Soybean MON 87751 × MON 87701 × MON 87708 × MON 89788

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

Agrobacterium & Morgellons Disease, A GM Connection? MW Ho, J Cummins - Sci. Soc, 2008 - Citeseer … Agrobacterium tumefaciens in agroinfected plants. Molecular Plant – Microbe Interactions 1993, 6(50), 673-5. 19. Ho MW and Cummins J. Horizontal gene transfer from GMOs does happen. Science in Society 38 (to appear). The association of Morgellons Disease with dirt and soil where Agrobacterium lives, the widespread use of Agrobacterium in genetic engineering of plants, and the ability of Agrobacterium to infect human cells, all point towards a possible role of genetic engineering in the aetiology of Morgellans disease via Agrobacterium. [PDF] http://www.i-sis.org.uk/agrobacteriumAndMorgellons.php -- Study Links Widely Used Pesticides to Antibiotic Resistance BY ELIZABETH GROSSMAN / CIVILEATS.COM MARCH 24, 2015 Now, the chemical has another strike against it. A new study published by the American Society of Microbiology's journal mBio has linked glyphosate and two other widely-used herbicides–2,4-D and dicamba–to one of the most pressing public health crises of our time: antibiotic resistance. https://time.com/3756870/pesticides-antibiotic-resistance/ --- Sublethal Exposure to Commercial Formulations of the Herbicides Dicamba, 2,4-Dichlorophenoxyacetic Acid, and Glyphosate Cause Changes in Antibiotic Susceptibility in Escherichia coli and Salmonella enterica serovar Typhimurium Brigitta Kurenbach,a Delphine Marjoshi,a Carlos F. Amábile-Cuevas,b Gayle C. Ferguson,c William Godsoe,d Paddy Gibson,a Jack A. Heinemanna School of Biological Sciences, University of Canterbury, Christchurch, New Zealanda; Fundación Lusara, Mexico City, Mexicob; Institute of Natural and Mathematical Sciences, Massey University, Palmerston North, New Zealandc; Bio-Protection Centre, Lincoln University, Lincoln, New Zealandd IMPORTANCE Increasingly common chemicals used in agriculture ,domestic gardens,and public places can induce a multiple antibiotic resistance phenotype in potential pathogens https://mbio.asm.org/content/mbio/6/2/e00009-15.full.pdf "Although this study only looked at two laboratory strains of human pathogens, the antibiotics examined represent what he calls "broad classes" of drugs we've come to depend on to fight infections and the herbicides are three of the most-used worldwide" #glyphosate via Twitter ---

Tweet Non gmo rapport: Pakistan has banned the import of #geneticallymodified maize seeds on health grounds. buff.ly/2pBAKHe https://tribune.com.pk/story/2081973/2-pakistan-banned-import-genetically-modified-maize-seeds-health-grounds/?amp=1&__twitter_impression=true 'Pakistan banned import of genetically modified maize seeds on health grounds' By APP Published: October 18, 2019

The ministry official remarked that the Bio-Safety Committee had approved the import of GM seeds for tests and trials but imposed a ban on the import of GM maize seeds in 2018. The committee wanted to engage in further deliberations on the health and environmental impact and effects of cross-pollination…...MORE see website. Published in The Express Tribune, October 18th, 2019.

-- This behavior suggests that if refuge areas and strategies such as pest monitoring are not established, these insects could generate higher resistances to the plants with the endotoxin Cry1F. Keywords : Fall armyworm Larvae; Pest insects Population dynamics; Transgenic. http://www.scielo.org.co/scielo.php?script=sci_abstract&pid=S0304-28472019000308953 --

Toxic substances such as pesticides can cause effects on sensitive individuals in concentrations up to ten thousand times lower than previously assumed. This was shown by Researchers at the Helmholtz Centre for Environmental Research (UFZ) in their latest study published in Scientific Reports. https://www.ufz.de/index.php?en=36336&webc_pm=46/2019 ---

NOV 22, 2019 — The pesticide industry and EU regulators knew as long ago as the 1980s-1990s that Roundup, the world's bestselling herbicide, causes birth defects but they failed to inform the public. https://www.researchgate.net/publication/258416831_Roundup_and_birth_defects_Is_the_public_being_kept_in_the_dark ---

Jeffrey Smith Webinar: How Glyphosate Causes Cancer https://vimeo.com/366811206 Webinar Highlights: 4:00 – What is sulforaphane? 8:00 – What are gap junctions? 18:00 – How glyphosate reduces gap junction function 22:30 – How sulforaphane improves gap junction function 32:30 – What is the Nrf-2 pathway? 41:40 – How glyphosate negatively impacts Nrf-2 and how sulforaphane improves In this revealing interview by Jeffrey Smith with Dr. John Gildea, and Dr. Martin Katz, you will discover their breaking research on how glyphosate wreaks havoc in our bodies by disrupting the communication network between cells and how sulforaphane - the good chemical from broccoli - prevents this. -- . This behavior suggests that if refuge areas and strategies such as pest monitoring are not established, these insects could generate higher resistances to the plants with the endotoxin Cry1F. Keywords : Fall armyworm Larvae; Pest insects Population dynamics; Transgenic. http://www.scielo.org.co/scielo.php?script=sci_abstract&pid=S0304-28472019000308953

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-- Fragment Beschouwing op bezwaarschriften resp. beroepschriften aan VROM en Raad van state Amsterdam, 11 augustus 2002.

SOME OBSERVATIONS

‘And they could put up a sign saying ‘No Entry’ or ‘Do not use’, or prevent public access by establishing plantations, as happened in the past when carcasses infected with anthrax were simply buried. The poor CTB! (Bt, Bc - bacillus cereus, Ba - bacillus anthracis - they are all related, can take on one another's characteristics. Soil life does not stand still!)’

EN

‘I am suspicious of arable crops which are genetically modified to be pesticide-resistant. The companies introducing GM crops which are resistant against substances used in pesticides, are responsible for damage to health. The largest company in this field in the Netherlands has told me that it does not know the substances used in the herbicides against which they make their plants resistant. It's a matter for Hoechst, apparently. But Hoechst just passes the buck back. Anyone introducing a new strain is responsible for its consequences. Even Monsanto claims that it bears absolutely no responsibility for the potential consequences of using its products in crop production. And that’s OK? A little aside: Foray 48B, a Bt-insecticide,– contains methylparaben as an ‘active ingredient’. This was listed by the EPA back in the day as an active ingredient. This stuff can also be found in ointments, etc., which you spread on your skin to prevent chapping. Can anyone explain that to me?’ L. Eijsten (used with permission).

https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/een-en-ander/

Others

We agree with Austria: CA Austria:” The assessment of toxic effects is largely based on the risk assessment of the single events. No toxicity or feeding studies using whole plant material of the GM soybean stack MON87751xMON87701xMON87708xMON89788 were conducted. However, a specific study to test for potential combinatory effects between the three Cry-proteins is presented.“ -- EU report on weedkiller safety copied text from Monsanto study This article is more than 2 years old Exclusive: EU’s food safety watchdog recommended that glyphosate was safe but pages of report were identical to application from pesticide maker The European food safety authority (Efsa) based a recommendation that a chemical linked to cancer was safe for public use on an EU report that copied and pasted analyses MORE from a Monsanto study, the Guardian can reveal. https://www.theguardian.com/environment/2017/sep/15/eu-report-on-weedkiller-safety-copied-text-from-monsanto-study

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. Critics say that the Roundup formula used in the U.S. also contains a surfactant that makes the herbicide far more toxic than the variation of the spray sold in the European market. https://theintercept.com/2019/08/23/monsanto-republicans-cancer-research/ The Monsanto Papers Updated 11 Oct 2018, 7:57amThu 11 Oct 2018, 7:57am The secret tactics used by global chemical giant Monsanto, to protect its billion-dollar business and its star product, the weed killer, Roundup. "Monsanto has engaged in a systematic and deliberate campaign to attack any science that says their product is not safe and to attack any scientist that has the MORE courage to say something." Lawyer https://www.abc.net.au/news/2018-10-08/the-monsanto-papers/10352384 --

"…75% of all the glyphosate ever used – since it was introduced in the 1970s – has been used in the last ten years…. " http://waronwildlife.co.uk/2019/11/15/new-podcast-nick-mole-pesticide-action-network-uk/ ---

Consumer confidence: On 27 March 2001, I wrote to you in connection with the article 'Landbouwer blieft geen genmais meer' [Farmers, please no more GM maize] in the newspaper of 10 March 2001, but unfortunately I did not receive any answer. An article in the paper of 4 April last by Mr Trommelen struck me in particular. In the report by 'experts' from alternative and ordinary agriculture - who are those experts? Are they 'manufactured' experts, as a result of a study commissioned by the Ministry for Economic Affairs and written by Schenkelaars Biotechnology, entitled 'Risico's van genetisch gemodificeerde organismen' [Risks of genetically modified organisms], on the basis of CCRO research programmes from 1991 to 1998, the aim being 'to gain and deepen the understanding that policy-makers and scientific advisers need in order to assess the potential risks of genetically modified organisms', in the words of Professor P.G. de Haan in the foreword. They were seeking a short-term risk assessment and it was impossible to say that major risks had been identified - or they had been overlooked. And now, what about long-term risks? In the piece about the need for understanding in order to make a risk assessment, there were five mentions of a literature study. Analyses had been conducted, mathematical models developed, the possible consequences simulated, experience gained using the safety assessment of field trials, etc., etc. All relating to the agricultural impact. And people? Adverse health effects? Is there a decision tree for those too? The policy staff at the Ministry for Economic Affairs will no doubt have an answer to this as well! Let us hear it! (I see that the Ministry of Health, Welfare and Sport did not take part in this study). The report from the Ministry of Agriculture, Nature and Food Quality states: 'the risk of statutory 'doses of pesticides' being exceeded ...' - should that not be: the standards for pesticide residues referred to in the Pesticides Act? The report is said to show (first paragraph of your article) that the food safety of common products is guaranteed. By whom? Bla, bla - which insurance provider? Government? Standards have been set for residues in food, e.g. for glufosinate in potatoes it is 0.5 mg/kg (ppm), for glyphosate in wild mushrooms 50 ppm, in soybean 20 ppm, in pigs' kidneys 0.5 ppm, in cows', goats', and lambs' kidneys 2 ppm, etc. The latest update from the EPA in the USA gives the following limits for glyphosate, for example: grain 20 ppm, sugar-beet pulp 25 ppm, rapeseed meal 15 ppm, rapeseed 10 ppm, etc., all without AMPA. And the limit for glyphosate residues in the kidneys of cattle, goats, hogs, horses, sheep is 4 ppm, and for the liver of these animals 0.5 ppm. The liver and kidneys of poultry (a lot of which are eaten) are permitted to contain 0.5 ppm of glyphosate residues. All this is calculated on the basis of the lifetime consumption of a 'normal' person. You can't go overboard then! Very small children, who have to eat more than would be normal per kg/own body weight, don't get a very good deal. HOWEVER ... the standards are based on the active substance, i.e. glufosinate technical and glyphosate technical, and not on the added substances which together constitute the formulation. I have a lot of documents on this. In the USA, the EPA thus sets standards that are also important for us, because of imported products, such as animal feed. As you have already stated, the substances in the formulation are more harmful than the active substance alone. This is true of Finale, Liberty, Basta and indeed Roundup. The active substances are often used in laboratories. Their harmfulness for e.g. skin, eyes, breathing, etc. is indicated using classes: I, II, III and IV, class I being the most toxic. There can be no misunderstanding, the EPA data on this are quite clear. For example, Basta - and therefore Liberty too probably - contains 30% AES (alkyl ether sulphate) which has cardiovascular effects and is class I toxic (Iskandarova). The College Toelating Bestrijdingsmiddelen (CTB) [Pesticide Authorisation Committee] is supposed to analyse all additives before granting approval! But what do I read in the Pesticides Act, on pages 143 and 144 (part 2)? ‘It is generally sufficient to perform these tests with the main formulation type to be authorised’. What do the experts say now? Either insufficient analyses have been done or the Government is NOT concerned about the harmfulness. Which is all to the detriment of the consumer - i.e. all of us.

Kind regards, L. Eijsten (used with permission). https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/consumentenvertrouwen/ -- Envi committee chair of European Parliament: We've just rejected new GMOs by a very large majority. The European Commission must include in the #greendeal a change to its practices and stop authorising GMOs despite the lack of a majority in the Council (of Ministers) & the Parliament. Tweet Gm watch https://www.europarl.europa.eu/news/en/press-room/20191113IPR66416/parliament-opposes-plans-to-authorise-four-herbicide-resistant-gmos --

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4. Conclusions and recommendations

How can people who would like to respond be well informed if the consultation document is only in English and not in other EU languages? Not even in the most important languages, such as German, French and Spanish? This error has to be corrected! This is why there are so few responses from countries where English is not spoken! To repeat: we do not want this GM soya!! How can the Netherlands approve this toxic soya! This is a mystery to us.

cry2Ab2

cry1A.105

Glyphosate

Poison, poison, poison. Insects etc. are being poisoned with built-in poison. And we eat it too. War against nature ... In the end, you can’t beat nature. The answer is to cooperate with nature.

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5. Others

Soja brok wordt in de Nederlandse landbouw al vervangen door granen en mais. Waarom deze giftige gentech soja nog toelaten?

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6. Labelling proposal

If you do not decide to ban this GM soya (which can never be the same as 'ordinary' soya, GM maize [sic] has after all always been altered!), which we would consider a real shame, a warning triangle with a skull and crossbones would be most effective. And not only where GM organisms form 0.9% of the ingredients, but whenever they are present. This response is also being sent on behalf of Stichting Ekopark, Donaustraat 152, Lelystad, NL.

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

28-11-2019 Supplement to our previous objections, also on behalf of Stichting Ekopark, Donaustraat 152, 8226 LC Lelystad. : Corrected (it was incomplete): Poison, poison, poison. Insects etc. are being poisoned with built-in poison. And we (and the animals) eat it too. War against nature ... In the end, you can't beat nature. The answer is to cooperate with nature.

cry1A.105

cry2Ab2

cry1Ac

dmo -> Dicamba

cp4 epsps (aroA:CP4) -> Glyphosate --

Others

28-11-2019. Addition to our previous objections: We read:

ONE: Quoted in the New York Times Magazine (October 25, 1998, ‘Playing God in the Garden’), Philip Angell, Monsanto's director of corporate communications, famously stated: ‘Monsanto shouldn't have to vouchsafe the safety of biotech food. Our interest is in selling as much of it as possible. Assuring its safety is the FDA's job.’

TWO: From the Federal Register, Volume 57, No.104, ‘Statement of [FDA] Policy: Foods Derived from New Plant Varieties’, here is what the FDA had to say on this matter: ‘Ultimately, it is the food producer who is responsible for assuring safety.’

All by: Jon Rappoport, No more fake news, 25-11-2019
https://blog.nomorefakenews.com/2019/11/25/monsanto-science-and-fraud-are-same-thing/

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4. Conclusions and recommendations

The Netherlands should not give any further aid to GM soya farmers in the Amazon - leave the Amazon and its people in peace!

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5. Others

Problems with Dicamba drift in the USA: Our remark: 200-year-old cypresses have been seriously weakened and are at risk of dying on account of Dicamba drift, as are many other trees and crops in the USA that are not resistant to this preparation. And we are supposed to eat the GM soybeans that have been made resistant to it? No thank you!

Quotes:

Rogue Weedkiller Vapors Are Threatening Soybean Science “Dicamba doesn't always stay where it belongs — even new versions of the chemical that have been reformulated to avoid this problem. All over the country, it's been evaporating and floating across the landscape, damaging vegetation that doesn't have those special dicamba tolerance genes. The victims include peach trees, tomato gardens, and….”MORE historic cypress trees. 53
https://www.npr.org/sections/thesalt/2019/07/19/742836972/rogue-weedkiller-vaporsare-threatening-soybean-science

July 19, 201911:26 AM ET National Public Radio A Drifting Weedkiller Puts Prized Trees At Risk September 27, 2018 4:09 PM ET

Dicamba hasn't killed the trees in the lake, but Hayes is convinced that the chemical has weakened them. And new cypress trees can't sprout and grow in the water. The trees that make Reelfoot Lake what it is — if they die, they're gone forever, he says.

https://www.npr.org/sections/thesalt/2018/09/27/651262491/a-drifting-weedkillerputs-prized-trees-at-risk A Wayward Weedkiller Divides Farm Communities, Harms Wildlife October 7, 20175:52 AM ET "My heart just came up in my throat, thinking, 'Oh my gosh, we've got a real problem,' " Wildy says. “He was seeing the telltale symptoms of dicamba damage. Apparently, dicamba fumes had drifted into his farm from fields up to a mile away where neighbors had sprayed the chemical on their new dicamba-tolerant soybeans and cotton.” October 7, 2017

https://www.npr.org/sections/thesalt/2017/10/07/555872494/a-wayward-weed-killerdivides-farm-communities-harms-wildlife?t=1563602709089 National Public Radio

https://text.npr.org/s.php?sId=555872494 -- Monsanto Attacks Scientists After Studies Show Trouble For Weedkiller Dicamba “The new "low volatility" versions of dicamba didn't stay where they belonged. They drifted into nearby fields, damaging crops there — mostly soybeans, but also vegetables and orchards. There were reports of damage from Mississippi to Minnesota, but the problem was worst in Arkansas, Missouri and Tennessee.” October 26, 20174:57 AM E https://www.npr.org/sections/thesalt/2017/10/26/559733837/monsanto-and-the-weedscientists-not-a-love-story?t=1563602824913

National Public Radio Alles door Mr. DAN CHARLES. --

Adding glyphosate to dicamba increases volatility, researchers find Published: 19 June 2019 Glyphosate is often tank-mixed with dicamba New research suggests spraying dicamba in warm temperatures and adding glyphosate to a dicamba spray mixture could increase dicamba volatility, potentially leading to increased off-target movement and damage to non-dicamba-tolerant plants.

https://www.gmwatch.org/en/news/latest-news/18996 Paper: Dicamba volatility in humidomes as affected by temperature and herbicide treatment Thomas C. Mueller (a1) and Lawrence E. Steckel (a2) DOI: https://doi.org/10.1017/wet.2019.36 Published online by Cambridge University Press: 06 June 2019

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

4-12-2019. Second supplement to our previous objections, and those from Stichting Ekopark, Lelystad, NL.

Austria is the first country in the EU to ban glyphosate - from 1 January 2020.

From GMWatch (Twitter) Quote:"EU Commission gives green light to Austria's glyphosate ban! Austria will become the 1st country in the EU to phase out glyphosate on 1 January 2020″. @global2000 call for support for farmers to help them transition away from #glyphosate. Bron. (Duits).

Dutch translation:

By GMWatch (Twitter). [translation into Dutch of immediately preceding EN text] . Source (German): https://www.gentechvrij.nl/2019/12/03/oostenrijk-ban-gly/ --- The Netherlands earns billions from Brazil, including the Amazon • Gidi Pols, Economics editor (NOS [Dutch Broadcasting Company])

Extract: 'Intensive livestock farming and soya cultivation is moving in on the edges of the Amazon' says Kees Koonings, Professor of Brazilian Studies at the University of Amsterdam. Farmers are burning areas of rain forest to make room for crops and cattle. 'We are a major importer of soya from Brazil.'

https://nos.nl/artikel/2298683-nederland-haalt-voor-miljarden-uit-brazilie-ook-uit-amazonegebied.html --- 29 November 2019. Subject: Reply to questions from the Dutch Labour Party MPs Ploumen and Van den Hul concerning the report 'Regenwoudmaffia vermoordt en bedreigt inwoners Amazone' [Rain forest mafia murdering and threatening populations in the Amazon].

Extract: 'Moreover, the EU wants to become less dependent on imports and more self-sufficient in the production of vegetable protein, because of the concerns and risks associated with soya production. This EU initiative will be developed further in a national protein strategy tailored to the situation in the Netherlands.'

https://www.rijksoverheid.nl/documenten/kamerstukken/2019/11/29/beantwoording-vragen-over-het-bericht-regenwoudmaffia-vermoordt-en-bedreigt-inwoners-amazone

Our question: Why does the Netherlands approve this GM soya for the EU market when the EU wants to become less dependent on imports and more self-sufficient in the production of vegetable protein, because of the concerns and risks associated with soy production? Moreover, this application is also being made through the Netherlands!

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

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a. Assessment:
4. Conclusions and recommendations

Supplement of 4-12-2019. Quote: After so many years of EFSA's poor implementation and partial disregard of repeated EU Parliament requests to fix its independence policy, the new Parliament would be wise to step up the pressure on this EU agency.
https://corporateeurope.org/en/2019/06/efsa-gene-drive-working-group-fails-independence-test

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

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a. Assessment:
4. Conclusions and recommendations

5-12-2019. Third supplement to our previous objections, and those from Stichting Ekopark, Leleystad.

We read: 'In the Amazon, the river is also being taken over by the soya farmers.

It is not only the Amazon rain forest that is at risk, but also the rivers. They are being used among other things to transport soya. The big food conglomerates that export the soya are building transshipment ports and these pose a threat to fishermen and other local communities.'

Trouw, Wies Ubags, 5 December 2019, 1:00

https://www.trouw.nl/buitenland/in-de-amazone-wordt-ook-de-rivier-ingepikt-door-de-sojaboeren~b6b0296e/

Our comment: All the more reason not to approve this toxic GM soya for the EU market! There are enough initiatives in the EU for alternative animal feed.

Such as:

We read (fragment): ‘Dairy cattle. Wheat DDGS is a good substitute for soya meal in dairy cattle feed. It provides a good protein supplement at both rumen and gut level. Because it digests slowly, there is little risk of ruminal acidosis and muscular rheumatism.’

And: ‘Availability

Wheat DDGS is available throughout the year and can be supplied per full load of 30 tonnes, tipped or blown.’

https://www.weidseblik.nl/producten/grondstoffen/tarweglutenvoer. And we, the consumers, absolutely do not want this toxic GM soya on our plates!

Organisation: Testbiotech e.V. - Institute for Independent Impact Assessment of Biotechnology
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

The process of genetic engineering involved several deletions and insertions in the parental soybean plants. 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; therefore, no detailed investigations were carried out in this regard. Furthermore, other gene products, such as dsRNA 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.

Furthermore, it seems EFSA (2019b) did not request specific data on the place of the insertion of the additional constructs in the genome. Instead, EFSA proposes that such data is not needed (“No requirements are laid down in the Implementing Regulation as to provide the exact location of the events in the plant genome.”) However, data are necessary to consider possible position effects. Therefore, EFSA should have requested much more detailed investigation into potential biologically active gene products, position effects and changes in metabolic pathways.

In regard to expression of the additionally inserted genes, Implementing Regulation 503/2013 requests “Protein expression data, including the raw data, obtained from field trials and related to the conditions in which the crop is grown” (in regard to the newly expressed proteins).”

However, there are three reasons why the data presented do not represent the conditions in which the plants will be grown: (1.1) the field trials were not conducted in all relevant regions where the soybeans will be cultivated, and no extreme weather conditions were taken into account; (1.2) the field trials did not take into account current agricultural management practices; (1.3.) only one transgenic variety was included in the field trials.

1.1 Environmental stress can cause unexpected patterns of expression in the newly introduced DNA (see, for example, Trtikova et al., 2015). More specifically, Fang et al. (2018) showed that stress responses can lead to unexpected changes in plant metabolism inheriting additional EPSPS enzymes. However, the expression of the additional enzymes was only measured under field conditions in the US.

As mentioned by the experts of Member States, higher application rates of the complementary herbicides can cause stress reactions in the plants and impact gene expression (EFSA, 2019b). Therefore, the plants should also have been tested in large soybean producing countries in South America, which not only differ in soil and climate but also in agricultural practice. For example, there are publications showing higher rates of glyphosate applications in South America compared to the US (Benbrook, 2016).

Whatever the case, the plants should have been subjected to a much broader range of defined environmental conditions and stressors (which, for example, have to be expected under ongoing climate change) to gather reliable data on gene expression and functional genetic stability.

1.2 Due to increased weed pressure, it has to be expected that these plants will be exposed to high and also repeated dosages of glyphosate alone and / or in combination with dicamba. Higher applications of herbicides 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. As mentioned by the experts of Member States, higher application rates of the complementary herbicides can cause stress reactions in the plants and impact gene expression (EFSA, 2019b). However, this aspect was ignored in the EFSA risk assessment. While currently, ‘on top’ glyphosate applications at an average rate of 3 to 4 kg / ha and an average overall rate of 6 to 7 kg /ha (USDA, 2019) can be expected in the US and even more in South America (see, for example, Bombardi, 2016), the amount of glyphosate used in the field trials was just 0,87 kg a.e./ha, which is close to the lowest limit of application recommended by the company (EFSA 2019b).

A statement made by EFSA (2019b) indicates that the design of the field trials should avoid major differences in the application of the herbicides: “The complementary herbicides are kept at a similar application rate across sites: indeed, for the experimental treatments to be comparable between different locations, the application rate should not differ too strongly between them.”

This statement is in direct contradiction to the requirements of Implementing Regulation 503/2013. If there are any problems in regard to comparability, EFSA should request more data which are necessary to establish a dose-response curve; using specific amounts of pesticide applied during the field trials. These data would allow the comparison and interpretation of the relevant findings.

EFSA should have requested the applicant to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying and the application of each of the relevant herbicides alone and in combination. 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 in the natural genome of the plants.

1.3. It is known that the genomic background of the variety can influence the expression of the inserted genes (see, for example, Trtikova et al., 2015). In this case, it was shown that the expression of the (naturally occurring) allergen Gly m 4 is lower in the stacked event compared to its conventional comparator. Further significant differences concern (naturally occurring) phyto-estrogens (daidzein and genistein) and the concentration of the newly expressed Cry1A.105, DMO and EPSPS enzymes. This indicates influences from the process of stacking and the resulting overall genomic background of the stacked event. Therefore, EFSA should have requested data from the parental plants to be grown in parallel. Further additional data from several varieties, including those cultivated in South America, would have been necessary.

The material derived from the plants should have been assessed by using 'Omics-techniques' to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products. Such in-depth investigations should not depend on findings indicating potential adverse effects, they should always be necessary to come to sufficiently robust conclusions to inform the next steps in risk assessment.

References:

Benbrook, C.M. (2016) Trends in glyphosate herbicide use in the United States and globally. Environ Sci Eur 28: 3. https://doi.org/10.1186/s12302-016-0070-0

Bombardi, L.M. (2016) Pequeno ensaio cartográfico sobre o uso de agrotóxicos no Brasil. Laboratório de Geografia Agrária-USP, São Paulo. OpenEdition. https://journals.openedition.org/confins/12594

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

Implementing Regulation 503/2013 requests: "In the case of herbicide tolerant genetically modified plants and in order to assess whether the expected agricultural practices influence the expression of the studied endpoints, three test materials shall be compared: the genetically modified plant exposed to the intended herbicide; the conventional counterpart treated with conventional herbicide management regimes; and the genetically modified plant treated with the same conventional herbicide management regimes."

"The different sites selected for the field trials shall reflect the different meteorological and agronomic conditions under which the crop is to be grown; the choice shall be explicitly justified. The choice of non-genetically modified reference varieties shall be appropriate for the chosen sites and shall be justified explicitly."

However, the data that were presented do not represent anticipated agricultural practices, or the different meteorological and agronomic conditions where the crop is to be grown. The following three reasons can be given: (2.1) the field trials were not conducted in all relevant regions where the soybeans will be cultivated, and no extreme weather conditions were taken into account; (2.2) the field trials did not take current agricultural management practices into account; (2.3) only one transgenic variety was included in the field trials.

2.1 Field trials for the compositional and agronomic assessment of the stacked soybeans were only conducted in the US, but not in other relevant soybean production areas such Brazil, Argentina, Paraguay or Uruguay. As stated in the EFSA opinion (2019a), "No exceptional weather conditions were reported at any of the selected field trial sites."

It is not acceptable that EFSA failed to require further studies, e.g. • Just one field trial was conducted that lasted more than one season. Thus, based on current data, it is hardly possible to assess site-specific effects. • Further, no data were generated representing more extreme environmental conditions, such as those caused by climate change.

More specifically, Fang et al. (2018) showed that stress responses can lead to unexpected changes in plant metabolism due the production of the additional EPSPS enzymes. However, no experiments were requested to show to which extent specific environmental conditions will influence plant composition or agronomic characteristics.

As mentioned by the experts of Member States, higher application rates of the complementary herbicides can cause stress reactions in the plants and impact gene expression (EFSA, 2019b). Therefore, the plants should have also been tested in large soybean producing countries in

South America, which not only differ in soil and climate but also in agricultural practice. For example, there are publications showing higher rates of glyphosate applications in South America compared to the US (Benbrook, 2016).

Whatever the case, the plants should have been subjected to a much broader range of defined environmental conditions and stressors (which, for example, have to be expected under ongoing climate change) to gather reliable data on plant composition and phenotypical characteristics.

2.2 Due to high weed pressure in many soybean growing regions, it has to be expected that these plants will be exposed to higher amounts and repeated dosages of the herbicides. It has to be taken into account that the herbicides can be sprayed in combination or individually at high dosages and repeatedly. These agricultural practices have to be taken into account to assess whether the expected agricultural practices will influence the expression of the studied endpoints. Higher applications of herbicides 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. As mentioned by the experts of Member States, higher application rates of the complementary herbicides can cause stress reactions in the plants and impact gene expression (EFSA, 2019b). However, this requirement was mostly ignored by EFSA and the company: the herbicides were only sprayed in combination, each just once, at an early stage of vegetation and at comparably low dosages: The amount of glyphosate used in the field trials was just 0,87 kg a.e./ha, which is close to the lowest limit of application recommended by the company (EFSA, 2019b).

Available publications show that the complementary herbicides are sprayed at much higher dosages and repeatedly onto the GE soybeans: on its product label Monsanto recommends spraying with about 7 kg (a.i.)/ha (Monsanto, 2017), with up to three applications during cultivation. Official figures from the USDA data base show that up to 6-7 kg (a.i.)/ha of glyphosate can be expected in soybean cultivation, including pre- and post-emergence applications (USDA, 2019). Data from South America show that even higher amounts are possible (Avila-Vazquez et al., 2018).

From the data that is available, it has to be assumed that the specific patterns of complementary herbicide applications will not only lead to a higher burden of residues in the harvest, but may also influence the composition of the plants and agronomic characteristics. This aspect was ignored in the EFSA risk assessment.

It is known that soybeans contain many biologically active substances, e.g. estrogens, allergens and anti-nutritional compounds, which may interact with trait-related characteristics and act as stressors. Changes in the composition of these components may not only be triggered by the process of genetic engineering, but also by interactions with the complementary herbicides. For example, Zobiole et al. (2012) and also Bøhn et al. (2014) found that glyphosate application can cause significant changes in soybean plant constituents. More specifically, Zobiole et al. (2012) applied glyphosate at three different dosages (800, 1200 and 2400 g/ha), which resulted in dose-correlated changes in plant agronomic performance and plant composition.

A statement made by EFSA (2019b) indicates that the design of the field trials should avoid major differences in the application of the herbicides: “The complementary herbicides are kept at a similar application rate across sites: indeed, for the experimental treatments to be comparable between different locations, the application rate should not differ too strongly between them."

This statement is in direct contradiction to the requirements of Implementing Regulation 503/2013. If there are any problems in regard to comparability, EFSA should request more data necessary to establish a dose-response curve; using specific amounts of pesticide applied during the field trials. These data would allow the comparison and interpretation of the relevant findings.

It also should be taken into account that a mixture of all the complementary herbicides will not always be used in the fields where the soybeans are cultivated; in some cases, just one of them will be used. This might lead to an increase in dosages of the respective complementary herbicides. The choice of herbicide will depend on the price of the herbicide formulations, the respective weed problem and regional agricultural practices. For example, it can be expected that in Argentina, Brazil and the US, there will be different prices, different herbicide formulations and varying regimes of herbicide applications under which the soybean is cultivated. None of these specific agronomic practices were considered in the design of the field trials or in EFSA risk assessment.

EFSA should have requested the company to submit data from field trials with the highest dosage of the complementary herbicides that can be tolerated by the plants, including repeated spraying with each active ingredient individually as well as in combination.

2.3 It is known that the genomic background of the variety can influence the expression of the inserted genes (see, for example, Trtikova et al., 2015). In this case, it was shown that the expression of natural allergen Gly m 4 is lower in the stacked event compared to its conventional comparator. Further significant differences concern isoflavones or so called phyto-estrogens (daidzein and genistein), and the concentration of the newly expressed Cry1A.105, DMO and EPSPS enzymes. This indicates influences from the process of stacking and resulting overall genomic background of the stacked event. Therefore, EFSA should have requested data from the parental plants to be grown in parallel as well as additional data from several varieties, including those cultivated in South America.

The material derived from the plants should have been assessed by using 'Omics-techniques' to investigate changes in the gene activity of the transgene and the plants genome, as well as changes in metabolic pathways and the emergence of unintended biological active gene products. Such in-depth investigations should not depend on findings indicating potential adverse effects, they should always be necessary to come to sufficiently robust conclusions to inform the next steps in risk assessment.

2.4 Only data from a low number of agronomic parameters (8), were subjected to statistical analysis in accordance with EFSA guidance; 2 of these were found to be significantly different in the stacked plants compared to their conventional counterparts. Against the backdrop of significant differences even in this small data set, EFSA should have requested much more data (see also above).

Compositional analysis of 53 endpoints in the grains revealed many (and partly major) statistically significant differences: in comparison to their conventional counterparts 25 endpoints were significantly different in plants not sprayed with the complementary herbicides and 16 in the stacked plants that were sprayed. One of them ("Gly m 4") protein indicated major differences between the transgenic stack and its comparator.

As shown above, the data show a much lower number of significant findings in the plant composition and the phenotypical characteristics if the plants were sprayed with the complementary herbicides. This indicates that metabolic pathways might have been impacted by the application of the complementary herbicide. This should have been investigated in more detail.

Therefore, EFSA should have requested further tests (toxicological data, repeated spraying with higher herbicide dosages or exposure to a wider range of environmental conditions). Furthermore, the plant material should have been assessed in more detail by using omics techniques to investigate changes in plant composition and agronomic characteristics.

But instead of assessing in more detail the overall pattern of changes in plant components, their causes and possible impacts, EFSA only assessed the observed changes in isolation. This approach turns the comparative approach into a trivial concept of assessing bits and pieces, and ignores questions concerning the overall safety of the whole food and feed.

More in-depth investigations should not depend on findings indicating adverse effects, they should always be necessary to come to sufficiently robust conclusions to inform the next steps in risk assessment. Even if changes taken as isolated data might not directly raise safety concerns, the overall number of effects and their clear significance has to be taken as a starting point for much more detailed investigations.

Based on the available data, no final conclusions can be drawn on the safety of the plants. In any case, the data do not fulfill the requirements of Implementing Regulation 503/2013.

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b. Food Safety Assessment:
Toxicology

Toxicology Implementing Regulation 503/2013 requests: "Toxicological assessment shall be performed in order to: (a) demonstrate that the intended effect(s) of the genetic modification has no adverse effects on human and animal health; (b) demonstrate that unintended effect(s) of the genetic modification(s) identified or assumed to have occurred based on the preceding comparative molecular, compositional or phenotypic analyses, have no adverse effects on human and animal health;"

"In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, the applicant shall ensure that the final risk characterisation clearly demonstrates that: (a) the genetically modified food and feed has no adverse effects on human and animal health;"

There were many significant changes in plant composition and agronomic characteristics, Furthermore, several uncertainties were identified in the feeding studies with the parental plants. Nevertheless, testing of the whole stacked plant (feeding study) was not requested. Even if changes taken as isolated data might not directly raise safety concerns, the overall number of effects should have been considered as a starting point for much more detailed investigation of their potential health impacts.

Beyond that, the residues from spraying were considered to be outside the remit of the GMO panel. However, without detailed assessment of these residues, no conclusion can be drawn on the safety of the imported products: due to specific agricultural practices in the cultivation of these herbicide-resistant plants, there are, e.g. specific patterns of applications, exposure, occurrence of specific metabolites and emergence of combinatorial effects that require special attention (see also Kleter et al., 2011).

More detailed assessment is also in accordance with pesticide regulation that requires specific risk assessment of imported plants if pesticide usage in the exporting countries is different compared to EU usage. In this regard, it should be taken into account that EFSA (2019c) explicitly stated that no conclusion can be drawn on the safety of residues from spraying with glyphosate occurring in genetically engineered plants resistant to this herbicide.

The analysis of the toxicity data for glyphosate and dicamba indicate a higher toxicity if the two herbicides are combined (Reuter, 2015). EFSA should have at least requested data on the combined toxicity of the residues from spraying with the complementary herbicides.

Further, there is a common understanding that commercially traded formulations of glyphosate, such as Roundup, can be more toxic than glyphosate itself. Therefore, the EU has already taken measures to remove problematic additives known as POE tallowamine from the market. Problematic additives are still allowed in those countries where the genetically engineered plants are cultivated. The EU Commission has confirmed the respective gaps in risk assessment: "A significant amount of food and feed is imported into the EU from third countries. This includes food and feed produced from glyphosate-tolerant crops. Uses of glyphosate-based plant protection products in third countries are evaluated by the competent authorities in those countries against the locally prevailing regulatory framework, but not against the criteria of Regulation (EC) No. 1107/2009. (…)." www.testbiotech.org/content/eu-commission-request-consider-impact-glyphosate-residues-feed-animal-health-february-2016

Consequently, EFSA should have requested the company to 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 have been assessed in regard to organ toxicity, immune system responses and reproductive toxicity, also taking combinatorial effects with other plant components into account.

It is known that soybeans contain many biologically active substances, e.g. estrogens, allergens and anti-nutritional compounds, which may interact with trait-related characteristics and act as stressors. Changes in the composition of these components cannot only be triggered by the process of genetic engineering but also by interactions with the complementary herbicides. For example, Zobiole et al. (2012) and also Bøhn et al. (2014) found that glyphosate application can cause significant changes in soybean plant constituents. More specifically, Zobiole et al. (2012) applied glyphosate at three different dosages (800, 1200 and 2400 g/ha) which resulted in dose-correlated changes in plant agronomic performance and plant composition.

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), poultry (Shehata et al., 2013) and rodents (Mao et al., 2018).

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. These adverse effects on health might be triggered by the residues from spraying with the complementary herbicide (see also van Bruggen et al., 2017). Furthermore, attention should be paid to the specific toxicity of the metabolites in the active ingredients of the pesticide that might occur specifically in the stacked event. Whatever the case, 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 regard to Cry toxins and their complex mode of action, EFSA only mentions two industry studies (Hammond et al., 2013; Koch et al., 2015) claiming that Bt toxins would only be active in targeted insects. However, these issues need to be assessed more thoroughly: as shown in publications, Bt toxins raise several questions in regard to feed and food safety:

(1) There are several partially diverging theories about the exact mode of action of the Bt toxins at the molecular level (see Then, 2010; Hilbeck & Otto, 2015). Thus, it cannot be assumed a priori that the toxins are inert in regard to human and animal health as argued in risk assessment for food and feed carried out by Monsanto.

(2) There are further uncertainties regarding the specificity of Bt toxins (Venter and Bøhn, 2016). Changes in specificity may emerge from structural modifications performed to render higher efficacy (see Hilbeck and Schmidt, 2006).

(3) In addition, there are findings in mammalian species showing that Bt toxicity is a relevant topic for detailed health risk assessment: some Cry toxins are known to bind to epithelial cells in the intestines of mice (Vázquez-Padrón et al., 1999).

(4) As far as potential effects on health are concerned, several publications (Thomas and Ellar 1983; Shimada et al., 2003; Mesnage et al., 2013; Huffman et al., 2004; Bondzio et al., 2013) show that Cry proteins may indeed have an impact on the health of mammals. For example, de Souza Freire et al., (2014) confirm hematotoxicity of several Cry toxins. Some of these effects seem to occur where there are high concentrations and tend to become stronger over longer periods of time.

(5) Further, the toxicity of Bt toxins can be enhanced through interaction with other compounds, such as plant enzymes (Zhang et al., 2000, Zhu et al., 2007; Pardo-López et al., 2009), other Bt toxins (Sharma et al., 2004; Tabashnik et al., 2013; Bøhn et al. 2016, Bøhn 2018), gut bacteria (Broderick et al., 2009), residues from spraying with herbicides (Bøhn et al. 2016, Bøhn 2018) and other co-stressors (Kramarz et al., 2007; Kramarz et al., 2009; Khalique and Ahmed, 2005; Singh et al., 2007; Zhu et al., 2005; Mason et al., 2011; Reardon et al., 2004).

In this context, it is relevant that Bt toxins can persist in the gut to a much higher degree than has been assumed by EFSA. Chowdhury et al., (2003) and Walsh et al. (2011) have found that when pigs were fed with Bt maize, Cry1A proteins could frequently and successfully still be found in the colon of pigs at the end of the digestion process. This means that Bt toxins are not degraded quickly in the gut and can persist in larger amounts until digestion is completed; and that there is enough time for interaction between various food compounds. Especially in soybeans, compounds such as trypsin inhibitors, can delay the degradation of Bt toxins (Pardo-López et al., 2009) and can therefore cause higher exposure and render higher toxicity compared to experiments with the proteins in isolation. It has to be emphasised that the data presented on thermal or enzymatic degradation of the isolated proteins do not allow the assessment of the true persistence of the Bt toxins in the food chain.

Further, as far as the exposure of the food chain with Bt toxins is concerned, EFSA should have requested data on the overall combined exposure to Bt toxins caused by the introduction of Bt plants in the EU. Currently, there are around 40 events that produce Bt toxins authorised for import. The exposure stemming from these imports, taking into account maize gluten, should have been added to that of the stacked soybean assess exposure in a much more realistic scenario.

EU legal provisions such as Regulation 1829/2003 (as well as Implementing Regulation 503/2013) state that "any risks which they present for human and animal health and, as the case may be, for the environment" have to be avoided. Therefore, potential adverse effects that result from combinatorial exposure of various potential stressors need specification, and their assessment needs to be prioritised. We conclude that the health risk assessment as currently performed by EFSA for the stacked soybean is unacceptable. We propose that these plants are tested following the whole mixture approach, considering them to be "insufficiently chemically defined to apply a component-based approach" (EFSA, 2019d).

Despite all these open questions regarding potential health impacts, we are not aware of a single sub-chronic or chronic feeding study performed with whole food and feed derived from the stacked soybean. This observation is supported by a literature review carried out by the company that did not yield any peer-reviewed publication.

In conclusion, the EFSA opinion on the application for authorisation of the stacked soybean (EFSA, 2019a) cannot be said to fulfill assessment requirements of potential synergistic or antagonistic effects resulting from the combination of the transformation events in regard to toxicology.

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

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Allergenicity

Implementing Regulation 503/2013 requests: “In cases when known functional aspects of the newly expressed protein or structural similarity to known strong adjuvants may indicate possible adjuvant activity, the applicant shall assess the possible role of these proteins as adjuvants. As for allergens, interactions with other constituents of the food matrix and/or processing may alter the structure and bioavailability of an adjuvant and thus modify its biological activity.”

“In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, the applicant shall ensure that the final risk characterisation clearly demonstrates that: (a) the genetically modified food and feed has no adverse effects on human and animal health;”

However, EFSA did not request the applicant to provide data to verify whether the source of the transgene is allergenic. According to Santos-Vigil et al. (2018), the Bt toxin Cry1Ac can act as an allergen if ingested. The Bt toxin Cry1Ac was also used as a source for the synthesis of Cry1A.105 expressed in the stacked soybean. Therefore, the synthetically derived Cry1A.105 toxin produced in the soybean has structural similarity with Cry1Ac. If Cry1Ac is suspected of being an allergen, the source of Cry1A.105 has to be verified as allergenic and therefore investigated in detail.

The EU Commission initially noted that the Santos-Vigil et al. (2018) publication was relevant for the risk assessment of genetically engineered plants producing Bt toxins, and therefore requested the European Food Safety Authority (EFSA) for an assessment. However, EFSA (EFSA, 2018) came to the conclusion that the Santos-Vigil et al. (2018) publication does not provide any new information and suffers from methodological flaws. However, this EFSA opinion is based on a rather biased interpretation of existing publications, and it does not provide any evidence that the Santos-Vigil et al. (2018) findings are invalid or irrelevant (Moreno-Fierros et al., 2018).

In conclusion, the EFSA assessment of the stacked soybean cannot be said to fulfil the requirements for assessing allergenicity of the source of the transgene. The Santos-Vigil et al. (2018) publication has to be considered valid and not properly assessed by EFSA (Moreno-Fierros et al., 2018). In awareness of these findings, EFSA should have started with the hypothesis that the consumption of products derived from the soybean can trigger allergic reactions – and should therefore have requested empirical investigations.

Furthermore, there are several studies indicating that immune responses such as adjuvanticity in mammals are triggered by Bt toxins and have to be considered in this context. Studies with the Cry1Ac toxin (Moreno-Fierros et al., 2000; Vázquez-Padrón et al., 1999; Legorreta-Herrera et al., 2010; Jarillo-Luna et al. 2008; González-González et al., 2015; Ibarra-Moreno et al., 2014; Moreno-Fierros, 2007; Guerrero et al., 2004; Moreno-Fierros et al. 2013; Rubio-Infante et al. 2018) are especially relevant (for review also see Rubio-Infante et al. 2016).

In this context, it is relevant that Bt toxins can persist in the gut to a much higher degree than has been assumed by EFSA. Chowdhury et al., (2003) and Walsh et al. (2011) have found that when pigs were fed with Bt maize, Cry1A proteins could frequently and successfully still be found in the colon of pigs at the end of the digestion process. This means that Bt toxins are not degraded quickly in the gut and can persist in larger amounts until digestion is completed; and that there is enough time for interaction between various food compounds. Especially in soybeans, compounds such as trypsin inhibitors, can delay the degradation of Bt toxins (Pardo-López et al., 2009) and can therefore cause higher exposure and render higher toxicity compared to experiments with the proteins in isolation. It has to be emphasised that the data presented on thermal or enzymatic degradation of the isolated proteins do not allow the assessment of the true persistence of the Bt toxins in the food chain.

Further, as far as the exposure of the food chain with Bt toxins is concerned, EFSA should have requested data on the overall combined exposure to Bt toxins caused by the introduction of Bt plants in the EU. Currently, there are already 30 events that produce Bt toxins authorised for import. The exposure stemming from these imports, taking into account maize gluten, should have been added to that of the stacked soybean assess exposure in a much more realistic scenario.

Given the fact that potential effects of Bt toxins on the immune system have meanwhile been discussed for many years (for overview see, for example, Then & Bauer-Panskus, 2017), and already around 40 GE crops events producing Bt toxins have been approved for the EU market, any further delay in resolving these crucial questions cannot be accepted. In accordance with EU Regulation 1829/2003, safety of whole food and feed has to be demonstrated before approval for import can be issued. Since this is not the case with the stacked soybean, the risk assessment is not conclusive and no market authorisation can be granted.

In summary, the EFSA assessment of the stacked soybean cannot be said to fulfill the requirements for assessing risks to the immune system.

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Others

(1) From studying the statements of the experts from Member States (EFSA, 2019b), we have the impression that EFSA (2019a) is not aware of more recent publications showing a higher degree of horizontal gene transfer (HGT) than previously thought. Further, in their interpretation of the data, EFSA seems to be adopting a biased approach based on the assumption that no HGT should be expected.

In addition, given the fact that stacked events always show a higher overall amount of additionally inserted DNA, the statistical expectation of HGT involving this specific DNA needs more consideration. We conclude that the EFSA conclusions in regard to HGT to the intestinal gut of livestock and humans as well as the fate of the DNA in the environment will need further assessment.

(2) For monitoring and methods to identify the specific event, Implementing Regulation 503/2013 requests: The method(s) shall be specific to the transformation event (hereafter referred to as 'event-specific') and thus shall only be functional with the genetically modified organism or genetically modified based product considered and shall not be functional if applied to other transformation events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised transformation events and conventional counterparts. This testing shall include closely related transformation events.

However, no such method for identification was made available. Based on the information that is available, it will not be possible to distinguish the stacked event from a mixture of single parental events or stacked events that overlap with the actual stack.

If approval for import is given, 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 products imported into the EU; ii) the ports and silos where shipments of the GE products were unloaded; iii) the processing plants where the GE products was transferred to; iv) the amount of the GE products used on farms for feed; v) transport routes of the GE products. Environmental monitoring should be run in regions where viable material of the GE products such as kernels are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels), all receiving environments need to be monitored. Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing GE products during or after the production process; and during or after human or animal consumption, should be part of the monitoring procedure (see also comments from experts of Member States, EFSA, 2019b).

(3) We agree with comments made by experts from Member States (EFSA 2019b), that the applicant should be asked to provide a detailed analysis of the fate of the Bt proteins in the environment and a quantitative estimate of subsequent exposure of non-target organisms.

Besides methods of detection, other methods for quantifying exposure to the insecticidal proteins need to be made publicly available in order to facilitate monitoring. Food and feed producers, farmers as well as experts dealing with environmental exposure (for example which waste material, spillage and manure) have to be able to gather independent information on their exposure to the toxins via independent laboratories. As yet, these methods are regarded as confidential business information and are not made available upon request by EFSA. Thus, the Commission should ensure that the relevant data are both publicly available and also reliable.

As existing evidence shows (Székács et al., 2011; Shu et al., 2018), the methods need to be carefully evaluated to ensure that the results are reliable, comparable and reproducible. Therefore, fully evaluated methods have to be published that allow the Bt concentration in the plants to be measured by independent scientists, as is the case for other plant protection compounds used in food and feed production. This is necessary to make sure that the environment as well as human and animals coming into contact with the material (for example, via dust, consumption or manure) are not exposed to higher quantities of Bt toxins than described in the application. But instead of requesting reliable testing methods, EFSA even refers to the insufficiency of the methods to explain unexpected and diverging results: “It is expected that variation in the protein quantification can occur in assays due to technical reasons”. (EFSA, 2019b) This statement and the approach of EFSA cannot be accepted, because it is not in line with the high scientific standards as requested in GMO Regulation 1829/2003.

(4) Finally, in regard to the literature research, we do not agree with the way it was carried out. The review should take into account all publications on the parental plants and provide all relevant information regarding gene expression, findings from field trials and feeding studies. Further, monitoring data should be provided on imports of parental plants into the EU.

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3. Environmental risk assessment

The EFSA (2019a) statement in regard to potential persistence of seeds and plants after spillage is not adequate: “It is unlikely that the intended traits of soybean MON87751 x MON87701 x MON87708 x MON89788 will provide a selective advantage to soybean plants, except when they are exposed to dicamba- and/or glyphosate-containing herbicides or infested by insect pests that are susceptible to the Cry1A.105, Cry2Ab2 and/or Cry1Ac proteins. However, this fitness advantage will not allow the GM plant to overcome other biological and abiotic factors (described above). Therefore, the presence of the intended traits will not affect the persistence and invasiveness of the GM plant.”

EFSA should reconsider this statement in the light of the findings of Fang et al (2018) which shows that there are unintended effects emerging from the production of the additional EPSPS enzymes in the plants. These findings make it necessary to request experimental data from the applicant regarding the real environmental persistence of the GE soybeans after spillage.

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4. Conclusions and recommendations

The EFSA risk assessment cannot be accepted.
