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Call for submissions – Application A1116 Food derived from Herbicide tolerant & Insect protected Corn Line MZIR098

The GM-Free Australia Alliance Inc (GMFAA) recommends that FSANZ does NOT approve Application A1116 MZIR098

Comments:
Our confidence in the regulatory processes of FSANZ is not strong.

A lack of response to your call for submissions does not mean that there is an increasing acceptance of GMOs in our food.

There is growing concern about GMOs, but the public has lost confidence that any of our submissions to FSANZ will be taken seriously or acted upon.

A sound basis for "rigorous" safety assessment is not past approvals of similar GM food and crops by regulatory authorities in other countries.

We note that Syngenta has an application in process for **MZIR098** in Canada.
http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/mzir098/eng/1447768819892/1447768912140

A GM application in Canada should not influence safety assessment by FSANZ.

We note the following, in page 1 of your Report:

This Safety Assessment Report for Application A1116, Food derived from Herbicide tolerant & Insect protected Corn Line MZIR098 addresses only food safety and nutritional issues of the GM food per se
It therefore does not address:

•environmental risks related to the environmental release of GM plants used in food production
•the safety of animal feed, or animals fed with feed, derived from GM plants
•the safety of food derived from the non GM (conventional) plant

We therefore ask: Where is the FSANZ report which DOES address the safety of food derived from Corn Line MZIR098 ????

Section 1.

Perceived "absence of evidence of harm" does not prove safety.

If FSANZ considers the referenced studies in Section 3, there is now a growing body of evidence showing harm from GM foods.

Syngenta claims that no potential public health and safety concerns have been identified with herbicide tolerant and insect protected corn line MZIR098.
Syngenta also claims that MZIR098 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

Claims from the proponent are not a basis for a safety assessment.

FSANZ suffers from a refusal to assess the potential of GM foods to cause harm, preferring to allow safety documentation from the GM proponent which owns the technology, to "prove" safety of their product.

Ease of insect control for farmers, the insect-killing potential of the plant and its resistance to herbicide does not equal safety for human consumption.

"Stacked" GM traits

We note that MZIR098 was developed by crossing with other previously approved GM corn lines, known as "stacking".

FSANZ is asked in the application to accept MZIR098 because of its previous approvals of A564 and A1060.

This is not an acceptable method to assess the safety of a new GM product, which must be thoroughly tested as a separate entity.

Dr Charles Benbrook commented on stacked varieties in 2013.

"The move to stacked varieties expressing multiple traits, coupled with the above changes in the intensity of chemical use required to bring GE crops to harvest, raises new questions about new routes of exposure and about cumulative levels of exposure to GE proteins, potential allergens and pesticides, especially via drinking water, certain foods made from corn or soybeans, and, for infants, breast milk, cow's milk, soymilk, and formula. It also raises new testing challenges arising from the likely presence of multiple transgenes, DNA fragments, promoters, regulatory sequences and chemicals from pesticides (active ingredients, metabolites, surfactants, adjuvants, etc).

http://www.foodsafetynews.com/2013/05/ge-crop-risk-assessment-challenges-an-overview/#.VtPL39CHTIU

Section 2.

Labelling

Quoting the FSANZ Safety Assessment Report for **MZIR098** :

"Standard 1.5.2 generally requires food produced using gene technology to be labelled as 'genetically modified' if it contains novel DNA or novel protein. That is, DNA or protein that is different to that found in the counterpart food produced without gene technology.
Some products derived from line MZHG0JG would be unlikely to require labelling as 'genetically modified'.
MZIR098 is a dent corn and therefore is not a popcorn or sweet corn line, but it is possible that it could be used as a parent in the development of sweet corn lines. The grain from dent corns is mostly processed into refined products such as corn syrup and corn starch which, because of processing, are unlikely to contain any novel protein or novel DNA. Similarly, in the production process for refined corn oil, novel protein and novel DNA are not likely to be present. Therefore such products derived from line MZIR098 would be unlikely to require labelling
MZIR098products such as meal (used in bread and polenta) and grits (used in cereals) would be likely to contain novel protein or novel DNA, and if so, would require labelling.
Sweet corn kernels containing the SYN 00098 3 event are also likely to require labelling".

We note the lack of clear information for food processors.

"Is possible" or "not likely" are not scientifically verifiable terms.

FSANZ must give clear direction on labelling so that food processors are informed and can then inform the public using full disclosure of GM-sourced ingredients.

This GM corn product may be included in many foods for human and animal consumption, including sweeteners and infant formula.

Due to our deficient labelling laws, which do not show clearly if the product is sourced from a GM crop, the product will not be identifiable as a GM ingredient in our food. This is not acceptable.

Section 3.

Safety issues with GM BT crops

Regulators have approved GM Bt crops on the assumption that the insecticidal toxin they contain is the same as the natural form of Bt toxin, a substance produced by the soil-dwelling bacterium Bacillus thuringiensis. Natural Bt is used as an insecticidal spray in chemically-based and organic farming, and is claimed to have a history of safe use and to only affect certain types of insect. Regulators assume that GM Bt crops must also be harmless to humans and other mammals. But these assumptions are **incorrect.** Natural Bt toxin is different from the Bt toxins produced in GM crops and behaves differently in the environment. GM Bt plants express the pesticide in every cell throughout their life, so that the plants themselves

become a pesticide. Even natural Bt has never intentionally been part of the human diet and cannot be claimed to have a history of safe use.

Animal feeding experiments with GM Bt crops have revealed toxic effects and a laboratory study showed toxic effects on human cells tested in vitro.

Contrary to claims by the GM industry and regulators, Bt toxin does not reliably break down in the digestive tract.

Bt toxin proteins have been found circulating in the blood of pregnant women and in the blood supply to their foetuses.

Regulatory approvals of GM Bt crops worldwide have been granted on the basis of poorly designed and interpreted experiments and false assumptions.

Bacillus thuringiensis (Bt) is a natural soil-dwelling bacterium that produces a protein complex called Bt toxin. Some types of Bt toxin possess selective insecticide properties: that is, they will specifically kill certain crop pests such as caterpillars. Therefore Bt toxin has been used for decades as an insecticidal spray in chemically-based and organic farming.

The Bt toxin expressed by GM Bt plants is different from natural Bt, both in terms of its structure and its mode of action.(1)

Structurally, there is at least a 40% difference between the toxin in Bt176 maize (formerly commercialized in the EU, now withdrawn) and natural Bt toxin. (2)

The US Environmental Protection Agency, in its review of the commercialized Monsanto GM maize MON810, said it produced a "truncated" version of the protein – in other words, a much shorter form of the protein that is different from the natural form. (3)

Such changes in a protein can mean that it has very different environmental and health effects. First, the GM Bt toxin loses its selectivity and can kill non-target insects including beneficial predators. Second, GM Bt toxin can have unsuspected negative health impacts on people or animals that eat a crop containing it. The protein may be more toxic or allergenic than the natural form of the protein. Even tiny changes in a protein can completely change its properties. For example, soybeans can be genetically engineered to tolerate a herbicide that would normally kill them by changing a gene that gives rise to a protein differing from the natural protein by just two amino acids. (4)

As researchers at the Centre for Integrated Research in Biosafety in New Zealand pointed out in a submission to FSANZ on the regulatory assessment of this soybean (5), a change even of a single amino acid can radically change the properties of proteins, which in turn can result in changed behaviour of a plant. (6,7)In some cases, not even an amino acid change is necessary to alter the characteristics of a protein. Differences in the sequence of the DNA base units in a gene can change the properties of the resulting protein without altering the amino acid sequence.(8)

Changes in the three-dimensional shape of the protein alone can turn harmless proteins into toxins (9,10), as demonstrated by the prion protein causing the "mad cow disease" BSE.

Natural Bt toxin also has a very different mode of action from the Bt toxin produced in GM plants. Natural Bt is not a toxin but a **protoxin.** That means it only becomes toxic when subjected to certain conditions, such as when made into a solution and broken down by enzymes in the gut of the insect that eats it. In the environment, natural Bt breaks down rapidly in daylight soon after it is sprayed, so it is unlikely to find its way into animals or people that eat the crop. With GM Bt crops, in contrast, the Bt toxin is present in every cell of the plant in pre-activated form (1,12).

The plant itself becomes a pesticide, and people and animals who eat the plant are eating a pesticide. Bt toxin does not only affect insect pests. GMO proponents claim that the Bt toxin engineered into GM Bt crops only affects the target pests and is harmless to mammals, including people or animals that eat the crops(13).

All regulatory approvals of GM Bt crops are based on this assumption and no regulatory body has ever required human toxicity studies to be carried out. However, these assumptions about the safety of GM Bt crops are constantly being challenged by new evidence.

In an in vitro study (laboratory experiment not carried out in living animals or humans), genetically engineered Bt toxins were found to be toxic to human cells. One type of Bt toxin killed human cells, albeit at the relatively high dose of 100 parts per million. **The findings showed that GM Bt toxin is not specific to insect pests and does affect human cells, contrary to claims from the GM lobby and regulators. (14)** In vitro studies may not accurately reflect what happens in a living human or animal that eats GM Bt crops, so they must be followed up with in vivo studies performed on living animals, and then on humans. However, it is unacceptable that Bt toxins were never even subjected to basic and inexpensive in vitro tests before they were released into the food and feed supply. Some feeding studies in mammals have been performed with GM Bt crops and have found adverse effects, such as:

➜ Toxic effects or signs of toxicity in the small intestine, liver, kidney, spleen, pancreas (15,16,17,18,19)

➜ Disturbances in the functioning of the digestive system (17,19)

➜ Increased or decreased weight gain compared with controls (15,20)

➜ Male reproductive organ damage (19)

➜ Blood biochemistry disturbances (20)

➜ Immune system disturbances. (21)

Laboratory studies in mice found that genetically engineered Bt toxin produces a potent immune response when delivered into the stomach by intragastric administration (a method considered similar to human dietary exposure), or injected into the abdomen (intraperitoneal immunization).(22,23)

The Bt toxin protein was found to bind to the mucosal surface of the small intestine of the mice, an effect that could lead to changes in the physiological status of the intestine.(24)

The Bt toxin protein also enhanced the immune response of the mice to other substances.(25)

GM Bt crops and the Bt toxins they are engineered to contain have been found to have toxic effects on butterflies and other non-target insects, (26,27,28)beneficial pest predators,(29,30,31,32,33,34) bees,(35) aquatic organisms, (36,37)and beneficial soil organisms.(38)

Toxic effects associated with GM Bt crops may be due to one or more of the following causes:

➜ The Bt toxin as produced in the GM crop

➜ New toxins produced in the Bt crop by the GM process, and/or

➜ Residues of herbicides or chemical insecticides used on the Bt crop. Many Bt crops have added herbicide-tolerant traits, (39)making it likely that herbicide residues will be found on them. In-depth toxicological research would have to be carried out in order to identify which factors are responsible. GMO proponents claim that the Bt toxin insecticidal protein in GM plants is broken down in the digestive tract and so cannot get into the blood or body tissues to cause toxic effects beyond the digestive system. But this claim has been shown to be false by several studies:

➜ A study in cows found that Bt toxins from GM maize MON810 were not completely broken down in the digestive tract.(40)

➜ A study simulating human digestion found that the Bt toxin protein was highly resistant to being broken down in realistic stomach acidity conditions and still produced an immune response.(41)

➜ A survey conducted in Canada found Bt toxin protein circulating in the blood of pregnant and non-pregnant women and the blood supply to foetuses. (42,43) Whether the Bt toxin originated from GM crops or elsewhere is not known. But wherever it came from, it clearly did not break down fully in the digestive tract. How selective are the Bt toxins in GM crops?

For example, in one study, Bt toxins were found to be toxic to the blood of mice.(45) This was not a feeding study with Bt crops, so the findings do not tell us whether **GM Bt crops** are toxic to the blood of mice. Instead the Bt toxins were fed to the mice in the form of spore crystals containing individual Bt toxins Cry1Aa, Cry1Ab, Cry1Ac, and Cry2A obtained from genetically engineered Bt bacteria. Different GM Bt crops are engineered to express these Bt toxins. The Bt toxins caused red blood cells of the mice to rupture, albeit they were fed at high doses. (45)This is of concern because Bt toxins exercise their toxic effects in target pests in a similar fashion, by rupturing the cells of the gut, causing the insect to die from starvation or septicaemia due to the gut contents, including pathogenic bacteria, leaking out into the body. This study showed that the assumption that Bt toxins are non-toxic to mammals is questionable, as the Bt toxins in the genetically engineered spore crystal form tested were toxic to the blood of mice, a species of mammal. (45)

A wide range of external factors can influence the selectivity and toxicity of Bt toxin proteins. These include interaction with infectious disease agents, nematodes (roundworms,

many of which are parasitic), gut bacteria, and other Bt toxins.(46) It cannot even be assumed that the natural Bt toxin used in insecticidal sprays is safe for those applying it or exposed to it immediately after spraying. In farm workers, exposure to Bt sprays was found to lead to allergic skin sensitization and immune responses.(47)

An immune response to Bt toxin was found in the blood serum of 23–29% of Danish greenhouse workers in a respiratory health study. (48)

Some of the safety tests carried out for regulatory approvals of Bt crops, such as investigation of allergenic, nutritional, and immunological properties, are not carried out with the Bt toxin protein as expressed in the GM plant. Instead, tests are carried out on a "surrogate" Bt toxin protein derived from genetically engineered E. coli bacteria, (49)as GM companies find it too difficult and expensive to extract enough Bt toxin from the GM crop itself. The problem with this is that the protein that is expressed in a plant will be different in structure, conformation and stability from the protein expressed in a bacterium. **Thus it is scientifically invalid to draw conclusions about the safety or digestibility of a protein in a GM plant on the basis of experiments on a protein produced in E. coli bacteria, even if the two proteins are coded for by the same gene.(49)**

This fundamental flaw in the regulatory process could partly be addressed by long-term animal feeding trials with the whole GM plant, which would contain the actual protein that people and animals eat. Although the 90-day animal feeding trials that are routinely carried out by GM developer companies are not long enough to identify the full range of potential toxic effects from GM crops, studies of even this short duration and less performed by both industry and independent scientists have revealed worrying health effects. (15,16,18,50,19,20)

Studies on GM Bt crops show that Bt toxin is not specific to a narrow range of insect pests but can affect a wide variety of non-target organisms. Taken together, the studies on GM Bt crops and natural Bt toxin raise the possibility that eating GM crops containing Bt toxin may cause toxic effects to multiple organ systems or allergic reactions and/or sensitize people to other food substances.

From GMO Myths and Truths – An evidence-based examination of the claims made for the safety and efficacy of genetically modified crops and foods, by John Fagan, PhD Michael Antoniou, PhD Claire Robinson, MPhil.

References for Section 3, above.

References 1. Székács A, Darvas B. Comparative aspects of Cry toxin usage in insect control. In: Ishaaya I, Palli SR, Horowitz AR, eds. Advanced Technologies for Managing Insect Pests. Dordrecht, Netherlands: Springer; 2012:195–230. 2. Séralini GE, Mesnage R, Clair E, Gress S, de Vendômois JS, Cellier D. Genetically modified crops safety assessments: Present limits and possible improvements. Environ Sci Eur. 2011;23. doi:10.1186/2190-4715-23-10. 3. Freese W, Schubert D. Safety testing and regulation of genetically engineered foods. Biotechnol Genet Eng Rev. 2004:299-324. 4. Food Standards Australia New Zealand (FSANZ). Application A1018 - Food derived from High Oleic Acid Soybean Line DP-305423-1 – Safety assessment report supporting document 1. Canberra, Australia; 2009. Available at: http://
www.foodstandards.gov.au/code/applications/documents/A1018%20High%20oleic%20GM

%20soybean%20AR%20 SD11.pdf. 5. Kurenbach B, Coray DS, Heinemann JA, Catchpole RJ, Turner LA. Submission II on the assessment report for Application A1018 food derived from high oleic acid soybean DP-DP-305423-1-1. Centre for Integrated Research in Biosafety; 2009. Available at: http://www.inbi.canterbury.ac.nz/Documents/submissions/A1018%20submission%20 II.pdf. 6. Doyle MR, Amasino RM. A single amino acid change in the enhancer of zeste ortholog CURLY LEAF results in vernalization-independent, rapid flowering in Arabidopsis. Plant Physiol. 2009;151:1688-97. doi:10.1104/ pp.109.145581. 7. Hanzawa Y, Money T, Bradley D. A single amino acid converts a repressor to an activator of flowering. Proc Natl Acad Sci U A. 2005;102:7748-53. doi:10.1073/pnas.0500932102. 8. Kimchi-Sarfaty C, Oh JM, Kim IW, et al. A "silent" polymorphism in the MDR1 gene changes substrate specificity. Science. 2007;315:525-8. doi:10.1126/science.1135308. 9. Bucciantini M, Giannoni E, Chiti F, et al. Inherent toxicity of aggregates implies a common mechanism for protein misfolding diseases. Nature. 2002;416:507-11. doi:10.1038/416507a. 10. Ellis RJ, Pinheiro TJ. Medicine: danger--misfolding proteins. Nature. 2002;416:483-4. doi:10.1038/416483a. 11. Caughey B, Baron GS. Prions and their partners in crime. Nature. 2006;443:803-10. doi:10.1038/nature05294. 12. Li H, Buschman LL, Huang F, Zhu KY, Bonning B, Oppert BA. Resistance to Bacillus thuringiensis endotoxins in the European corn borer. Biopestic Int. 2007;3:96–107. 13. GMO Compass. Environmental safety: insects, spiders, and other animals. 2006. Available at: http://www.gmocompass.org/eng/safety/environmental_safety/169.effects_gm_plants_insects_spiders_animals.html. 14. Mesnage R, Clair E, Gress S, Then C, Székács A, Séralini G-E. Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide. J Appl Toxicol. 2011. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22337346. 15. Séralini GE, Cellier D, Spiroux de Vendomois J. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Arch Environ Contam Toxicol. 2007;52:596–602. 16. De Vendomois JS, Roullier F, Cellier D, Séralini GE. A comparison of the effects of three GM corn varieties on mammalian health. Int J Biol Sci. 2009;5:706–26. 17. Trabalza-Marinucci M, Brandi G, Rondini C, et al. A three-year longitudinal study on the effects of a diet containing genetically modified Bt176 maize on the health status and performance of sheep. Livest Sci. 2008;113:178–190. doi:10.1016/j.livsci.2007.03.009. 18. Fares NH, El-Sayed AK. Fine structural changes in the ileum of mice fed on delta-endotoxin-treated potatoes and transgenic potatoes. Nat Toxins. 1998;6(6):219-33. 19. El-Shamei ZS, Gab-Alla AA, Shatta AA, Moussa EA, Rayan AM. Histopathological changes in some organs of male rats fed on genetically modified corn (Ajeeb YG). J Am Sci. 2012;8(10):684–696. 20. Gab-Alla AA, El-Shamei ZS, Shatta AA, Moussa EA, Rayan AM. Morphological and biochemical changes in male rats fed on genetically modified corn (Ajeeb YG). J Am Sci. 2012;8(9):1117–1123. 21. Finamore A, Roselli M, Britti S, et al. Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice. J Agric Food Chem. 2008;56:11533–39. doi:10.1021/jf802059w. 22. Vázquez-Padrón RI, Moreno-Fierros L, Neri-Bazan L, de la Riva GA, Lopez-Revilla R. Intragastric and intraperitoneal administration of Cry1Ac protoxin from Bacillus thuringiensis induces systemic and mucosal antibody responses in mice. Life Sci. 1999;64:1897-912. 23. Vázquez-Padrón RI, Moreno-Fierros L, Neri-Bazan L, Martinez-Gil AF, de-la-Riva GA, Lopez-Revilla R. Characterization of the mucosal and systemic immune response induced by Cry1Ac protein from Bacillus thuringiensis HD 73 in mice. Braz J Med Biol Res. 2000;33:147-55. 24. Vázquez-Padrón RI, Gonzales-Cabrera J, Garcia-Tovar C, et al. Cry1Ac protoxin from Bacillus thuringiensis sp. kurstaki HD73 binds to surface proteins in the mouse small intestine. Biochem Biophys Res Commun. 2000;271:54-8. doi:10.1006/bbrc.2000.2584. 25. Vázquez-Padron RI, Moreno-Fierros L, Neri-Bazan L, De La Riva GA, Lopez-Revilla R. Bacillus thuringiensis Cry1Ac protoxin is a potent systemic

and mucosal adjuvant. Scand J Immunol. 1999;49:578-84. 26. Losey JE, Rayor LS, Carter ME. Transgenic pollen harms monarch larvae. Nature. 1999;399:214. doi:10.1038/20338. 27. Jesse LCH, Obrycki JJ. Field deposition of Bt transgenic corn pollen: Lethal effects on the monarch butterfly. J Oecologia. 2000;125:241–248. 28. Lang A, Vojtech E. The effects of pollen consumption of transgenic Bt maize on the common swallowtail, Papilio machaon L. (Lepidoptera, Papilionidae). Basic Appl Ecol. 2006;7:296–306. GMO Myths and Truths 186 29. Hilbeck A, Baumgartner M, Fried PM, Bigler F. Effects of transgenic Bt corn-fed prey on immature development of Chrysoperla carnea (Neuroptera: Chrysopidae). Environ Entomol. 1998;27(2):480–487. 30. Hilbeck A, McMillan JM, Meier M, Humbel A, Schlaepfer-Miller J, Trtikova M. A controversy re-visited: Is the coccinellid Adalia bipunctata adversely affected by Bt toxins? Environ Sci Eur. 2012;24(10). doi:10.1186/2190-4715- 24-10. 31. Hilbeck A, Meier M, Trtikova M. Underlying reasons of the controversy over adverse effects of Bt toxins on lady beetle and lacewing larvae. Environ Sci Eur. 2012;24(9). doi:10.1186/2190-4715-24-9. 32. Hilbeck A, Moar WJ, Pusztai-Carey M, Filippini A, Bigler F. Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator Chrysoperla carnea. Entomol Exp Appl. 1999;91:305–316. 33. Marvier M, McCreedy C, Regetz J, Kareiva P. A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. Science. 2007;316:1475-7. doi:10.1126/science.1139208. 34. Lövei GL, Arpaia S. The impact of transgenic plants on natural enemies: A critical review of laboratory studies. Entomol Exp Appl. 2005;114:1–14. doi:10.1111/j.0013-8703.2005.00235.x. 35. Ramirez-Romero R, Desneux N, Decourtye A, Chaffiol A, Pham-Delègue MH. Does Cry1Ab protein affect learning performances of the honey bee Apis mellifera L. (Hymenoptera, Apidae)? Ecotoxicol Environ Saf. 2008;70:327–333. 36. Rosi-Marshall EJ, Tank JL, Royer TV, et al. Toxins in transgenic crop byproducts may affect headwater stream ecosystems. Proc Natl Acad Sci USA. 2007;104:16204-8. doi:10.1073/pnas.0707177104. 37. Bøhn T, Traavik T, Primicerio R. Demographic responses of Daphnia magna fed transgenic Bt-maize. Ecotoxicology. 2010;19:419-30. doi:10.1007/s10646-009-0427-x. 38. Castaldini M, Turrini A, Sbrana C, et al. Impact of Bt corn on rhizospheric and soil eubacterial communities and on beneficial mycorrhizal symbiosis in experimental microcosms. Appl Env Microbiol. 2005;71:6719-29. doi:10.1128/ AEM.71.11.6719-6729.2005. 39. GMO Compass. Maize. 2014. Available at: http://www.gmo-compass.org/eng/gmo/db/. 40. Paul V, Guertler P, Wiedemann S, Meyer HH. Degradation of Cry1Ab protein from genetically modified maize (MON810) in relation to total dietary feed proteins in dairy cow digestion. Transgenic Res. 2010;19:683-9. doi:10.1007/s11248-009-9339-z. 41. Guimaraes V, Drumare MF, Lereclus D, et al. In vitro digestion of Cry1Ab proteins and analysis of the impact on their immunoreactivity. J Agric Food Chem. 2010;58:3222-31. doi:10.1021/jf903189j. 42. Aris A, Leblanc S. Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. Reprod Toxicol. 2011;31. 43. Aris A. Response to comments from Monsanto scientists on our study showing detection of glyphosate and Cry1Ab in blood of women with and without pregnancy. Reprod Toxicol. 2012;33:122-123. 44. Betz FS, Hammond BG, Fuchs RL. Safety and advantages of Bacillus thuringiensis-protected plants to control insect pests. Regul Toxicol Pharmacol. 2000;32:156-73. doi:10.1006/rtph.2000.1426. 45. Mezzomo BP, Miranda-Vilela AL, de Souza Freire I, et al. Hematotoxicity of Bacillus thuringiensis as spore-crystal strains Cry1Aa, Cry1Ab, Cry1Ac or Cry2Aa in Swiss albino mice. J Hematol Thromb Dis. 2013;1. Available at: http:// esciencecentral.org/journals/JHTD/JHTD-1-104.pdf. 46. Then C. Risk assessment of toxins derived from Bacillus thuringiensis - synergism, efficacy, and selectivity. Env Sci Pollut Res Int. 2010;17:791-7. doi:10.1007/s11356-009-0208-3. 47. Bernstein IL, Bernstein JA, Miller M, et al. Immune responses in farm workers after exposure to Bacillus thuringiensis pesticides. Environ Health Perspect. 1999;107:575–582. 48. Doekes G, Larsen P, Sigsgaard

T, Baelum J. IgE sensitization to bacterial and fungal biopesticides in a cohort of Danish greenhouse workers: the BIOGART study. Am J Ind Med. 2004;46:404-7. doi:10.1002/ajim.20086. 49. Pusztai A, Bardocz S. Potential health effects of foods derived from genetically modified plants: What are the issues? Penang, Malaysia: Third World Network; 2011. 50. Ewen SW, Pusztai A. Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. Lancet. 1999;354:1353-4. doi:10.1016/S0140-6736(98)05860-7.

Section 4.

Herbicide tolerant crops – not substantially equivalent

This is an excerpt from GMO Myths and Truths, Second edition, published in Great Britain in 2014 by Earth Open Source.

Herbicide residues in GM herbicide-tolerant crops mean they are not substantially equivalent to non-GM crops.

Over 80% of GM crops worldwide are engineered to tolerate glyphosate herbicides. These GM crops are approved by regulators on the grounds that they are substantially equivalent to the non-GM parent crops. This assumption was tested in a comparative analysis of GM glyphosate-tolerant soy, non-GM soy cultivated under a conventional "chemical" regime, and non-GM soy grown organically. All crops tested were grown in Iowa, USA.[49]

The GM soy was found to contain high residues of glyphosate and its breakdown product AMPA. Conventional and organic soybeans contained neither of these chemicals.[49]

Organic soybeans showed the healthiest nutritional profile, with more sugars, such as glucose, fructose, sucrose and maltose, and significantly more protein and zinc and less fibre than conventional and GM soy. Organic soybeans also contained less total saturated fat and omega-6 fatty acids than conventional and GM soy.[49]

Using 35 different nutritional variables to characterise each soy sample, the researchers were able to discriminate GM, conventional and organic soybeans without exception.[49]

The study showed that GM glyphosate-tolerant soy is not substantially equivalent to non-GM soy, not only because of the herbicide residues in the GM soy, but because of the different nutritional profile.[49]

1. Bøhn T, Cuhra M, Traavik T, Sanden M, Fagan J, Primicerio R. Compositional differences in soybeans on the market: glyphosate accumulates in Roundup Ready GM soybeans. Food Chem. 2013. doi:10.1016/j.foodchem.2013.12.054.

Section 5.

Syngenta – a company with a history

We question whether FSANZ is putting public safety at risk by accepting submissions from corporations such as Syngenta, which, if approved, result in the introduction of their products into our food chain.

A scientific assessment should take into consideration the ability of the owner of the technology to comply with the law of the land. Although Syngenta's legal problems (below)

do not all directly relate to GM food safety, they help to paint a picture of the company as a corporate entity.

Some examples of Syngenta's past legal "issues".

2006

EPA Fines Syngenta $1.5 Million for Distributing Unregistered Genetically Engineered Pesticide http://yosemite.epa.gov/opa/admpress.nsf/e987e762f557727d852570bc0042cc90/2df47c51f639be4e8525724b0069655c!OpenDocument

Syngenta fined over GM tests in Brazil http://www.swissinfo.ch/eng/syngenta-fined-over-gm-tests-in-brazil/5083122

2012

Syngenta Crop Protection has agreed to pay a $102,000 civil penalty to the U.S. to settle a series of environmental violations related to the sale or distribution of misbranded pesticides through its facility in Omaha, NE, as well as through a farm supply retailer in Savannah, MO. http://www.croplife.com/crop-inputs/fungicides/syngenta-fined-102000-for-misbranded-pesticides/

In conclusion, as stated above, the GM-Free Australia Alliance Inc (GMFAA) recommends that FSANZ does NOT approve Application A1116 MZIR098

Please acknowledge receipt of this submission and respond to our concerns, detailed above.

Jessica Harrison, Coordinator, GM-Free Australia Alliance Inc