submissions

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Sent: Wednesday, 26 August 2015 10:12 AM
To: submissions
Subject: Application A1110 MON 87751

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Postal Address : PO Box 333, Wonthaggi Vic 3995

26-8-15

Re: Call for submissions – Application A1110 Food derived from Insect-protected Soybean Line MON87751

Dear FSANZ,

Monsanto seeks approval for food derived from a genetically modified insect-protected soybean line, MON8751.

The GM-Free Australia Alliance Inc (GMFAA) recommends that FSANZ does not approve Application A1110 MON87751.

General comment:

Our confidence in the regulatory processes of FSANZ is at an all-time low. We are almost completely resigned that any objections to GM applications are merely added as an addendum when the application is routinely approved by FSANZ.

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

On the contrary, there is growing concern, but the public has lost confidence that any of our comments will be taken seriously and acted upon.

FSANZ suffers from a refusal to assess the potential of GM foods to cause harm, preferring to sit on their (metaphorical) hands and allow safety documentation from the GM company which owns the technology, to “prove” safety of their product.

Previous approvals by regulatory authorities in other countries for identical or similar GM food and crops does not equal a sound basis for safety assessment, however "rigorous".

Why ? GM BT crops are not proven safe.

Section 1.

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.

MON 87751:
"Monsanto Company has developed insect-protected soybean MON 87751 that produces the CrylA.105 and Cry2Ab2 insecticidal (Cry) proteins derived from *B. thuringiensis*. Cry1A.105 is a modified Cry1A protein and Cry2Ab2 is derived from *B. thuringiensis* subsp. *kurstaki*. The CrylA.105 and Cry2Ab2 proteins provide protection from feeding damage caused by targeted lepidopteran insect pests. "

Our comment: Ease of insect control for farmers and the insect-killing potential of the plant does not equal safety for human consumption.

Monsanto states blithely in their application that:

"MON 87751 is intended ***primarily*** for use as a broad-acre commodity (or field) soybean and not for vegetable, garden, or food-grade soybean that are generally used to produce tofu, soybean sprouts, soymilk, green soybean (*e.g.*, edamame) or other similar food items. Vegetable and food-grade soybean generally have a different size, flavour, texture and other characteristics than field soybean, and are more easily cooked. Other than the introduction of the insect protection trait, MON 87751 is not materially different from conventional field soybeans and can be processed into a wide variety of food products as described in Section A2(b)(iii) and Section A2(b)(iv). Field soybean is ***a blended commodity*** that is highly processed before being consumed by humans. Thus, most food products derived from MON87751 would likely be blended with those derived from other commercial soybean varieties before entering the human food supply. ***(Our italics)***

As soy is blended, it is likely that MON87751 will enter the food chain, blended with other soy bean varieties and be included in food for human consumption.

Monsanto states:

"It is anticipated that MON 87751 will be generally consumed in soybean products entering Australia and New Zealand. ……..soybean is highly versatile and can be processed into a wide variety of food products including soybean oil, traditional soyfoods, soybean protein products, modern soyfoods, soybean-enriched foods, and functional soybean ingredients/dietary supplements"

Our comment : This GM soy product is also likely to be included in many foods for human and animal consumption, including soy-based infant formula. Due to our deficient labelling laws, the product will not be identified as a GM ingredient in food.

2. 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.

Bt toxins and Bt crop pollen and debris have toxic effects on non-target and beneficial organisms.

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.

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Please acknowledge recipt of this submision and respond to the concerns detailed above.

[redacted] **for GM-Free Australia Alliance Inc**