GE Free New Zealand

In Food And Environment Inc.

PO Box 13402, Wellington, NZ

1 February 2018

Re: Draft approval of A1138 Pro vitamin A rice GR2E line.

Dear Hon. Minister O'Connor,

1. GE Free NZ is calling on the Minister for Food Safety, Hon Damien O'Connor, as a member of the Ministerial Council and his Food Regulation Standing Committee (FRSC) members, Ministry for Primary Industries (MPI), to instruct Food Standards Australia New Zealand (FSANZ) to review the draft of their GM rice approval (A1138), under sec: 21 of the FSANZ Act.

2. We have had a meeting with Jenny Reid of MPI, who told us that she would advise you of our meeting but would not pass on our concerns and that we should do that instead, as our views were opposed to each other.

3. The FSANZ approval raises many concerns regarding the safety of application A1138 Provitamin Rice. Due to unknown circumstances we did not receive notification of this application in August, otherwise we would have raised these concerns. It appears that normally there would have been a large number of submissions if we had known. As we can see by the amount of submissions FSANZ received it appears that a section of the concerned population was not informed of the application as normally they would have received at least 1000 submissions on a GE food application of as much concern as this.

4. It is also of concern that if submitters do not make submissions. FSANZ did not consider any science except that provided by the applicant. This can be seen by the final approval decision, made on the best available data, all unpublished and provided by the applicant.

5. As this GE rice is only going to be approved of the basis of it contaminating the rice supplies means 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 Minister and Forum members have to the public. Especially as there is enough data out there to raise concerns as to its safety.

6. There are three new proteins expressed in the Rice event GR2E and these proteins have changes that are potentially toxic, allergenic or have sub chronic histological effects.

7. **The unintended effects of GR2E regarding the PMI protein**. The applicant detailed alterations to the proteins expressed and stated that these changes had not been assessed by FSANZ. FSANZ acknowledged in their Supporting Document 1 that the PMI protein was different to the ones assessed in the maize (p.23 footnote 8). The protein changes caused by the PMI in rice might be similar to the MIR162, line 3272 and line 5307 but the MIR162 line did not produce alterations to the proteins in the maize in the way the PMI protein in the rice has done. Therefore these new proteins need to be tested for as stated in the Codex guidelines.

8. **Regarding, similarity of LAAO to snake venom**, the LAAO enzyme has a myriad of biological activities including apoptosis-induction, edema-induction, hemorrhaging, and inhibition or induction of platelet aggregation. As the control rice does not contain LAAO it is not acceptable to bring in a wild rice that may not be eaten by the population. This misleads and dismisses the serious nature of the presence of the toxic similarities to snake venom of these LAAOs. There needs to be feeding tests undertaken on the GR2E rice on consumption.

9. Dr. Pusztai an expert on plant lectins and author of over 700 research papers and books. His research on GM potatoes, comparing the isolated snowdrop lectin (GNA) as a powder with the transgenic GNA expressing potatoes, found there were significant differences in the rat intestines[1]. So regarding the microbial expressed CRTI that was isolated and fed to rats there is a strong possibility that the transgenic carotene CRTI expressed in GR2E would have similar differences to Puztai's potatoes. Further, Poulsen *et al* (2007) conducted GM rice studies over 90 days and found significant changes, affecting the liver and kidneys, with immune system depression; the study could not verify the safety of the rice[2]. As there are no feeding studies required or provided, ingesting this rice could be a health hazard for all consumers.

10. **There is an absence of feeding studies and published data on A1138**, and considering this rice has significantly altered, potentially toxic and allergenic properties. Especially as babies first food is often rice-based, as rice allergy is relatively uncommon[3] it is a safe baby food. It is essential that this rice does not increase the hazard levels like anaphylaxis, allergies and gut disorders to our children, the elderly or those who use rice as a staple food and are high consumers.

11. There is no safety data asked for or provided, to show if this rice is safe to eat yet there are significant nutritional changes that have occurred as well as the levels

---

[1] http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(98)05860-7.pdf

[2] Poulsen M, Kroghsbo S, Schroder M, et al. A 90-day safety study in Wistar rats fed genetically modified rice expressing snowdrop lectin Galanthus nivalis (GNA). Food Chem Toxicol. Mar 2007; 45(3): 350-363. http://www.sciencedirect.com/science/article/pii/S0278691506002559?via%3Dihub

[3] http://www.swallergy.com/rice-allergy.html

of metabolites produced. These concern come from Bollinedi H, et al (2017)[4] study showing significant changes to the grain and plant. They found

> *"…analysis of the transgenes (ZmPsy and CrtI) driven by endosperm-specific promoter revealed the leaky expression of the transgene in the vegetative tissues. We propose that the disruption of OsAux1 disturbed the fine balance of plant growth regulators viz., auxins, gibberellic acid and abscisic acid, leading to the abnormalities in the growth and development of the lines homozygous for the transgene." (Bollinedi H, 2017)*

12. These changes have not been tested for safety to eat. The EU guidelines for any transgenic food that has significant biological/nutritional/toxic changes compared to its conventional comparator require a 90-day oral feeding test with the whole genetically modified as set out in the Commission Implementing Regulation (EU) No 503/2013 1.4.4 -1.4.4.2 (p.32-33). [5]
13. The levels of vitamin A are greatly over-estimated, the amount of beta carotene in R2E, given that it was based on the 7.31ug/g from a one-off trial site, frozen dry rice and tested in low light.

14. The average from the trial plots was 3.57 ug/g, not the 7.31 ug/g used in the 'maximum consumption' estimate. Furthermore, we now know that degradation of the beta-carotene in Golden Rice follows a half-life of 25 days, with 87% of the 3.57 ug/g being lost after 75 days, before plateauing[6]. NB: The initial figure of 30 ug/g shows this was the pre-back-crossed grain, line R probably, not GR2E. There was only no degradation if stored in oxygen deprived low light conditions.

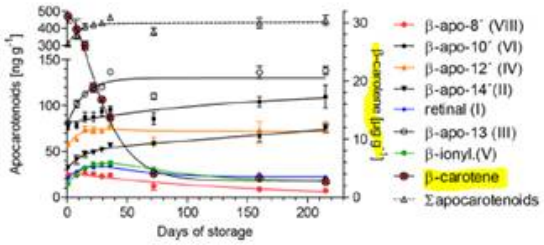

Figure 4. Time course of *β*-carotene-derived apocarotenoid formation in an experimental (cv. Kaybonnet) GR line. Sampling and analysis were performed as outlined in the Methods section. *β*-Carotene decays during early phases with a half-life of 25 days, followed by a plateau. Note that *β*-carotene is given in $\mu g\ g^{-1}$ (right axis), while derived apocarotenoids are given in $ng\ g^{-1}$ (left axis). Roman numerals of cleavage products refer to Figure 1. Data represent the mean ± SEM of three technical replicates.

(Schaub P. 2017, p.6592)

15. At average of 3.57ug/g – eaten immediately after harvest, – a consumer needs to

[4] Bollinedi H, S. GK, Prabhu KV, Singh NK, Mishra S, Khurana JP, et al. (2017) Molecular and Functional Characterization of GR2-R1 Event Based Backcross Derived Lines of Golden Rice in the Genetic Background of a Mega Rice Variety Swarna. PLoS ONE 12(1): e0169600. doi:10.1371/journal.pone.0169600

[5] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0503&from=EN

[6] Schaub, P., Wüst, F., Koschmieder, J., Yu, Q., Virk, P., Tohme, J., & Beyer, P. (2017). Nonenzymatic β-Carotene Degradation in Provitamin A-Biofortified Crop Plants. Journal Of Agricultural And Food Chemistry, 65(31), 6588-6598. http://dx.doi.org/10.1021/acs.jafc.7b01693

eat 3.9kg of cooked rice, When processed, imported and shelved, which could take up to 75 days, the levels of beta carotene are so low that 31kgs of cooked rice will be required, compared to what one medium carrot provides.

Golden Rice (max possible)	7.31	ug/g	dry rice		
Child rice consumption	12.5	g/kg			
Adult weight	57.7	kg			
Rice consumption/day	721	g dry	or	1967	g cooked
Max possible b-caro	5272	ug	or	5.272	mg
b-caro concentration in carrot	82.9	ug/g	(IRRI numbers)		
medium carrot (I weighed one)	62	g			
b-caro in medium carrot 62*82.9	5140	ug	or 5.140 mg		
Golden Rice (ave. freezer, no O2,low light)	3.57	ug/g			
b-caro in medium carrot	5140	ug			
dry rice needed for equivalent	1440	g			
cooked rice equivalent	3927	g or 3.9 kg			
Golden Rice (75 days)	0.45	ug/g			
b-caro in medium carrot	5140	ug			
dry rice needed for equivalent	11422	g or 11.4 kg			
cooked rice equivalent	31152	g or 31.2 kg			

16. We would like the FSANZ Forum members at MPI to reflect our concerns and our recommendations to the Minister, Hon Mr. Damien O'Connor, in their report to him.

17. We would ask that the Food Regulation Standing Committee (FRSC) New Zealand members, MPI, and Minister for Food Safety, instruct FSANZ to review the decision to approve the Provitamin rice (A1138) and follow the EU guidelines on genetically modified foods. We ask that FSANZ require the applicant to provide comprehensive safety data including 90-day feeding studies that are peer reviewed and published. When these results are peer reviewed and published we can then proceed to evaluate its safety.

Sincerely,
Claire Bleakley
President GE Free NZ
president@gefree.org.nz
06 3089842 / 027 348 6731

Jon Muller
secretary@gefree.org.nz
Secretary GE Free NZ

Jon Carapiet
Spokesperson GE Free NZ

References:
We have sought expert advice and attach the relevant articles for your consideration

Bollinedi H, S. GK, Prabhu KV, Singh NK, Mishra S, Khurana JP, et al. (2017) Molecular and Functional Characterization of GR2-R1 Event Based Backcross Derived Lines of Golden Rice in the Genetic Background of a Mega Rice Variety Swarna. PLoS ONE 12(1):

Harrison E.H., dela Sena C., Eroglu A., and Fleshman M.K. (2012) The formation, occurrence, and function of b-apocarotenoids: b-carotene metabolites that may modulate nuclear receptor signaling *Am J Clin Nutr*.

Schaub, P., Wüst, F., Koschmieder, J., Yu, Q., Virk, P., Tohme, J., & Beyer, P. (2017). Nonenzymatic β-Carotene Degradation in Provitamin A-Biofortified Crop Plants. Journal Of Agricultural And Food Chemistry, 65(31), 6588-6598.

Testbiotech comment on risk assessment of Provitamin A Biofortified Rice Event GR2E submitted to Food Standards Australia New Zealand by IRRI.