GE Free New Zealand

In Food And Environment Inc.

PO Box 13402, Wellington, NZ

16 January 2018

Dear Ms. Reid,

Thank you for the conversation on the 10 January. Please can we arrange a meeting with you in the next few weeks, the 25, 30 or 31st January would be good for me?

The reasons for this meeting are to do with the draft approval of A1138 Provitamin A Rice GR2E line that is now due for Ministers sign off.

We would like to ask that the forum members call for FSANZ to review their decision to approve the Provitamin rice by calling for comprehensive safety data including feeding studies based on the concerning absence of data on long term safety of this rice.

GE Free NZ is an organization membership represents a wide range of the community. All who are consumers, so the safety of the food they eat is highly important.

The safety of the food we eat is of paramount importance and often the main concern for consumers. This application raises many concerns regarding the safety of A1138 Provitamin Rice.

I have had a long conversation with Mary Jordan from FSANZ, written to the CEO Mark Booth. In spite of asking for the studies on safety to eat A1138 appears that there is a total absence of supporting data on the safety of the rice. This has led us to believe that the Codex Alimentarius on Foods derived from Modern Biotechnology[1] has not been followed by FSANZ.

As this food is only going to be approved of the basis on it contaminating the rice supplies means, and there are real dangers from the unknown risks that will not be able to be traced. This does not uphold the duty of care that the FSANZ regulators have to the public.

The Principles of Risk assessment outlined by Codex FSANZ basis for approval outline the sources that should be relied on. It appears that the only data relied upon is supplied by the Applicant and only refers to unpublished studies. Further we have been told that the "applicant did not provide any data on the safety for either animal or human consumption". So there is no data to show if heightened allergies, anaphylaxis, immune system reactions, organ damage will occur. So FSANZ or consumers do not know how mammals will react to eating this rice.

Unintended Effects of GR2E – Regarding the questions around GR2E as stated in the FSANZ report. We note that because FSANZ had previously evaluated as safe the PMI construct in the MIR604 maize the applicant did not conduct a safety studies. The applicant stated

[1] Codex Alimentarius – Foods Derived from modern biotechnology https://www.bibliotecapleyades.net/archivos_pdf/foods-derived-modern-biotechnology.pdf

> "Based on its presence in a wide range of foods derived from genetically engineered maize lines, and on the extensive history of prior regulatory reviews, additional characterization of the PMI protein was unnecessary" (Executive summary, p.4).

However this is fraudulent, as the PMI protein expressed in the GR2E are different to the ones in the MIR604 maize, and should be tested for the changes, as stated below –

> *As a consequence of the genetic modification resulting in event MIR604, two nucleotide sequence changes occurred within the pmi gene resulting in two amino acid changes; a valine to alanine substitution at position 61 and a glutamine to histidine substitution at position 210 (FSANZ 2006). Because of these changes, the amino acid sequence of the PMI protein in GR2E rice was not identical to the corresponding sequence of the PMI protein expressed in MIR604 maize*.

As Codex outlines unintended effects are either "predicted" or "unexpected". As the changes were unexpected there is no data or information to show any unlikely effects. As this is a novel food there is no evidence of safe consumption. The absence of evidence cannot be proof of safety.

There are significant susceptibilities to certain illnesses when there are protein substitutions as between the maize and GR2E[2]. These protein changes are material and should be tested for not disregarded.

It is also concerning that it was the applicant who drove what should be evaluated not the expert regulator FSANZ. This gives rise by the applicant to the provision of selective evidence and biasing the evaluators favourably toward a positive decision by deciding how FSANZ the Regulator should assess the safety of this application. This leads to a serious error of judgment, a conflict of interest, as the most vital data regarding safety is missing. This leaves the applicant to decide what to provide and manipulating the safety of product by the omission of vital relevant data.

The applicant for A1138 states clearly that the CRTI sequence from the toxin database is 35% similarity to three highly toxic snake venoms.

> "The three sequence alignments (Figure 23) were similar to the N-terminal regions of L-amino acid oxidase (LAAO) enzymes from three species of venomous snakes: *Bungarus multicinctus* (many-banded krait, also known as the Taiwanese krait or the Chinese krait), *B. fasciatus* (banded krait), and *Daboia russelii* (Russell's viper)
>
> In snake venoms, LAAOs are found in high concentrations that vary according to each species of snake, which may contribute to the toxicity of ophidian envenomation. Snake venom LAAOs are non-toxic via the oral route of exposure. LAAOs exhibit catalytic specificity for long chain hydrophobic and aromatic amino acids and are active in a wide range of pHs and temperatures. Their structures, molecular masses, and isoelectric points are quite varied. They are able to induce changes in platelet function, which cause local effects on plasma clotting disorders among other things. LAAOs are capable of inducing apoptosis in various cell lines and show antimicrobial and anti-parasitic activity. The existence of LAAOs may be a means of protection against natural agents, parasites,

[2] Inherited prion disease with an alanine to valine mutation at codon 117 in the prion protein gene https://academic.oup.com/brain/article/122/10/1823/343728

and bacteria. For a recent review of LAAOs, see Izidoro et al. (2014)" (International Rice Research Institute 2016, p.57)[3].

FSANZ final assessment says: -

a. Snake venom LAAOs are not toxic via the oral exposure route
b. LAAOs are widely distributed in many species that are not considered to be sources of toxins.

People in New Zealand do not commonly ingest snake venom and therefore find the statement opinion rather than fact and FSANZ supposition of safety is concerning. Just because something is not considered as sources for toxicity, FSANZ is a regulatory body reliant on scientific proof, it is important that any conclusion is based on rigorous science.

Studies have shown that there are unexpected immunological changes and anti body response that could lead to organ damage, in rats fed GM rice[4]. (Yan Q 2017) Though these changes and not deemed toxic the changes could be life threatening.

We have concerns that the in-vitro digestive tests do not adequately reflect the variation of susceptibilities people have regarding the medications they are on, the age they are or the illness they have. As rice is a valuable baby and elderly food and is many processed products and well as a staple food for many people the engineering of this food has cause for concern to our members.

There are no diagnostic tests that can be carried out if a person or health professional has cause for a health concern from this rice.

There is evidence that some of the DNA sources in GR2E come from disease causing bacteria. Namely the *Pantoea ananatis* (Erwinia uredovora) causes rust and grain deformities and infects woody plants[5]. *Erwinia* species cause plant diseases which include blights, cankers, die back, leaf spots, wilts, discoloration of plant tissues, and sot rots variously described as stalk rot, crown rot, stem rot, or fruit collapse. Our native trees are already threatened by new diseases, fire blight is a comercial threat to our aple industry. Any GMO's carrying pathogenic DNA giving the the possibility of a selective advantage to a disease organism should be considered a biosecurity threat.

The *Pantoea ananatis* (Erwinia uredovora) have a modes of action that induce the expression of efflux pump genes in response to plant-derived antimicrobials, therebye making multi resistance properties to antibiotics[6].

As people in New Zealand do not commonly ingest snake venom there is no evidence that the

---

[3] www.foodstandards.gov.au/code/applications/Documents/A1138%20Application_Redacted.pdf

[4] Yang, Q., He, X., Wu, H., Zhang, C., Zou, S., & Lang, T. et al. (2017). Subchronic feeding study of high-free-lysine transgenic rice in Sprague-Dawley rats. *Food And Chemical Toxicology*, *105*, 214-222. http://dx.doi.org/10.1016/j.fct.2017.04.023

[5] Yan H., Yu S.H., Xie G.L., Fang W., Su T., and Li B. (2010) Grain Discoloration of Rice Caused by *Pantoea ananatis* (synonym *Erwinia uredovora*) in ChinaJ. Plant Disease. 94:4;482. https://apsjournals.apsnet.org/doi/abs/10.1094/PDIS-94-4-0482B

[6] *Pantoea ananatis* (Erwinia uredovora) Multidrug Efflux Pumps in the Genus *Erwinia*: Physiology and Regulation of Efflux Pump Gene Expression (2010) https://www.sciencedirect.com/science/article/pii/S1877117316300278

approval is safe. Just because something is not considered as sources for toxicity, FSANZ is a regulatory body reliant on scientific proof, it is important that any conclusion is based on rigorous science.

We were told that FSANZ has no data provided by the applicant nor has there been any published peer reviewed research to back up the safety conclusions.

This application is being approved in the case of contamination from GR2E to the rice supply. There is no advantage to the consumer, but there could be unknown risks from the adventitious contamination form this GR2E rice. And at what levels is this rice considered adventitious before it becomes a considerable part of the contamination event? Our food supply has a large number of foods that supply the daily needs for our community.
(https://www.healthaliciousness.com/articles/natural-food-sources-of-beta-carotene.php)

Nutrition Risk Assessment Report – Application A1138

FOOD	COOKED/RAW	COUNTRY	β-carotene concentration (µg/100g)
Carrot	Raw		4,965
Standard white rice	Raw	Australia	0
	Boiled	Australia	0
		New Zealand	0
GR2E	Raw		380

p.11 FSANZ

In Summary:

FSANZ approval A1138 does not meet with the Codex Allimentarius for food produced by modern Technology.

We ask the Minister and the Forum Members to question the robustness of this approval and ask that FSANZ require more information and research, to ensure the safety to the public and the animals that will be eating it.

We ask the Minister to appeal approval A1138 and ask FSANZ to write to the applicant asking for comprehensive peer reviewed published data on feeding studies showing long term safety of consumption.

Once these have been provided and if they fulfill the safety guidelines then

To label any foods containing GR2E

As the food is only being approved for adventitious contamination any levels over 0.9% must be withdrawn from sale immediately.

I have attached correspondence the reply from the FSANZ CEO Mark Booth.

Yours sincerely,

Claire Bleakley
President GE Free NZ
06 3089842/ 027 3486731