



GE Free New Zealand

In Food And Environment Inc.

PO Box 13402, Wellington, NZ Ph +64- 4 - 477 4744
www.gefree.org.nz

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

Re: Application A1042 Food derived from herbicide-tolerant Corn line DAS-40278-9

15/04/2011

Dear FSANZ,

GE Free New Zealand in Food and Environment members oppose the approval of Application A1042 Food derived from herbicide-tolerant Corn line DAS-40278-9

We submit FSANZ should reject the application A 1042 DAS Corn line.

An approval would constitute a gross breach of FSANZ's duty of care and mission obligations. The data assessed is insufficient to justify confidence that an approval will not result in harm to public health.

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

In 2005 FSANZ Act introduced the need for safety studies in their assessments. A1042 lacks any data on long term safety. The adverse events in the small subject numbers requires that this application be sent back for long term independent studies using the proper UN guidelines.

We have read the assessments that are on your website and believe that it is wrong to use the wording:

"The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce corn line DAS-40278-9"

The absence of evidence is an unacceptable approach to public health when novel gene

technology is proven to create subtle and unexpected effects that can be harmful.

The claim of 'no concerns identified' in every application suggests a failure of regulation and undermines any confidence that consumers are being properly protected or impartially treated in light of the dangers posed by the spraying of 2, 4-D & Quizalofop-P-ethyl on the food crops.

There is no data to identify health and safety concerns either on the individual or the interaction between the two herbicides or their actions on the introduced engineered gene constructs.

This lack of assessment of interaction events means that health concerns are identified but not addressed. In this case the application cannot be approved. The precautionary principle does not assume that a lack of data means safety. Where is the data to confirm that this product will not cause harm, given we know there is potential harm from the GE processes used and associated increased use of toxins in food?

1. Option1 Reject Application

We note that this assessment is no longer a protection of the food supply ensuring safety but assessed under the laws of Government and Trade agendas. The statements in the assessment directly conflict with your Mission statement, values and responsibilities to protect Consumers: [1]

Consumers:

- *Possible restriction in the availability of imported corn products to those products that do not contain corn line DAS-40278-9.*
- *No impact on consumers wishing to avoid GM foods, as food from corn line DAS-40278-9 is not currently permitted in the food supply.*
- *Potential increase in price of imported corn foods due to requirement for segregation of corn line DAS-40278-9.*

Government:

- *Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue.*

Industry:

- *Possible restriction on imports of corn food products if corn line DAS-40278-9 were to be commercialised overseas.*
- *Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on food industry."*

It appears that FSANZ cannot reject an application as it will endanger the trade deals Australia has entered into. This clause might be a responsibility under your Australian / US Free Trade deal but it is not binding on the New Zealand population.

2. The Precautionary Principle

This principle is defined as by the APA [2]

"the precept that an action should not be taken if the consequences are uncertain and potentially dangerous"

This is the case here and requires the application be declined.

The lack of any data to back up the assertions that the spraying to the maximum limit of 2, 4-D on the crop food is safe does not take into account the fact that this herbicide is not part of a crop growing regime.

Analysis of the breakdown products of 2, 4-D has found that the metabolite 2,3,7,8 TCDD a dioxin can be produced (US EPA 1993). The PAN UK report on 2,4-D [4] point out the large number of major data gaps in health and safety of 2,4-D.

The WHO Fourth Ministerial Conference on Environment and Health Report [3] outline the "precaution" that regulators should take state in section 18

(iii) considering and examining all available relevant evidence on exposure, hazard and risk in an interdisciplinary manner and taking account of variability as well as relevant direct, indirect, cumulative and interactive effects; this can include conducting routine health and environmental monitoring to provide a baseline understanding of health and ecological impacts, as well as health trends;

(v) comprehensively examining uncertainty and gaps in information, performing sensitivity analyses and identifying research and other ways to reduce uncertainties and gaps in knowledge where appropriate;

The lack of safety data shows that these precautions cannot be carried out as there is no data to show health and safety to the public.

On this basis the application must be declined by FSANZ.

2, 4-D has been "off patent" for many years and this fact causes concern about the type of generic 2, 4-D that will be sprayed. This then clearly raises concerns for safety of the food as the growing conditions and usage cannot be assumed to be the same across all farms, therefore the toxicity levels will be different. As FSANZ has not set any levels because it has no parameters to work on, there are clear concerns for health that cannot be further ignored.

The internal insertion of the AAD-1 gene could cause unintended effects and change the growth of the plant. For example:

There is moderation towards safety in conventional corn seed variety where there are limits to the pesticides that the crop will tolerate. This means that there is a safety net in the amount of pesticides that a Food Authority can monitor and evaluate on any given crop. The 5 yearly diet surveys are conducted as an audit to ensure consumer safety and pesticide residues are tested for.

On the introduction of herbicide tolerant chlorine based 2, 4-D [4] corn this safety net will become difficult to police. Levels of unexpected metabolites, new breakdown products, or

stored toxic by-products in food corn are undefined. Will any dioxin be produced?

2, 4-D being a phenoxy based herbicide has been linked to soft tissue carcinoma, Non-Hodgkin's lymphoma, multiple myeloma and neurological problems. It lesser adverse effects are nausea, headache, vomiting and skin rashes. There have been no long term ingestion studies. The WHO puts it in the class II moderately toxic class, the same category rating as endosulphan which ERMA has just banned from use.

Unless there is adequate data to show that there are no adverse health effects, consumers cannot be assured that FSANZ has completed and assessed this application to the standards expected of a Food Authority protecting the health of its consumers.

This lack of safety data should put the application on hold until comprehensive safety studies are conducted that meet the International Codex parameters.

3. NZFSA / MAF Reply to Assessment Report

It is highly concerning that NZFSA / MAF has to bring to your attention the missing data and lack of data which has not been addressed by the FSANZ experts. We support the findings by NZFSA / MAF in their submission [5] statements

Section 5 (Herbicide Metabolites) of the Safety Assessment Report (Supporting Document 1). This section states that 2, 4 - dichlorophenol and quizalofop-P acid (called quizalofop phenol in Figure 7) are generated from herbicides applied to DAS-40278-9 corn, and that these products are also generated in conventional crops treated with the same herbicides (i.e. 2-4-D and quizalofop-P-ethyl). As the AAD-1 enzyme is unlikely to be present, then it is possible that other biochemical pathways (or environmental factors) cause cleavage of the herbicides. This is not explained in the Safety Assessment Report. In our view, additional evidence that these products occur in conventional crops through degradation of the herbicides should be presented.

Section 6 (Compositional Analysis) of the Safety Assessment Report. Statistically significant treatment effects are identified for a number of the reported compositional analysis. We presume that treatment effects relate to differences between sprayed and unsprayed DAS-40278-9. This could be clarified in the report, and perhaps a comment made about the significance or otherwise, of these differences.

4. Safety Studies

There is no data provided as to what type of investigation was undertaken in relation to the statement -

The AAD-1 protein was investigated for its potential to be a toxin or allergen. Bioinformatics studies with the AAD-1 protein have confirmed the absence of any biologically significant amino acid sequence similarity to known protein toxins or allergens and digestibility studies have demonstrated that the protein would be rapidly degraded following ingestion, similar to other dietary proteins. Taken together, the evidence indicates that the AAD-1 protein is neither toxic nor likely to be allergenic in humans p. ii

The unconfirmed statement that "species within the genus *S. herbicidovorans* where the

Aryloxyalkanoate dioxygenase (AAD-1) is sourced has a wide distribution in nature and has a significant exposure in animals and humans” is opinion and undocumented. There have been many unforeseen and unanticipated adverse effects that are documented from the use of genetically engineered herbicide tolerance RR and insecticide *Bt* genes. It cannot be assumed that the food is safe just because it is in the soil or has been deemed 'substantially equivalent' without credible scientific justification.

Sphingomonas spp bacteria are associated with nosocomial infections that can lead to serious illnesses such as pneumonia, urinary and renal infections. There is no data to show if transformation events could occur in the digestive tract between the engineered gene and similar species bacteria.

The nature of the AAD-1 gene is also unknown in the mammalian system and its effects on the liver or if it could alter the metabolic pathways. The 2, 4 –D is also implicated in liver degeneration.

This gene AAD-1 has been isolated from the bacteria. As animals and human does not eat soil in quantities that would be able to detect if the isolated gene is toxic or not, this is an unsubstantiated and erroneous supposition. The lack of any data to back this statement up should have been addressed by the assessment team.

5. Anomaly in testing regime:

In the second assessment report you state

The amount of AAD-1 protein produced in DAS-40278-9 plants was insufficient for safety evaluations p.15

And your conclusion at 4.2.4

A range of characterisation methods confirmed the identity of AAD-1 protein produced both in P. fluorescens and in corn DAS-40278-9. Protein from both sources was found to migrate at identical molecular weights, to be recognised by anti-AAD-1 antibodies and to lack glycosylation. Sequencing analysis confirmed that the plant-derived protein amino acid sequence matched that of the microbial-derived protein. Thus the AAD-1 proteins from DAS- 40278-9 and P. fluorescens can be said to be equivalent. Thus the P. fluorescens-derived AAD-1 protein was used as a surrogate for plant-derived AAD-1 in subsequent studies for the safety assessment (i.e. in vitro digestion studies, acute toxicity studies). p17

We are highly concerned that the AAD-1 that was tested was isolated from a different bacteria *Pseudomonas* and fed to animals in its un-engineered state as reported in the 2007 Early Food Safety Evaluation by Dow Chemical [6].

The study on mice quoted in the “summary and conclusion” report at p.20 cannot be assumed as scientific as it does not meet the International Codex parameters.

The small sample size means the margin of error will be no more than chance. Assessment of no risk on this sampling size leads us to draw the conclusion that the lack of robust analysis is alarming as the sample size, length of time and number of studies is so small they do not meet the parameters of scientific testing.

What is significant is on looking at the sample subject mice, 5 female and 5 male, is the changes in two of the 10 mice – shadowing of the brain and stomach ulcers. A shadowing of the brain, these mice were given 2 doses and killed after 14 days. It is easy to believe

that just two doses would not have that effect however there is no evidence to show that the adverse changes were not treatment related and should not be assumed as co-incidental.

6. Codex Guidelines

The assessment required under the Codex guidelines [7] has not conclusively provided data to show safety of the two herbicides and the gene interaction on

- a) *expressed substances (non-nucleic acid substances);*
- b) *compositional analyses of key components;*
- c) *evaluation of metabolites ;*
- d) *food processing;*
- e) *nutritional modification;*

The Codex guidelines state in Section 5 – Other Considerations

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

54 *Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health.*

The safety assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied. (p.8)
(our emphasis).

There are still many gaps that require evaluation, especially as the 2,4-D herbicide is also missing essential data as to its safety (see PAN UK report [4]). It appears that FSANZ has been remiss in omitting to require further procedures to assess human safety in light of these large and potentially dangerous health hazards.

Further if 2, 4-D on reassessment is banned from New Zealand agriculture, where does this put the validity of the application if approved under international law?

7. Expert studies of GE plants

In his expert report to the Royal commission on Genetic Engineering (New Zealand) Dr. Pusztai [8] drew the conclusion that -

The results also suggest that a major part of these differences was not caused by the expression of the GNA gene in the transgenic potato lines but that these could have been due to the presence of one or more of the other gene(s) in the vector used in the gene transfer or to the possibility of disturbances in the functioning of potatoes' own genes caused by the random incorporation of the vector in the potato genome (positioning effect).p.1

It may be that the concentrated salt isolate from the plant source was not toxic but the engineered product was. It appears that when the gene cassette is introduced into a cell it works differently to its straight isolate.

Further, stomach lesions have been detected in earlier GE tomato studies [9]. These findings show that there is good reason to require the applicant to conduct meaningful larger generational feeding studies on the safety of the transgenic corn.

Data should not be comparing alone non-engineered events with engineered ones but also looking across to other GE studies to see if there are patterns showing that are similarities to other transgenic studies. Another study on AAD-1 on 3 female mice for 4 days is not acceptable in light of the lifetime ingestion of a staple food such as corn.

This error must be addressed first in providing robust long term safety data on the engineered corn product and secondly tested with the same bacterial gene.

The synthesis gastro in vitro assays on AAD-1 are unacceptable as the long term cellular changes cannot be studied further as they are of a different bacterial genus.

The inability to be able to conclude that the AAD-1 gene was not destroyed in 16 minutes because of its binding to the SGF protein requires further long term in vivo studies.

8. FSANZ Safety Assessment Report (2nd Assessment) Nutritional Impact

The lack of any nutritional impact either adverse or beneficial as stated is not valid as there have been no studies conducted.

The detailed compositional studies are considered sufficient to establish the nutritional adequacy of food derived from corn DAS-40278-9. No biologically significant differences in the nutritional content between DAS-40278-9 and non-GM corn varieties could be established. As such, the introduction of corn DAS-40278-9 into the food supply would be expected to have little nutritional impact. p 34

There appears to be a degradation of nutritional values as shown up by the significant nutritional differences in both the vitamin, protein, carbohydrate and fat levels.

There are no robust animal safety studies completed on this food. It is not acceptable to approve a potentially anti-nutritional or reduced-nutritional product for human consumption. This could be detrimental to consumer health, as there is no monitoring, labeling or protection afforded consumers exposed to eating a nutritionally degraded food.

Summary:

A1042 composes health risks that have not been assessed properly under International Codex guidelines. There is the absence of any safety studies on humans and lack of robust studies on animals. It fails to meet the standards required of a Food Safety Authority charged with guarding the safety of the food supply.

We ask that you reject this application and send it back for long term independent feeding studies.

Until then the product should not be approved for sale in Australasia.

Yours sincerely,

Jon Muller

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

References:

[1] Food Standards Supporting Document 1 Application A1042 – Food Derived From Herbicide tolerant Corn Line Das-40278-9 Safety Assessment Report (2nd Assessment) Summary And Conclusions

[2] American Psychological Association (APA): precautionary principle. (n.d.). *Collins English Dictionary - Complete & Unabridged 10th Edition*. Retrieved April 14, 2011, [http://dictionary.reference.com/browse/precautionary principle](http://dictionary.reference.com/browse/precautionary%20principle)

[3] World Health Organisation, Fourth Ministerial Conference on Environment and Health Budapest, Hungary, 23–25 June 2004
http://www.tekno.dk/pdf/projekter/p04_boernene_og_miljoet-Dealing_with_uncertainty-WHO_april_2004.pdf

[4] 2, 4-D fact sheet <http://www.pan-uk.org/pestnews/Actives/24d.htm>

[5] NZFSA Application A1042– Food derived from herbicide-tolerant Corn Line DAS-40278-9 - Assessment Report, 8th February

[6] Early Food Safety Evaluation Aryloxyalkanoate Dioxygenase (AAD1) Protein Agrigenetics, Inc. Mycogen Seeds, FDA, Center for Food Safety and Nutrition, Office of Food Additives Part 11. *Federal Register*, Vol. 71, No. 119, June 26, 2006
<http://www.fda.gov/downloads/Food/Biotechnology/Submissions/UCM222235.pdf>

[7] Guideline For The Conduct Of Food Safety Assessment Of Foods Derived From Recombinant-DNA Plants, CAC/GL 45-2003

[8] Submission of Dr Árpád Pusztai Royal Commission on Genetic Engineering (NZ) 2000
<http://www.freenetpages.co.uk/hp/a.pusztai/NewZealand/nz-arpad.htm>

[9] Flavr Savr Tomato Pathology Review Fred A. Hines, DVM, Staff Pathologist, Pathology Branch, HFS-716 Department of Health & Human Services 16 June 93
<http://www.mindfully.org/GE/FlavrSavr-Pathology-Review.htm>