Soybean MON 87708 x MON 89788 x A5547-127

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

The three-event stack soybean was produced by conventional crossing to combine three single soybean events: MON 87708 (producing DMO), MON 89788 (producing CP4 EPSPS) and A5547-127 (producing PAT), to confer tolerance to dicamba, glyphosate and glufosinate-ammonium containing herbicides. So, highly toxic!

Why glyphosate should be banned.

GM soybean-fed female rats gave birth to excessive numbers of severely stunted pups, with over half of the litter dead by three weeks, and the surviving pups were sterile. Clinical data from Argentina are consistent with lab findings of increases in birth defects and cancers in regions with large areas cultivating glyphosate-tolerant soybean. http://www.i-sis.org.uk/Why_Glyphosate_Should_be_Banned.php GM panel you should have a look at this sometime!

We endorse the critical remarks made by the Member States, and would ask you to regard them as included and repeated as part of our remarks. http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2016-00688

It is not by chance that authorisation goes through the Netherlands. They are still welcoming these artificial GM crops with open arms.

Roundup is being banned by more and more countries and cities:

https://www.ad.nl/wonen/oostenrijk-verbiedt-als-eerste-land-onkruidverdelger-glyfosaat~a4673db2/?referrer=https://www.google.nl/: ‘Austria is the first European

country to ban the herbicide glyphosate. With its new legislation, Austria may be on a collision course with the European Union (EU).'

London Set to Ban Glyphosate Use over Public and Occupational Health Concerns Posted on Jul 7 2019 - 11:47am by Sustainable Pulse https://sustainablepulse.com/2019/07/07/london-set-to-ban-glyphosate-use-over-public-and-occupational-health-concerns/?fbclid=IwAR3bqOaNRJhYgtBR46VIvKO9lCxR4t-8PmtxJVo6L6fZyfjzV2uWYeyMIhY#.XSrg0m5uKUl On Thursday, the London Assembly called on the Mayor to cease the use of the herbicide on Greater London Authority (GLA) land and the Transport for London (TfL) estate. July 16, 2019 Sick Children Among Cancer Victims Suing Monsanto Over Roundup Print Email Share Tweet Posted on July 16, 2019 by Carey Gillam A 12-year-old boy suffering from cancer is among the newest plaintiffs taking on Monsanto and its German owner Bayer AG in growing litigation over the safety of Roundup herbicides and Monsanto's handling of scientific concerns about the products. https://usrtk.org/monsanto-roundup-trial-tacker/sick-children-among-cancer-victims-suing-monsanto-over-roundup/

Dicamba a disaster for farmers.

Environment October 31, 2018 / 11:47 PM / 9 months ago EPA adds restrictions to use of Bayer, BASF weed killer linked to crop damage.

https://www.reuters.com/article/us-usa-pesticides-dicamba/epa-adds-restrictions-to-use-of-bayer-basf-weed-killer-linked-to-crop-damage-idUSKCN1N534A

FILE PHOTO: Soy leaves that were damaged by the weed killer dicamba as part of University of Wisconsin research into whether the herbicide drifted away from where it was sprayed in Arlington, Wisconsin, U.S., August 2, 2018. REUTERS/Tom Polansek/File Photo

Glufosinate-ammonium is not harmless either, and is related to glyphosate.

Allergenicity

Fragment (quoted with permission): an AgrEvo file includes evidence purported to show that the herbicide (GLA) does not have a sensitising effect. A group of people was sent into the 'crop' and returned a short while later 'unharmed'! Nothing to be

seen! Are consumers just supposed to accept this nonsense? This so-called ‘evidence’ is too insane for words. For example, there is no indication of when the crop had last been sprayed, whether the people concerned had been tested to see if they were atopic or not, and whether they were also not Caucasian (who are more susceptible), or whether the same people were, for instance, again let loose in a field of sprayed crops a year later.https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/brief-aan-vrom-ggo-9905-suikterbieten-van-der-have-advanta/

In 1987, the following article was published: Thomson, C.J. et al. ‘Characterisation of the herbicide-resistance gene bar from S.hygroscopicus’, The EMBO Journal, Vol. 6, No 9, pages 2519-23. It describes how phosphinothricin-acetyltransferase also has glutamic acid as a substrate (by mixing the two substances together and demonstrating the reaction product). Hoechst contests this in a report (93-01): Dr Arno Schulz ‘L-phosphinothricin N acetyltransferase - Biochemical Characterisation’. In the report, glufosinate TOGETHER with an excessively large amount of glutamic acid (and other amino acids) was exposed to the effect of the acetyltransferase (with acetyl source). Schulz was unable to demonstrate any reaction product with glutamic acid and thus simply concluded that glutamic acid was not a substrate. THIS IS INCORRECT AND HIGHLY MISLEADING because in situations in which the acetyltransferase (present in the modified plant) could have a toxic effect, such as in our digestive tract, large quantities of glufosinate are not simultaneously present (see Thomson). Unbelievable! Under Schulz’s test conditions it is logical that the acetyltransferase should acetylise the glufosinate using not only the added acetyl source but also acetylised glutamic acid as an acetyl source (because the transferase has a higher affinity for glufosinate). In a mixture, a reaction product will be produced only with the substrate for which there is the highest affinity. A VERY MISLEADING REPORT. We object to the development of a GMO in which this gene product occurs.
https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/bezwaarschrift-bij-een-ontwerpbeschikking-betreffende-herbicide-resistentie/

This genetically modified soya will thus enter the EU market via the Netherlands. The EFSA GMO panel has again in this case failed to have the combination of events investigated; no feed tests have been conducted. Only the individual events (GM soybean MON 87708 x MON 89788 x A5547-127 are three events) have been assessed. Fragment: response from Hungary: MON 87708 × MON 89788 × A5547-127 expresses the Dicamba mono-oxygenase (DMO) protein from MON 87708, the CP4 5- enolpyruvylshikimate-3-phosphate (EPSPS) protein from MON 89788 and the phosphinothricin acetyltransferase (PAT) protein from A5547-127. Indeed, none of the donor organisms have ever been consumed as food or feed. All three proteins code for herbicide resistance. Consequently, a mixture of herbicides will be used on these crops. However, the safety of this herbicide mixture is not guaranteed. Indeed, the

residues and metabolites of dicamba, glyphosate and glufosinate in combination have not been studied. This is thus a GM soybean that has been made resistant to the herbicides glyphosate, glufosinate-ammonium and Dicamba. Many critical remarks have been made. The Netherlands is again happy for this GM soybean to be authorised, but it nonetheless adds a critical note: 'The applicant (= 'aanvrager' webmaster's note) claims that the information in the application is confidential. The Aarhus Convention regularises the right of the public to access environmental information and has been implemented in the European legislation. According to Article 30 of Regulation (EC) No 1829/2003 information on amongst others the composition of a GMO, physico-chemical and biological characteristics, and effects on human and animal health and the environment cannot be declared confidential. The EFSA has informed the European Commission on the claim for confidentiality of the application and awaits its decision. Information which is crucial to assess potential risks of a GM crop should not be declared confidential, because a lack of transparency undermines public trust in the risk assessment.' Nonetheless, the possible exchanges between the sub-combinations must be investigated. This is piling up poison upon poison upon poison!

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4. Conclusions and recommendations

We cannot permit this GM soybean to be placed on the market! We, the GMO-free Citizens (De Gentechvrije Burgers) (www.gentechvrij.nl) do not want to eat it; as time goes by, glyphosate and Roundup, GLA and Dicamba are increasingly being banned, and countries will refuse this toxic soya! You are lagging behind events! We are also sending these objections to you on behalf of Stichting Ekopark in Lelystad, the Netherlands.

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6. Labelling proposal

Warning logo featuring a skull and crossbones. And not only where there are 0.9% GM ingredients, but wherever GMOs are involved!

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

Addition to our previous objections:

Cancer Maps and Glyphosate – Zach Bush MD – Farmer's Footprint Behind the Scenes "According to triple board certified doctor Zach Bush….the cause is primarily glyphosate. This is a bold statement, and one that the agriculture industry and our government would not want us to believe. However the problem is pervasive. Glyphosate is contaminating our water, urine, breast milk, food, vaccines and cotton products." Cancer Maps and Glyphosate – Zach Bush, MD
https://vimeo.com/315920699

On top of it all, Glyphosate also pollutes the air we breathe!

'Argentinians sick to death of pesticides on soya' (29-07-2015). Since the introduction in 1996 of Monsanto's pesticide-resistant GM crops in Argentina, the use of pesticides has increased ninefold. People living near the plantations claim that the crops make them very sick, and they have brought legal proceedings against the soya industry.' Article by Ynske Boersma, One World.
https://www.oneworld.nl/bedrijfslobby/argentijnen-doodziek-van-soja/

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

Second addition to the previous objections submitted by De Gentechvrije Burgers, European Consumer Platform, also on behalf of Stichting Ekopark in Lelystad, NL. https://www.gentechvrij.nl/2019/07/12/weer-nieuwe-toelatingen-op-de-eu-markt-van-gentech-soja-en-mais-u-kunt-uw-mening-geven-tot-8-augustus-2019/

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-vapors-are-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-weedkiller-puts-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-killer-divides-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-weed-scientists-not-a-love-story?t=1563602824913 National Public Radio Alles door Mr. DAN CHARLES.

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4. Conclusions and recommendations

Quote from the joint statement by the US and the EU after the visit of President Juncker to the White House (2018): ‘We will also work to reduce barriers and increase trade in services, chemicals, pharmaceuticals,’ [personal footnote: and GMOs] ‘medical products,’ [idem] ‘as well as’ [idem GMO] ‘soybean.’ So it is going ahead regardless, but this is repressive tolerance, it’s no longer democracy!
http://europa.eu/rapid/press-release_STATEMENT-18-4687_nl.htm

Article 2 of the ECHR guarantees the right to life; Article 8 guarantees the right to respect for private and family life. The European Court has ruled in a number of cases that certain industrial applications infringe Articles 2 and 8 of the [Convention on] Human Rights. These toxic GM soybeans, which are resistant to three suspect herbicides, should not be allowed onto our EU market!

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

Third addition from De Gentechvrije Burgers. Also on behalf of Stichting Ekopark, Lelystad.

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: dietist
Country: The Netherlands
Type: Others...

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a. Assessment:
Molecular characterisation

Experimenting with and manipulating genetic material from all kinds of organisms and thus changing food crops may very well be exciting and interesting, but it is a hobby that has got massively out of hand, engaged in by a number of mega companies whose only objective is to maximise profits, while food safety, nature, the landscape,

farmers, etc. all suffer. I would like members of parliament to do what they were elected to do, namely defend the interests of the people and let the voice of the people be heard in the parliaments to which they were elected. Of course, this applies particularly to the people who work on behalf of members of parliament in committees and councils and take decisions that concern us all. The way food is produced concerns us all. There are few people who look forward to food made from crops treated with poison so as to increase profits, despite poor cultivation methods, by destroying all insects and organisms that live in the vicinity of such genetically modified crops, these being treated with poison and cultivated on a massive scale. Shouldn't be allowed! These products should not be admitted to the market, and the crops that have already been admitted, into which the genes of other organisms have been inserted, whether they are maize or soy or other crops, should be taken off the market. Farmers should be retrained and compensated; they should start working with nature again. It is a calamitous path, nobody benefits, except Bayer and others. The decision-making on these issues concerns everybody but only a few manage to follow these ridiculously complicated procedures and put forward their objections to the decisions taken in the manner required. Why ? What is life really about? Why don't you just throw the whole sorry mess into the bin and go and do something nice, or something that has meaning and contributes in some way to the welfare of people, animals and nature? I wish with all my heart that you can take this step and go and enjoy life, instead of mindlessly doing what other people tell you. The choice is up to you.

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

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b. Food Safety Assessment:
Toxicology

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Allergenicity

Experimenting with and manipulating genetic material from all kinds of organisms and thus changing food crops may very well be exciting and interesting, but it is a hobby that has got massively out of hand, engaged in by a number of mega companies whose only objective is to maximise profits, while food safety, nature, the landscape, farmers, etc. all suffer. I would like members of parliament to do what they were elected to do, namely defend the interests of the people and let the voice of the people be heard in the parliaments to which they were elected. Of course, this applies particularly to the people who work on behalf of members of parliament in committees and councils and take decisions that concern us all. The way food is produced concerns us all. There are few people who look forward to food made from crops treated with poison so as to increase profits, despite poor cultivation methods, by destroying all insects and organisms that live in the vicinity of such genetically modified crops, these being treated with poison and cultivated on a massive scale. Shouldn’t be allowed! These products should not be admitted to the market, and the crops that have already been admitted, into which the genes of other organisms have been inserted, whether they are maize or soy or other crops, should be taken off the market. Farmers should be retrained and compensated; they should start working with nature again. It is a calamitous path, nobody benefits, except Bayer and others. The decision-making on these issues concerns everybody but only a few manage to follow these ridiculously complicated procedures and put forward their objections to the decisions taken in the manner required. Why ? What is life really about? Why don’t you just throw the whole sorry mess into the bin and go and do something nice, or something that has meaning and contributes in some way to the welfare of people, animals and nature? I wish with all my heart that you can take this step and go and enjoy life, instead of mindlessly doing what other people tell you. The choice is up to you.

Nutritional assessment

Experimenting with and manipulating genetic material from all kinds of organisms and thus changing food crops may very well be exciting and interesting, but it is a hobby that has got massively out of hand, engaged in by a number of mega companies whose only objective is to maximise profits, while food safety, nature, the landscape, farmers, etc. all suffer. I would like members of parliament to do what they were elected to do, namely defend the interests of the people and let the voice of the people be heard in the parliaments to which they were elected. Of course, this applies particularly to the people who work on behalf of members of parliament in committees and councils and take decisions that concern us all. The way food is produced concerns us all. There are few people who look forward to food made from crops treated with poison so as to increase profits, despite poor cultivation methods, by destroying all insects and organisms that live in the vicinity of such genetically modified crops, these being treated with poison and cultivated on a massive scale. Shouldn't be allowed! These products should not be admitted to the market, and the crops that have already been admitted, into which the genes of other organisms have been inserted, whether they are maize or soy or other crops, should be taken off the market. Farmers should be retrained and compensated; they should start working with nature again. It is a calamitous path, nobody benefits, except Bayer and others. The decision-making on these issues concerns everybody but only a few manage to follow these ridiculously complicated procedures and put forward their objections to the decisions taken in the manner required. Why ? What is life really about? Why don't you just throw the whole sorry mess into the bin and go and do something nice, or something that has meaning and contributes in some way to the welfare of people, animals and nature? I wish with all my heart that you can take this step and go and enjoy life, instead of mindlessly doing what other people tell you. The choice is up to you.

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3. Environmental risk assessment

Experimenting with and manipulating genetic material from all kinds of organisms and thus changing food crops may very well be exciting and interesting, but it is a hobby that has got massively out of hand, engaged in by a number of mega companies whose only objective is to maximise profits, while food safety, nature, the landscape, farmers, etc. all suffer. I would like members of parliament to do what they were elected to do, namely defend the interests of the people and let the voice of the people be heard in the parliaments to which they were elected. Of course, this applies particularly to the people who work on behalf of members of parliament in committees and councils and take decisions that concern us all. The way food is produced concerns us all. There are few people who look forward to food made from

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4. Conclusions and recommendations

Experimenting with and manipulating genetic material from all kinds of organisms and thus changing food crops may very well be exciting and interesting, but it is a hobby that has got massively out of hand, engaged in by a number of mega companies whose only objective is to maximise profits, while food safety, nature, the landscape, farmers, etc. all suffer. I would like members of parliament to do what they were elected to do, namely defend the interests of the people and let the voice of the people be heard in the parliaments to which they were elected. Of course, this applies particularly to the people who work on behalf of members of parliament in committees and councils and take decisions that concern us all. The way food is produced concerns us all. There are few people who look forward to food made from crops treated with poison so as to increase profits, despite poor cultivation methods, by destroying all insects and organisms that live in the vicinity of such genetically modified crops, these being treated with poison and cultivated on a massive scale. Shouldn't be allowed! These products should not be admitted to the market, and the crops that have already been admitted, into which the genes of other organisms have been inserted, whether they are maize or soy or other crops, should be taken off the market. Farmers should be retrained and compensated; they should start working with nature again. It is a calamitous path, nobody benefits, except Bayer and others. The decision-making on these issues concerns everybody but only a few manage to follow these ridiculously complicated procedures and put forward their objections to the

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5. Others

Experimenting with and manipulating genetic material from all kinds of organisms and thus changing food crops may very well be exciting and interesting, but it is a hobby that has got massively out of hand, engaged in by a number of mega companies whose only objective is to maximise profits, while food safety, nature, the landscape, farmers, etc. all suffer. I would like members of parliament to do what they were elected to do, namely defend the interests of the people and let the voice of the people be heard in the parliaments to which they were elected. Of course, this applies particularly to the people who work on behalf of members of parliament in committees and councils and take decisions that concern us all. The way food is produced concerns us all. There are few people who look forward to food made from crops treated with poison so as to increase profits, despite poor cultivation methods, by destroying all insects and organisms that live in the vicinity of such genetically modified crops, these being treated with poison and cultivated on a massive scale. Shouldn't be allowed! These products should not be admitted to the market, and the crops that have already been admitted, into which the genes of other organisms have been inserted, whether they are maize or soy or other crops, should be taken off the market. Farmers should be retrained and compensated; they should start working with nature again. It is a calamitous path, nobody benefits, except Bayer and others. The decision-making on these issues concerns everybody but only a few manage to follow these ridiculously complicated procedures and put forward their objections to the decisions taken in the manner required. Why ? What is life really about? Why don't you just throw the whole sorry mess into the bin and go and do something nice, or something that has meaning and contributes in some way to the welfare of people, animals and nature? I wish with all my heart that you can take this step and go and enjoy life, instead of mindlessly doing what other people tell you. The choice is up to you.

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6. Labelling proposal

A saltire

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

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a. Assessment:
3. Environmental risk assessment

Addition 3: also on behalf of Stichting Ekopark, Donaustraat 152, 822 LC Lelystad.

There are increasing numbers of reports from the USA indicating that the weed Palmer amaranth has become resistant to numerous pesticides. GMWatch: 'King of weeds' Palmer amaranth resistant to herbicides used on GM crops. https://www.gmwatch.org/en/news/latest-news/19078

Published: 05 August 2019 As glyphosate, dicamba and 2,4-D fail to kill the superweed, chemical company experts recommend turning to agroecological practices Scientists in the US are sounding the alarm about a crop-smothering weed that is growing resistant to multiple herbicides used on GM herbicide-tolerant crops, according to an article in Chemical & Engineering News. (CEN).https://cen.acs.org/business/specialty-chemicals/Palmer-amaranth-king-weeds-cripples/97/i31

Palmer Amaranth Management in Soybeans

Palmer Amaranth Distribution and Biology For example, many Palmer amaranth populations exhibit resistance to both ALS-inhibiting herbicides (Group 2) and glyphosate (Group 9), and a more recently identified Palmer amaranth population has shown resistance to herbicides from three different sites of action: ALS- (Group 2), Photosystem II- (Group 5) and HPPD-inhibiting (Group 27) herbicides.https://weedscience.missouri.edu/publications/50737_FINAL_FactSheet_PalmerAmaranth.pdf

8 maart 2019: K-State researchers confirm case of 2,4-D resistance in Palmer amaranth Study is first-ever confirming the noxious weed's resistance to the common herbicide

HAYS, Kan. – A Kansas State University researcher is reporting the first-ever study confirming that Palmer amaranth has developed resistance to the herbicide 2,4-D, findings that may signal an important step in developing future controls for the pesky weed. https://www.ksre.k-state.edu/news/stories/2019/03/palmer-amaranth-resistance-to-herbicides.html

These are just a few examples from the many reports on this subject.

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4. Conclusions and recommendations

You can read the latest news on developments regarding GMOs on www.gentechvrij.nl

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

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a. Assessment:
Others

Communication: Mr Wilbrord Braakman, De Verbinding 5, 1741 DB Schagen, the Netherlands, and Ms L. Mast, Nieuwstraat 62, 1404 JN Bussum, GMO-free citizens, have instructed us to inform you that they support our objections to this application, as previously communicated.

Organisation: Transition Coalition Food
Country: The Netherlands
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

The actual history shows still more negative facts. An organism is only in thermodynamic balance when it is dead. But when it is still alive, then there is a dynamic balance with the surronding environment. In addition, the organism is able to absorb energy and information from the environment so that it is available for the functioning and streamlining of its own life functions. This is a crucial point. It is impossible to claim all the influences of life for to modifiy their basic own capacities.

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.

Therefore, EFSA should have requested much more detailed investigation into potential biologically active gene products 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 for one year. 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. Whatever the case, they should have been tested in large soybean producing countries in South America.

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 the other complementary herbicides. 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. This aspect was completely ignored in the EFSA risk assessment.

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). Therefore,

EFSA, should have requested 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.

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Fang, J., Nan, P., Gu, Z., Ge, X., Feng, Y.-Q., Lu, B.-R. (2018) Overexpressing Exogenous 5-Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS) Genes Increases Fecundity and Auxin Content of Transgenic Arabidopsis Plants. Frontiers in Plant Sciences, 9: 233. https://doi.org/10.3389/fpls.2018.00233

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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 conducted in the US for only one year, but not in other relevant soybean production areas such as 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. • No field trials were 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 inheriting additional EPSPS enzymes. However, no experiments were requested to show to which extent specific environmental conditions will influence plant composition or agronomic characteristics. Whatever the case, the plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data.

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. However, this requirement was mostly ignored by EFSA and the applicant: the herbicides were only sprayed in combination, each just one time, at early stage of vegetation and comparably low dosages.

Available publications show much that the complementary herbicides get sprayed at much higher dosages and repeatedly on the GE syobeans: on its product label Monsanto recommends about 7 kg (a.i.)/ha is sprayed (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). The same data base (USDA 2019) also shows that spraying with dicamba reached up to 3,5 kg (a.i.)/ha in soybean cultivation, and glufosinate was around 660 g (a.i.)/ha. In its patent application concerning the "cropping systems for managing weeds", Monsanto recommends spraying up to 8 kg (a.i.)/ha onto HT soybeans, in addition 2,2kg (a.i.)/ ha Dicamba and 907 g (a.i.)/ha glufosinate. 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.

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 maize 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). Therefore,

EFSA should have requested additional data from several varieties, including those cultivated in South America, to see how the gene constructs interact with the genetic background of the plants.

2.4. Only data from a low number of agronomic parameters (8), were subjected to statistical analysis in accordance with EFSA guidance; 5 of these were found to be statistically and significantly different in plants sprayed with the complementary herbicides (!). Against the backdrop of many 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: 28 endpoints were statistically and significantly different (!), with 2 indicating major differences between the transgenic stack and its comparator.

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.

It has to be assumed that this event is essentially different from its comparator in regard to composition as well as biological characteristics. 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. The data do not fulfill the requirements of Implementing Regulation 503/2013.

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b. Food Safety Assessment:
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, but testing of the whole stacked plant (feeding study) was not requested. It has to be assumed that this event is essentially different from its comparator in regard to several compositions and biological characteristics. 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 (2018) 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. In addition, glufosinate is classified as showing reproductive toxicity (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN) and there are indications of additive or synergistic effects of the residues from spraying (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. (…)."
(https://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). Such effects might be also be caused by the residues from spraying with glufosinate since glufosinate interferes with bacterial growth and, in certain circumstances, acts as an antimicrobial agent causing shifts in bacterial community structures (Ahmad and Malloch 1995; Hsiao et al. 2007; Pampulha et al. 2007; Kopcáková et al. 2015). In general, antibiotic effects and other adverse health effects might occur from exposure to a diet containing these plants which 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 .

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.

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, 2019b).

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 maize. This observation is supported by a literature review carried out by the applicant 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 fulfil assessment requirements of potential synergistic or antagonistic effects resulting from the combination of the transformation events in regard to toxicology.

For this purpose, EFSA should have requested Monsanto to submit data from field trials with the highest dosage of 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 responses and reproductive toxicity, also taking combinatorial effects with other plants components into account.

Further, EFSA should have rejected the feeding study carried out with parental plant MON89788, which used material that was stored for up to 27 months (!). It cannot be assumed that the identity of this material was sufficiently preserved over such a long period of time.

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;”

For this purpose, EFSA should have requested Monsanto to submit data from field trials with the highest dosage of 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 responses and reproductive toxicity, also taking combinatorial effects with other plants components into account.

Others

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, 2019c).

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.

EFSA (2019c) Application application EFSA-GMO-NL-2016-135, Comments and opinions submitted by Member States during the three-month consultation period, Register of Questions, http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=ALL

4. Conclusions and recommendations

The EFSA risk assessment cannot be accepted.