GE Free New Zealand

In Food And Environment Inc.

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Dear Minister,

We ask that you urgently intervene and call for a review in light of the pending approval by Food Standards Australia New Zealand (FSANZ) of A1042 corn line DAS –40278-9 [1]

As the New Zealand Ministerial representative on The Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) you and your colleagues have the ability to request a review of any decision pending as stated

***For decisions relating to applications received and proposals prepared from 1 October 2007**, within 60 days after the notification of an approval of a draft variation to the Code by the FSANZ Board, by majority decision, the Ministerial Council can either request the FSANZ Board to review its decision, or advise that it does not seek a review. If a review is requested, FSANZ must complete the review within three months, or a longer period if specified by the Ministerial Council.under its aims that fall within the FSANZ Act. .[2]*

We would like to draw your attention to the final report on A1042 from FSANZ. We believe that this report has not dealt with the concerns raised by submitters in the two rounds of submissions related to the DAS –40278-9 corn line. These concerns include food safety for consumers and the provision of information so people can make the most appropriate choices to remain healthy.

With the lack of safety data we also believe that serious implications into life threatening health sicknesses may occur.
A review is made necessary for the reasons discussed below.

In the "Overarching Strategic Statement for the food regulatory system" [2]
the document outlines the regulatory responsibilities, of which we believe that none have been addressed to give consumer safety. We outline these below -

Protecting health and safety of consumers (p.10/25)
The primary goal of the regulatory system is to protect the health and safety of consumers of food - in other words, to protect Australians and New Zealanders from preventable health risks associated with the consumption of food.

This means: helping to prevent people becoming sick or dying as the result of the consumption of unsafe food; and

- *Providing consumers with information so that they can choose appropriate food and remain healthy over time.*

- *The food regulatory system aims to reduce risks related to food by:*
  For example, one of the purposes of the food regulatory system is to thoroughly assess novel foods or new additives to foods to ensure that they are safe for consumption before being made available to the public. A further example is the assessment of naturally occurring toxins that may be present in foods.

Enabling consumers to make informed choices about food (p.11/25)

- *First; labelling requirements can enable consumers to make choices about the safety of food (either the safety of the food generally or for them as individuals). For example, allergen labelling alerts individuals to foods to which they may have an allergic response. This overlaps with the objective of protecting the health and safety of consumers.*

- *Second, the food regulatory system can assist consumers to choose appropriate foods. For example, Nutrition Information Panels on foods inform consumers of the nutritive value of the foods they are selecting. This overlaps with the aim of supporting public health objectives.*

- *Third, the food regulatory system has at times been used to provide information to consumers about where the food has been produced and by what methods (for example, country of origin and GM labelling).*

- *The food regulatory system is also aimed at minimising misleading conduct in relation to food. A key role of regulation in this regard is to prevent sellers from misleading consumers about the nature of food such that the health of consumers is at immediate risk.*

- *Another purpose is to prevent sellers from misleading consumers on the health-giving qualities of food such that the consumers' longer term health may be adversely impacted. An example is misleading consumers as to the health benefits of a certain food.*

- *A further purpose is to prevent consumers from being exploited as a result of sellers representing food to be something that it is not.*

Supporting public health objectives (p.12/25)

- *Public health is defined as "the organised response by society to protect and promote health, and to prevent injury, illness and disability".*

- *Public health and safety in relation to food refers to all those aspects of food consumption that could adversely affect the general population or a particular community's health either in the short or long term. Adverse impacts include preventable diet-related disease, illness and disability as well as acute food safety concerns.*

- *Food regulation, as one of a range of strategies, may play an important role in preventing and reducing disease, illness and disability, including by:*

    - *facilitating healthy food choices – for example by labelling foods to indicate their nutritive value;*

    - *maintaining and enhancing the nutritional qualities of food – for example, providing storage and handling information and enabling fortification to restore nutrients lost during processing; and*

    - *responding to specific public health issues through the food supply – for example, by requiring mandatory fortification of foods with substances designed to address specific public health needs.*

In 2005 FSANZ Act introduced the need for safety studies in their assessments. A1042 lacks any data on long term safety of this corn line. The adverse events reported in the small subject numbers requires that this application should be put on “stop clock” so as long term independent studies using the proper UN guidelines.

The final report reiterated that the FSANZ 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 they assess 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 introduction of two novel proteins never been found in the food system before to tolerate two chemicals 2, 4-D and glufosinate that have never been approved as food crop sprays.

The Final report also states that

For GM applications, at the time of preparation of this Approval Report Minimum Residue levels (MRLs) still needs to be undertaken with regard to corn line DAS-40278-9. (p.12)

We presume that FSANZ has undertaken a review with no data to weight up against chemical residues that might affect human safety. As the Maximum Recommended Intake (MRI’s) levels are yet to be assessed.

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 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"*

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.
There fore without MRI'S and long term and safety data the consequences of approving the genetically engineered corn line are uncertain and potentially dangerous.

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.

With 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.

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. 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 here 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.

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. There fore we believe that it is premature and dangerous to assume that these sprays are safe for human consumption if they have never been assessed for human safety.

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?

We believe that this is a breach of the primary goals of protecting the health and safety of consumers as set out in the Ministerial objectives for its consumers in relation to novel foods and their safety.

Supporting public health objectives (12/25)

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.

Safety Studies

There are 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.

Sphingomona 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 do 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.

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.

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?

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 finding 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-I 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.

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.

There have been no published long term data of GE food safety in humans; however studies by Aris and LeBlanc in the Journal of Reproductive toxicology [10] on pregnant women and their babies have shown that novel DNA has been found in the blood of fetuses from crossing the placental barrier. Netherwood et al [11] study on a meal containing transgenic (Ready Round up) soy DNA was not broken down in the digestive juices but found in the small bowel of human subjects.

We have also referenced below published peer reviewed data on animal studies and the deleterious health effects that GE foods have shown on the immune system, organs, reproductive, endocrine system and bloods. [12 -18]

The lack of independent studies that FSANZ agency is required to carry out as part of its duty to the public have not been conducted. The reliance on Industry assurances when their novel proteins and chemicals have not even had the chemicals assessed for human safety does not give consumers that confidence that FSANZ has fulfilled its duty of care to its consumers.

Our Country has high levels of illness due to cancers that is overloading our health system. A majority of Cancers can be attributed to nicotine smoking, even though the Tobacco Companies at the time stated that smoking was not deleterious to health. Approval by Governments went ahead relying on Industry rhetoric and selected data. It appears that GE Industry is following the same route and yet again endangering human health

In this light we believe that FSANZ has been less that rigorous in its assessment of the A1042 and has not been able to properly demonstrate whether this food may cause sickness or death to its consumers.

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 believe that every principle that you are bound to uphold in your Ministerial responsibilities has been breached.

Consumer's right to know -The lack of consumer information and lack of compulsory labeling allowing the ability of consumers to choose the types of foods to consume with the knowledge of what their food contains;

The lack of safety data does not assure or guarantee that the foods will maintain or enhance consumer's health;

The lack of data on the RDI and MRI's of 2, 4-D or which of the 22 off patent versions of the chemical on the market with certain ones producing dioxins have been approved. The mixture of herbicides does not preclude that stacking with other herbicide resistant events would not occur.

The lack of safety data on long term ingestion could affect the general population or a small section of vulnerable in the society however there is no data to indicate how prevention is possible, this is not due to robust data but the fact such studies have never been carried out.

The lack of any diagnostic tools to detect if there are any consumer health effects does not allow the ability of public health response to an allergic or serious health reaction;

In light of this we ask that you call for a full review of the application A1042. That a full Science evaluation by a renowned independent scientist/s to re evaluates and review all the information to see if these concerns are valid and act accordingly on the results.
Until then the product should not be approved for sale in Australasia.

We would like to ask that you consider an independent review by a renowned New Zealand Scientist in this area to evaluate if there is any reason for the New Zealand consumers to be concerned.

Also, that all health professionals are educated on the potential effects of GE and give them access to diagnostic tools to detect whether illness changes in their patients is not attributable to the ingestion of GE foods.

We ask that before approving this food into the food chain you ask that diagnostic tools for health professionals and labeling are part of the approval process.

We would like to schedule a meeting with you to discuss why we would like this review of the pending approval in 60 days of the FSANZ application A1042.

Yours sincerely,

Jon Muller
Secretary for GE Free NZ in Food and Environment

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[2] Ministerial Council Review of FSANZ Approvals
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[2] The Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC)
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