GE Free New Zealand

In Food and Environment Inc.

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28/07/2011

Food Standards Australia New Zealand submissions@foodstandards.gov.au

Re: Application A1046 - Food derived from herbicide-tolerant soybean line DAS-68416-4
28/07/2011

Dear FSANZ,

GE Free New Zealand in Food and Environment members recommend that FSANZ decline the approval of A1046 Food derived from herbicide-tolerant soybean line DAS-68416-4

We submit FSANZ cannot approve Soybean Line A1046 without a gross breach of its duty of care and mission obligations under which it operates.

We note that there is scant data on both the sprays and novel proteins detailed in this document. We would like to submit the 2,4-D, Human Health and Ecological Risk Assessment USDA, Forest Service (2006), specifically sections 3-4 detailing health data and effects of the pesticide, for using as a critique against the data you have looked at.

We note that Food Standards Australia New Zealand (FSANZ) legal requirements as stated in their mission statement are:

> To protect, in collaboration with others, the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply.

FSANZ Values are:

To be impartial, open and accountable;
To use the best available sciences and evidence to guide decision-making;
To seek, respect and be responsive to the issues raised by others;

FSANZ Responsibilities are

Provide information to consumers to enable better consumer choice
Undertake dietary exposure modeling and scientific risk assessments
Provide risk assessment advice on imported food

We have read all the assessments that are on your website and believe that you have led stake holders and consumers astray. We outline our concerns below.

The soybean line DAS-68416-4 contains novel genes that have never been considered by FSANZ before.
The lack of NOEL/RDI data on the ingestion of the novel protein and chemical combination Soybean food line does not give confidence that consumers will be protected or that the soybean is safe for those in the population who regularly eat it.

Soybean is used in 65% of processed foods such as breads, flours, sausages, soy sausage, as well as it is a food source of its own as tofu, tempeh, Soy Milk etc.

The concerning lack of safety assessment of the two herbicide interactions as well as the novel proteins inserted to withstand the spraying of these soy plants together, is in breach of your responsibilities for dietary exposure modeling and scientific risk assessments.

The acceptance that the levels of 2,4-D are the same as those plants that are not sprayed shows no evidence of good decision making or objectivity or even any modeling around safety as to the possibility of differing levels of the pesticides or proteins expressed only that there were "very minor levels" stated in your report..

The herbicide 2, 4-D has never been used to directly spray on food plants before. Therefore it has never been assessed. The superficial and largely acquiescent reliance on the applicant's data shows that impartiality, transparency and accountability are compromised to the benefit of the applicant and promoting a trade position, but not to the benefit of the Australasian consumer public.

The lack of any labeling of the Soybean is an abdication of responsibility. So is the failure to research the potential range of effects depending on which type of 2, 4-D is used. 2, 4-D is off patent and has 8 differing formulations, some more able than others to break down into other toxic metabolites, including dioxins.
The authority has also failed to take into account the negative impacts problems from over use of the patent chemicals on the crop and the unknown effects of higher levels of toxic pesticides in human diets.

Compulsory labeling of all approved GE foods regardless of their levels, is necessary in light of the changing herbicide use and vector sequences associated with each event.

Herbicide Metabolites – (p.ii)

Concerns are also raised by the small sample size. Only two samples per plot were taken i.e. 2 x 24 = 48 (p.29) as there is no record of the size of the plots it could be assumed that each plot was small and carefully managed. Commercial soybeans are grown over vast hectares and the herbicide tolerant lines are aerial sprayed for ease of management. There is no consideration of overspray, residue build up in the soil or re uptake of chemical metabolites that might affect the soy crop ergo human health on ingestion.

A study conducted by Greenpeace[1] (2007) on the levels of transgenic Bt gene expression in the same field plot, at the same time on the same day found expression levels ranged from 0.1 -10ugBt/g (p.9). This differing unstable gene expression level does not give confidence and assurance for consumers that the assessed gene expression or the sprays and their metabolite persistence levels are able to be stable and consistent with the approval standard criteria recommended for safety due to the lack of data and studies conducted for this review.
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All new protein expression and spray concentrations must have documented standard safety levels set and monitored against. This is different to the proportion of a GE food contained in a food that triggers labeling laws.

A recent study published by Aris and LeBlanc[2], 2011, on the Maternal and fetal exposure to pesticides associated to genetically modified foods, Canada has found that pesticides and Bt genes associated with diet are able to survive into the fetal blood system. The effects of this are as yet unknown and should be studied to show that there are no deleterious effects. The study did link the high levels of metabolites and genes found to GE foods. There also needs to be a study on the synergistic effects of the entire GE chimera's together.

Nutritional Impact (p.iii)
The nutritional impact statement is a simple generic statement not founded in the scientific expertise the public expect and require of the FSANZ, in order for the authority to live up to public interest and safety legislation.

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[1] How much Bt toxin do genetically engineered MON810 maize plants actually produce? Greenpeace e.V., Hamburg, 05/2007

[2] Aris A, Leblanc S. Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. Reprod Toxicol (2011), doi:10.1016/.reprotox.2011.02.004

The statement “Soybean line DAS-68416-4 is the result of a simple genetic modification to confer herbicide tolerance with no intention to significantly alter nutritional parameters in the food”.

This does not give assurance that the introduced engineered event has not altered the non tested parameters of the soybean. The novel protein expressed are not known as to their effects as they have not been tested in the animal or human feeding studies. Demonstration (extensive) of substantial equivalence on the existing parameters only goes to allow the applicant to avoid labeling, but it does not show how the new protein will affect the population. This is a gap in information that rules against approval of the soy line. The finding that it is "expected” to have little nutritional impact is subjective and lacks scientific meaning. It indicates that FSANZ has not used the best possible science to look into the new proteins.

Further, the new protein line, AAD-12, was isolated from the bacteria itself and not the protein expressed in the soybean, as quoted in the 2nd Assessment report

> *Because the expression of proteins in planta is usually too low to allow purification of sufficient quantities for safety assessment studies, a bacterial expression system was used to generate large quantities of both proteins.* (p.16)

This inability to conduct studies with the newly expressed novel protein does not show safety in equivalence as many new proteins express slightly differently when inserted into other organisms. Therefore there has been no ability for safety evaluation on how the novel protein as expressed in the soybean plant affects the human population acutely or long term.

There is mounting evidence of a differing of protein expression between the bacteria and the plant genes that appear to affect animals in feeding studies. The plant expressed protein must be studied to rule out any subjective opinion, especially with the chimera of novel genes such as cassava mosaic viral vector promoter which is a new vector and has replaced CAMV as a promoter.

The primary clinical effects of 2, 4-D

The USDA Forestry Service report[3] documents from section 3 -4 Human Health Risk assessments.

The report documents sub-lethal and synergistic effects in laboratory animals and the maternal, reproductive toxicity, and neurotoxicity are of great importance.

We ask that the authority halt any consideration for approval in light of the issues detailed in this section of the 2,4-D, Human Health and Ecological Risk Assessment 2006, USDA, Forest Service report: specifically –

- Effects observed following acute oral exposure of laboratory animals are ataxia, myotonia, and decreased limb tone (U.S. EPA/OPP 2005a). (sec: 3-8)

- Of particular significance, is the maternal toxicity observed among pregnant rats and rabbits exposed orally to 2, 4-D acid, salts, and esters for several days during organogenesis.

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[3] 2,4-D, Human Health and Ecological Risk Assessment FINAL REPORT, 2006, USDA, Forest Service http://www.fs.fed.us/foresthealth/pesticide/pdfs/093006_24d.pdf

- The neuro-toxic effects observed in dogs and rodents are also of concern, and are addressed further in the neurotoxicity section of this report. (3.1.6).

- After acute lethal exposure, the signs of toxicity in humans include convulsions, vomiting, congestion of various organs, and degenerative changes in nerve cells (Mullison 1981).

- In non lethal but toxic oral exposure to 2, 4-D, the signs and symptoms of toxicity in humans include irritation to mouth, throat, and gastrointestinal tract, vomiting, chest and abdominal pain, diarrhea, muscle twitches, tenderness, and stiffness (Mullison 1981).

- Faustini et al. (1996) evaluated short-term immunological changes in farmers who handled commercial formulations containing of 2,4-D and MCPA (4-chloro-2-methylphenoxyacetic acid) for 3 days…The concentrations of 2,4-D and MCPA in the blood were not determined; however, statistically significant reductions in the following variables were determined within 1-12 days post-exposure: circulating helper and suppressor T cells, suppressor T-cell diameter, cytotoxic T lymphocytes, natural killer cells, suppressor T cells expressing the surface antigens HLA-DR, lymphoproliferative responses to mitogen stimulation.

- The immunosupression observed in this study is supported by previously cited results by Kaioumova et al. (2001a, b) which demonstrate that the DMA salt of 2, 4-D kills human lymphocytes through induction of apoptosis.

- Studies conducted by De La Rosa et al (2003, 2005) demonstrate that combining herbicides may have a synergistic effect in terms of adverse effects on immune function. Thymic atrophy and depletion of thymocytes were observed only in mice treated with the combination of 2, 4-D and propanil at a concentration of 150 mg each of 2, 4-D and propanil/kg body weight.

3.1.8. Effects on Endocrine System

Concerns arise on the effects on the endocrine system in both men and women.

> *From a different perspective and potentially of greater concern may be the effects of a minor increase in LH secretion on the menstrual cycle and ovulation. Whether small fluctuations of the level of LH can affect women's fertility is uncertain.* (Garry et al., 2001, p. 500, column 1) 3-13

> According to Lerda and Rizzi (1991): *It can be concluded that exposure to 2, 4-D at the above concentrations produces a harmful effect on the germinal epithelium, causing alterations of spermatogenesis* (p. 49).

As found in the USDA report there were confirmed neurological and endocrine effects that have been reported when 2, 4-D has been used. We do acknowledge that the chemical assessed for synergistic effects are not the same as what is being applied for. This extensive report does not ever evaluate the mixture of 2, 4-D and glufosinate which is a new chemical combination.

This combination could have unexpected synergistic effects and could produce new metabolites or differing alkaloid expression that has not been required to be evaluated along the "normal" equivalency parameters. As is recognised by the evaluators in their safety assessment -

> *None of the DNA samples from AAD-12 negative plants or 'Maverick' negative control showed any hybridisation bands. p.17*

No AAD-12 or PAT proteins were detected in samples taken from 'Maverick' plants. p.19

This statement of fact indicates that FSANZ should have carried out its own toxicity and allergy exposure modeling, as these proteins do not exist in the non-modified parent line. This then makes a scientific nonsense of the allergenicity and toxicity search as this protein does not exist in the plant kingdom. There can be no similar amino acid sequences identified for reference since they have been created especially for this event.

Exposure modeling should have been conducted in light of the detection of immuno -reactivity to discover whether this event could cause life threatening allergy anaphylaxis in the susceptible population.

This standard of safety inquiry by FSANZ is especially necessary as soybean is now a staple ingredient in processed foods and eaten by those with allergies (p.22) to grain products, and a common dietary food for the elderly, ill, children, and vegetarians and vegan population.

The one study quoted by FSANZ on ingestion of the bacterial isolated AAD-12 gene by mice (p.26) is a terrible indictment on the poor rigor and seriousness with which FSANZ experts have met their responsibilities.

A cyst in the kidney cortex of the mouse after necropsy must be taken seriously especially as longer term studies have shown how GE soy has caused liver and kidney abnormalities. This poor study (un published) appears to have been done to tick the box for FSANZ, but not for a genuine or credible scientific understanding of the possible risks and effects.

The mice only had two gastric lavages1hour apart; this would by-pass an initial immune system reaction and does not reflect a normal eating pattern. The lack of any daily records to observe any initial reactions actually makes a mockery of the 2 week delay in assessment and makes the finding of a cyst even more important as an outlier on a trial of only 8 animals. This study and assessment does not at any time take into account the vegetarian and vegan population who eat soy as their main daily protein source and will have a significantly different expose profile to others.

The FAO has set the recommended daily intake of 2, 4-D as 0.01mg /kg /day. But there is no indication of just how this is going to be monitored. As seen in the table pasted below recommended general public levels are much lower than have been set by the applicant.

The 2, 4-D report goes on to say

> *"2, 4-D exposures associated with the consumption of contaminated water or fish range from about 0.0000004 to about 0.0001 mg/kg/day. The upper bound of this range is associated with the longer-term consumption of contaminated water. The longer-term consumption of contaminated vegetation leads to much higher estimated doses, ranging from 0.001 to about 0.2 mg/kg bw/day.* (clause 3-22)

What levels have 2, 4-D and its metabolites been set at? FSANZ will be aware that it is the metabolites that are often far more toxic and persistent. Recorded long term effects include: on the thyroid, testes, ovarian, nervous and immune system; health effects which have all been associated with 2, 4-D and the breakdown products. (USDA /FS p. xvi -xvii)

The USDA report, p xviii, there is also a clear concern over the short term consumption of contaminated fruits and vegetables on maternal toxicity or acute neurotoxicity when using either of the existing acute RfDs for 2, 4-D.

8.1.2.2 Metabolism of 2, 4-D in non-GM plants

There is an anomaly in the 2nd Assessment report (p.9) evaluation on the levels of dichlorophenol.

It is reported that the control plants did not produce the metabolite dichlorophenol, nor is our food supply sprayed with the pesticide 2, 4-D so the clarification given to NZ MAF is disingenuous as the Safety Assessment has not evaluated, as required in legislation, the levels of dichlorophenol (DCP) residue that would cause acute / non-lethal effects. It indicates only that it is the same metabolite found in plants when sprayed with 2, 4-D.

There has been no long term toxicity studies evaluated on the EPA-required, 2, 4-D esters. The USDA report states:

> *These appear to be more toxic when used as a direct spray than when used as a pre emergent one. Farmers today only use 2, 4-D as a pre emergent spray.*

So the metabolites that have been indicated by the applicant have come as a result of uptake from the soil. There does not appear to be any evaluation of the differing levels of residue in the seed, the edible part of the plant.

It was noted that 2, 4-D appears to be more toxic following direct spray than by pre-emergent application.

> *In pre-emergent soil applications (i.e., seedling emergence studies), the NOAEC values for the most sensitive and tolerant combination of species and 2, 4-D ester are 0.045 and >0.96 lb a.e./acre, respectively. The corresponding values for direct spray (post-emergent bioassays) are 0.0075and >0.96 l b a.e./acre.* (p.xxii)

Consideration of the non-lethal effects have not been taken into account.

Though it is acknowledged that effects of acute toxicity will not necessarily occur, it is the long term sub acute damage that is very possible and could present as common adverse effects like weight loss and reproductive difficulties. These effects would likely not be considered by the health professionals and causality of disease will go unexamined.

It is concerning that all these effects are so unknown and have no diagnostic tests available to allow health professionals to rule out allergies or ill effects from ingestion of GE soy.

There has been no studies on the synergistic, antagonistic effects that may occur with the ingestion of a variety of GE foods in the diet. What are the problems with stacking of different GE pesticide flied foods and their vector systems?

It is therefore unacceptable to our members that FSANZ is recommending releasing yet another GE soy (A1046) event into the food chain and still has available no diagnostic tests or public health approach to deal with toxic reaction. It appears that FSANZ is allowing this and other pesticide-containing foods without the requisite safety studies and tools.

This further endangers consumer's health and should not be approved until more comprehensive studies have been conducted.

Summary

We ask that FSANZ decline approval of A1046

- There has been inadequate provision in the risk assessment and evaluation of novel soy bean line A1046.
- There have been no dietary exposure modeling and scientific risk assessments undertaken by FSANZ.
- The Applicant information provided on safety is insufficient for entry into the food chain.
- The assessment is deficient in information in light of novel protein never part of the food chain and for which no health safety studies have been conducted on its expression in the actual soybean line.
- There is a lack of scientific data necessary to protect and maintain a safe food supply for the health and safety of people in Australia and New Zealand.
- There is evidence that the best available science has not been used to properly guide decision-making.
- The reliance on applicant's data has not shown impartiality, openness and accountability. By not allowing for labeling of GE Soybean A1046 FSANZ has not provided information to consumers that will enable better consumer choice.

Yours sincerely,

Jon Muller

Secretary of GE Free (NZ) in food and environment.

References:

Application A1046 - Food derived from herbicide-tolerant soybean line DAS-68416-42nd Assessment Report - 6 July 2011

Supporting document 1 - Safety assessment report

http://www.foodstandards.gov.au/_srcfiles/A1046%20GM%20Soybean%20DAS-68416-4%202AR%20SD1%20Safety%20Assess.pdf

MAF letter to FSANZ, 25 March 2011 on Application A1046 – Food Derived from Herbicide-tolerant Soybean Line DAS-68416-4 – First Assessment Report

2,4-D, Human Health and Ecological Risk Assessment FINAL REPORT, 2006, USDA, Forest Service
http://www.fs.fed.us/foresthealth/pesticide/pdfs/093006_24d.pdf

Aris A, Leblanc S. Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec , Canada . Reprod Toxicol (2011), doi:10.1016/j.reprotox.2011.02.004 http://www.ncbi.nlm.nih.gov/pubmed/21338670

How much Bt toxin do genetically engineered MON810 maize plants actually produce? Greenpeace e.V., Hamburg, 05/2007

George M. Rusch 2000 Applied Occupational and Environmental Hygiene Chemical Exposure Guidance Levels Consistency, Integrity and Public Trust Volume 15, Issue 10, p. 734-739 **DOI:** 10.1080/10473220050129356 Table 2-1. 2,4-D Commercial formulations covered in this risk assessment (p.185)

Dow chemical use has only been assessed for non-crop use.

Table 2-2. Commercial formulations containing mixtures of 2,4-D with other herbicides (p.186)

Table 3-3: Summary of critical neurotoxicity, sub chronic, chronic, developmental and reproductive toxicity data for 2,4-D tables17.

Table 3-11: EPA/OPP (2005a) Risk Numbers for Human Health (p.Tables 26)

EPA Exposure Scenario	Dose Used, Uncertainty Factor	FQPA SF	Basis Study and Effect Levels
Acute Dietary, Females aged 13-49	NOAEL = 25 mg/kg/day UF = 1000 Acute RfD = 0.025 mg/kg/day	FQPA SF = 1X aPAD = 0.025 mg/kg/day	Rat developmental toxicity; NOAEL = 25 mg/kg/day; LOAEL = 75 mg/kg/day; Nemec et al. 1983a (MRID 00130408)
Acute Dietary, General Population	NOAEL = 67 mg/kg/day UF = 1000 Acute RfD = 0.067 mg/kg/day	FQPA SF = 1X aPAD = 0.067 mg/kg/day	Acute neurotoxicity study in rats, NOAEL = 67 mg/kg/day, LOAEL = 227 mg/kg/day Mattsson et al. 1994a (MRID 43115201)
Chronic Dietary, All populations	NOAEL = 5 mg/kg/day UF = 1000 Chronic RfD = 0.005 mg/kg/day	FQPA SF = 1X cPAD = 0.005 mg/kg/day	Rat Chronic Toxicity study; NOAEL = 5 mg/kg/day LOAEL = 75 mg/kg/day Rowland 1996a (MRID 43612001)

aPAD = acute population adjusted dose; NOAEL ÷ (UF x FQPA SF)
cPAD = chronic population adjusted dose; NOAEL ÷ (UF x FQPA SF)
FQPA = food quality protection act
SF = safety factor
UF = uncertainty factor