



Submission to FSANZ requesting the refusal of
Application 1097
GM corn line MON87411

10th February 2015

Recommendation:

FSANZ must reject Application 1097 for GM corn line MON87411 as FSANZ's legislated obligations are:

- 1) Protection of public health and safety
- 2) Provision of adequate information to consumers
- 3) Prevention of misleading or deceptive conduct

Approving MON87411 would break all three obligations.

Reasoning:

1. GM constructs in MON87411:

GM corn line MON87411 contains three expression cassettes. They are:

- The DvSnf7 cassette that creates double stranded RNA (dsRNA). When this dsRNA is eaten by an insect (the corn rootworm) it interferes with a vital gene leading to the death of the insect
- The cry3Bb1 cassette that produces a protein that kills insects by poking holes in their guts
- The cp4 epsps cassette that encodes a protein to allow the GM corn to survive being sprayed with the weed killer glyphosate (Roundup)

2. Problems with FSANZ's assessment of dsRNA

FSANZ ignores or dismisses peer-reviewed science:

- Lukaski and Zielenkiewicz, 2014ⁱ shows that dsRNAs derived from plants are found in human (and pig) breast milk. This shows the possibility that dsRNA from GM MON87411 may survive digestion, build up in tissues and be fed to the most vulnerable segment of the population, nursing babies. FSANZ does not mention this study.
- Baier et al., 2014ⁱⁱ shows dsRNA (miRNA) found in cows' milk survived digestion and can alter human gene expression. "We conclude that miRNA's in milk are bioactive food compounds that regulate human genes." FSANZ does not mention this study either.
- Heinemann, Agapito-Tenfen and Carman, 2013ⁱⁱⁱ shows the flaws in current regulation of dsRNA with suggestions for improvements. These include using modern techniques to find all intended and unintended dsRNA in the GM plant. Testing these on animal and human cells in vitro, long-term animal testing and, possibly, clinical trials on human volunteers.

FSANZ dismisses this paper saying "FSANZ does not consider the weight of

scientific evidence published to date supports the view that RNAi mediators (siRNAs, dsRNAs, miRNAs) in foods are likely to have adverse consequences for humans.” This is not an adequate response from FSANZ.

FSANZ makes an obviously incorrect and illogical statement:

“The data provided do not indicate this dsRNA possesses different characteristics, or is likely to pose a greater risk, than other RNAi mediators naturally present in corn.”

The corn rootworm evolved eating corn yet the new GM dsRNA in the corn kills them. Therefore it necessarily possesses different characteristics to non-GM dsRNA. To dismiss further investigation into the health effects for humans saying the GM dsRNA is the same as previous corn dsRNA is therefore wrong.

3. Problems with FSANZ’s assessment of the cry3Bb1 cassette

This *Bacillus thuringiensis* (Bt) toxin will be produced within the plant. It is unable to be washed off and so we will eat it. The Bt toxin in GM plants is not the same as that produced in naturally occurring soil bacteria. Natural Bt is not a toxin but a pro-toxin that only becomes toxic in certain conditions, for example when broken down by enzymes in an insect’s gut. Natural Bt, when used as a spray to kill insects by farmers and gardeners, breaks down quickly in sunlight and so it is unlikely to be eaten by humans or animals.

In contrast in GM crops the toxin is present in active form. The plant is therefore a pesticide and people and animals that eat it are eating a pesticide.^{iv}

Some animal feeding trials of GM Bt crops have shown adverse effects including:

- Toxic effects or signs of toxicity in the small intestine, liver, kidney, spleen, pancreas^v
- Disturbances in the functioning of the digestive system^{vi}
- Increased or decreased weight gain compared with controls^{vii}
- Male reproductive organ damage^{viii}
- Blood biochemistry disturbances^{ix}
- Immune system disturbances^x

These are only some of the issues raised by GM Bt crops that FSANZ has not addressed or acknowledged.

4. Problems with FSANZ’s assessment of the cp4 epsps cassette

This GM cassette allows the corn to be sprayed with glyphosate, the active ingredient of the weedkiller Roundup. This submission will not deal with the specific problems with this GM cassette but instead focus on the harmful effects of Roundup/glyphosate.

We are eating increasing amounts of glyphosate based herbicides due both to its use on Roundup Ready GM crops and its use as a desiccant on crops like wheat and pulses before harvest. There is mounting evidence that the assumed safety of glyphosate based herbicides is incorrect for the following reasons:

- Only the active ingredient, glyphosate, has been tested. In vitro studies show the complete formulation is up to 1000 times more toxic to human cells than glyphosate on its own.^{xi}
- Glyphosate herbicides are shown to damage DNA. The following lists of studies are only a very small sample of the studies showing this:
 - DNA damage in human mouth cells in vitro after single 20-minute exposure at lower doses than used in agriculture.^{xii}
 - DNA and chromosomal damage in the bone marrow of mice in vivo and in human cells in vitro.^{xiii}
- Glyphosate herbicides are endocrine disruptors:
 - In vitro experiment on human cells showed the masculinising hormones, androgens, were prevented from acting at levels up to 800 times lower than glyphosate residue levels allowed in some GM crops used for animal feed in the USA.^{xiv}
 - Causing the dysregulation of large numbers of genes in human breast cancer cells in vitro. Roundup was shown to work synergistically with estrogen, which is required for growth of breast cancer cells.^{xv}
- Glyphosate herbicides are linked to birth defects and infertility:
 - Malformations in chickens and frog embryos were caused at doses far below that used in agricultural spraying. These birth defects are similar to those reported in human populations in GM soy producing regions of South America.^{xvi}
 - A study of farming families in Ontario, Canada found a higher than normal rate of late miscarriages and premature births associated with male glyphosate herbicide exposure.^{xvii}
 - Male rats exposed to Roundup in utero had a decrease in sperm production and number in adulthood, an increase in the percentage of abnormal sperm, a decrease in testosterone level at puberty and sperm cell degeneration.^{xviii}

Roundup has also been linked to cancer, neurotoxicity, negative effects on gut bacteria and nutrient deficiencies in plants, and therefore the animals that eat them.^{xix}

FSANZ's concludes, "No potential public health and safety concerns have been identified in the assessment of herbicide-tolerant and insect-protected corn line MON87411-9. On the basis of the data provided in the present Application, and other available information, food derived from MON87411 is considered to be as safe for human consumption as food derived from conventional corn varieties."

This statement is hard to believe considering the evidence produced above.

FSANZ describes: “The safety assessment of a GM food is conducted within the established risk assessment framework used by FSANZ. In the case of GM food, the primary purpose is: (i) to identify new or altered hazards associated with the food as a result of the genetic modification; (ii) to assess whether there is any risk associated with any identified hazards under the intended conditions of use; and (iii) to determine if any new conditions of use are needed to enable safe use of the food.”^{xx}

It is clear from this submission that the new and altered hazards from GM corn MON87411 have not been adequately identified or assessed. Therefore the safety assessment has not been properly carried out.

FSANZ’s legislated obligations must be fulfilled:

FSANZ must reject application A1097 regarding GM corn line MON87411 to be in accordance with its legislated obligations.

- 1) Protection of public health and safety
 - Allowing MON87411 onto our plates without proper consideration of the DvSnf7 cassette, the cry3Bb1 cassette and the use of glyphosate based herbicides is damaging to public health and safety
- 2) Provision of adequate information to consumers
 - Consumers have a right to know what they are eating. It appears that since the FSANZ document is silent on labelling, that MON87411 will escape labelling. This is not providing consumers with adequate information
- 3) Prevention of misleading or deceptive conduct
 - The public is being deceived that GM crops are “as safe for human consumption as food derived from conventional corn varieties”. This is despite scientific studies showing harm and reports from GM growing areas showing cancer, birth defects and illness resulting from GM crops.

In 2013 a group of 30 organisations from 12 countries in Latin America analysed the effects of GM crops in their area. They wrote this open letter^{xxi} to, among others, the UN High Commissioner for Human Rights.

They state:

“Far from fulfilling the promises that the companies once made to enter the region, GM crops have planted desolation and death in Latin America. These crops have expanded vastly and now the region is ranking second in the world in area planted with GM crops.

The companies that produce seeds and pesticides and trade GM food together with local elites and in complicity with the government in office have turned Latin America

into a maquila of GM crops, and now they pretend to impose the massive trade liberalization of transgenic corn in its center of origin and diversification. The impacts of their activities have been: genetic contamination of agricultural biodiversity, destruction of natural ecosystems, subjecting the population to health problems due to the extensive use of pesticides, close to genocide. Thus, in the Southern Cone, glyphosate resistant soybeans cover an area of 475,700 Km². This whole area is sprayed with a cocktail of pesticides including glyphosate, affecting millions of people living not only in the main spraying area but also in its buffer zone.

The impacts that the agrobiotech model have produced are so enormous, that they can't be solved by techniques such as risk assessment and risk management because they have violated the human rights of entire populations. Therefore, this discussion should not be deal only in international forums such as the Cartagena Protocol, because it just analyzes the impacts of genetic modification on biodiversity. Instead this issue should be evaluated by the Human Rights agencies of the United Nations as a problem of systematic and legalized violation of rights."

Recommending for approval GM MON87411 on the basis of narrow and inadequate science based reasoning while ignoring the huge and growing evidence of multiple harms from GM is deceptive and misleading. Enabling a food that has been described as "subjecting the population to health problems due to the extensive use of pesticides, close to genocide" is a crime against humanity.

ⁱ Lukaski, A., and Zielenkiewicz, P. (2014). In silico identification of plant miRNAs in mammalian breast milk exosomes – a small step forward? PLoS ONE 9, e99963.

ⁱⁱ Baier, S.R., Nguyen, C., Xie, F., Wood, J.R., and Zemleni, J. (2014). MicroRNAs are absorbed in biologically meaningful amounts from nutritionally relevant doses of cow milk and affect gene expression in peripheral blood mononuclear cells, HEK- 293 kidney cell cultures, and mouse livers. J Nutr144, 1495- 1500.

ⁱⁱⁱ Heinemann, J.A., Agapito- Tenfen, S.Z., and Carman, J.A. (2013). A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environ Int 55, 43- 55.

^{iv} Szekacs 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.

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.

^v Seralini 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.

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^{vii} Seralini 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.

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^{viii} 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.

^{ix} Gab-Alla AA, El-Shamer ZS, Shatta AA, Moussa EA, Rayan AM. Morphological and biochemical changes in male rats fed on genetically modified corn (Ajeeb YG). *Ja Am Sci.* 2012;8(9):1117-1123.

^x 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.

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^{xix} Earth Open Source 2nd Edition GMO Myths and Truths 2014.
<http://earthopensource.org/index.php/reports/gmo-myths-and-truths>

^{xx} <http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx>

^{xxi} Network for a GM-Free Latin America. (RALLT) 2013. "At almost two decades from the introduction of GM crops in Latin America." <http://www.madge.org.au/Docs/GE-Free-Latin-Amer.pdf>