toxicity of the residues from spraying to be outside its remit, it is nevertheless 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 needs 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 the plants. Therefore, EFSA should request the notifier to present data regarding the residue levels of glufosinate and its respective metabolites (such as NAG) in the soybean A2704-12.

According to JMPR (Joint Meeting on Pesticide Residues administered by FAO and WHO) data, field trials in the US with glufosinate-resistant soybeans led to residue levels close to the currently applied MRL of 2 mg/kg (JMPR, 2012). This shows that careful monitoring of the residues in the imported soybeans is urgently needed.

In addition, as mentioned, a higher number of applications of the complementary herbicide 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; this is due to interaction with the additionally inserted gene constructs. These changes can have a serious impact on health since soybeans are known to produce many bioactive compounds, such as allergens and estrogens.

There are further relevant issues: for example, the potential impact on the intestinal microbiome also needs to be considered. Such effects might be caused by the residues from spraying with glufosinate because glufosinate interferes with bacterial growth and in certain circumstances acts as an antimicrobial agent; this can lead to shifts in bacterial community structures (Ahmad and Malloch 1995; Hsiao et al. 2007; Pampulha et al. 2007; Kopcáková et al. 2015; see also comments from Experts of Member States). In general, antibiotic effects and other adverse health effects might occur from exposure to a diet containing these plants that were not assessed under pesticide regulation. 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 that most of the conversion was caused by bacteria in the colon and rectum, although toxicity findings indicate partial bioavailability (Bremmer & Leist, 1997).

Despite all these open questions regarding potential impacts on health, we are not aware of a single sub-chronic or chronic feeding study carried out with whole food and feed derived from the soybeans.

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

Ahmad I, Malloch D, 1995. Interaction of soil microflora with the bioherbicide phosphinothricin. Agriculture, Ecosystems and Environment 54(3): 165-174.

Bremmer, J.N. and Leist, K.-H.7 (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. Hsiao C-L, Young C-C, Wang C-YW, 2007. Screening and identification of glufosinate-degrading bacteria from glufosinate-treated soils, Lawrence, KS, ETATS-UNIS, Weed Science Society of America.

JMPR (2012) Pesticide residues in food 2012, Report 2012. Joint FAO/WHO Meeting on Pesticide Residues. http://apps.who.int/pesticide-residues-jmpr-database/pesticide?name=GLUFOSINATE-AMMONIUM

Kopcáková A, Legáth J, Pristaš P, Javorský P, 2015. Already a short-term soils exposure to the field-rate glufosinate concentration significantly influences soil bacterial communities. Soil and Water Research 10(4): 271-277.

Pampulha ME, Ferreira MASS, Oliveira A, 2007. Effects of a phosphinothricin based herbicide on selected groups of soil microorganisms. J Basic Microbiol 47(4): 325-331.

Allergenicity

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

As mentioned, a higher number of applications of the complementary herbicide 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. These changes can have serious impacts on health since soybeans are known to produce many allergens.

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 soybean imported into the EU, ii) the ports and silos where shipments of the GE soybean were unloaded, iii) the processing plants where the GE soybean was transferred to, iv) the amount of the GE soybean used on farms for feed, and v) transport routes of the GE soybean.

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

Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing the GE soybean during or after the production process, and during or after human or animal consumption should be part of the monitoring procedure.

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4. Conclusions and recommendations

The EFSA risk assessment cannot be accepted.