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**Attention: Ministerial Forum on Food Regulation (as detailed below, assuming current)**

AUS: The Hon Bridget McKenzie MP, Minister for Rural Health  
AUS: The Hon David Littleproud MP, Minister for Agriculture and Water Resources  
NZ: The Hon Damien O'Connor, Minister for Food Safety  
ACT: Ms Meegan Fitzharris, MLA, Minister for Health  
NSW: Lead Minister: The Hon Niall Blair, MLC, Minister for Primary Industries  
The Hon Brad Hazzard, MP, Minister for Health  
NT: Lead Minister: The Hon Natasha Fyles, MLA, Minister for Health  
QLD: Lead Minister: The Hon Dr Steven Miles, MP,  
Minister for Health and Minister for Ambulance Services  
The Hon Mark Furner, MP, Minister for Agricultural Industry Development  
and Fisheries  
SA: Lead Minister: Hon Peter Malinauskas MLC, Minister for Health  
The Hon Leon Bignell, MP, Minister for Agriculture, Food and Fisheries  
TAS: Lead Minister: The Hon Michael Ferguson, MP, Minister for Health  
VIC: Lead Minister: The Hon Jill Hennessy, MP, Minister for Health  
The Hon Jaala Pulford, MLC, Minister for Agriculture  
WA: Lead Minister: The Hon Roger Cook, MLA, Minister for Health  
ALGA: Mayor David O'Loughlin, President

**This communication provides**

- **Early advice to the Ministerial Forum on Food Regulation of FSANZ's corruption as a Regulator for the Australian and NZ people, and**
- **An urgent request for the Ministerial Forum on Food to initiate a Review of FSANZ's approval for Provitamin A Rice Line GR2E (Application1138)**

Data on 23 synthetically engineered "Bt" insecticides in GM food crops approved by FSANZ were collectively tabled for the first time in a Review in the peer reviewed journal "Biotechnology and Genetically Engineering Reviews" (Latham et al 2017, Latham 2017(commentary)). The Review was conducted by Dr Jonathan Latham, genetic engineer and virologist based in the US, Dr Angelika Hilbeck, multiply published specialist in Bt toxins and senior scientist at the Institute of Integrative Biology of the Swiss Federal Institute of Technology (ETH Zurich) **and myself, independent scholar based in north east Victoria.**

The Review provides the scientific evidence that FSANZ profoundly misrepresented in-crop GM Bt insecticides in a communiqué to the public, against the words in its own documents, on a matter of great health importance to Australians. The FSANZ communiqué was a response to the **published detection of GM Bt insecticides in fetal cord blood** (Aris & Leblanc 2011, Monsanto 2012, Aris 2012a, FSANZ 2012, Aris 2012b). These detections contradicted the FSANZ regulatory assumptions that GM Bt insecticides would be fully digested. This regulatory assumption had been demonstrated to be false in 2010, after Guimaraes et al 2010 found these proteins were stable in realistic stomach acid conditions, and remained immunologically reactive. These insecticides would be free to be taken up by the body. **The Aris and Leblanc 2011 study was so devastating it should have triggered an immediate follow-up.** Any advice FSANZ provided to government on this subject should be investigated.

The Review reported the scientific evidence that the GM Bt insecticides were not safely bound in crystals as in the natural environment, but rather, in solution in the GM plant cells. It reported the scientific evidence that the GM Bt insecticides were processed inside the plant down to active or near active states, where not deliberately engineered to be as such. There was evidence presented that the type of in-crop GM Bt insecticides detected by Aris & Leblanc 2011 were far more toxic, with a broader spectrum, than their counterparts in the natural environment. The review made clear that regulatory assumptions used by FSANZ were corrupt, being inadequate for the protection of public health and safety. It was also found that FSANZ routinely failed to pursue evidence that contradicted these regulatory assumptions. ***FSANZ has failed in its duty to act as a scientific body, it has failed to use the best available scientific evidence in its GM crop assessments, it has failed to do its duty to ensure the protection of public health and safety.***

The Review is recently published, and at this time these findings remain as unfinished business. The findings are presented here to underscore the fact that FSANZ has once again given a corrupt approval for a GM crop, failing in its public health responsibilities to the Australian and New Zealand people, this time for a crop that could have devastating effects on the poorest people in South East Asia, Provitamin A Rice Line GR2E, colloquially known as “Golden Rice”.

### **FSANZ did not test the food of Provitamin A Rice Line GR2E**

FSANZ is obligated under the Codex Alimentarius Principles and Guidelines for the assessment of Genetically Modified Foods to do a comparison of the **GM food** with its non-GM comparator to look for any unintended effects of the Genetic Modification. But beyond a sole comparison for 5 carotenoid values, ***there was no food comparison data provided on the milled rice.***

FSANZ acknowledged in Safety Document 1 (SD1) that **milled rice** is the usual form of rice eaten in Asia. In the same document FSANZ acknowledged that there was a trade concern that GM Rice Line GR2E could enter Australia and New Zealand via exports from countries that supply significant quantities of **milled rice.**

However IRRI only supplied, and FSANZ only cited, the required detailed comparative data of proximates, fatty acids, amino acids, vitamins and minerals on the **grain**, which includes the husks (20-25%) and the bran (10%). Milled rice was reported to be only 65% of the grain, but the majority of vitamins, minerals and fats are in the husks and bran. *A compositional comparison using **grain** would mask significant differences in these elements in the **milled rice**.*

If this was a usual GM crop, with a constitutive promoter that produced the products of the transgenic elements throughout the plant, this might not be so important. But *Provitamin A Rice Line GR2E is not a usual crop*. Rather, the promoter for the beta carotene components of the genetic code was only supposed to be active in the endosperm – *the white rice part of the grain*.

Thus it seems doubly corrupt to add the plant material where the GM promoter was **not even supposed to be active** into the compositional comparison that was supposed to be done on the **food**.

Indeed, the author/s of the FSANZ nutritional safety assessment document (SD2) had certainly expected that FSANZ would be doing a full compositional comparison for the milled rice, writing

“With the exception of provitamin A carotenoids, the compositional parameters measured in **milled samples** of GR2E were similar to, or within the natural variability range of, those components in conventional rice varieties as indicated in the Application and SD1.”  
[emphasis added]

However, checking a second and third time, beyond the provitamin A carotenoid comparisons cited, there was no data provided for the usual compositional comparisons for milled rice (proximates, fatty acids, amino acids, minerals and vitamins other than carotenoids) in the FSANZ Safety Document SD1, nor was there any provided in the IRRI Application, nor the cited studies.

Reinforcing this fact, FSANZ made this conclusive statement in respect of the grain:

“It can therefore be concluded that apart from the elevated levels of carotenoids, the **grain** in GR2E is compositionally equivalent to **grain** from conventional rice varieties.”  
[emphasis added]

but there was no such conclusion in respect of the actual **food that is coming into Australia, as milled rice**.

***FSANZ failed to comply with signed obligations, consequently failing in its duties to protect health and safety. For this reason alone the Ministerial Forum on Food Regulation should call for an immediate review.***

**FSANZ did not acknowledge or was unaware that B-carotene breaks down very quickly in this Provitamin A Rice Line GR2E, leading to high concentrations of apo-carotenoids, some of which are associated with lung cancer, and other byproducts**

In 2017, while FSANZ was assessing the crop, a critical study came out from the heart of the Golden Rice project. [Schaub et al 2017] FSANZ did not cite it, yet its data is pivotal for the safety assessment of this Provitamin A Rice Line GR2E. ***FSANZ did not use the best available science in its assessment, and this should trigger a Ministerial Review.***

The paper, authored by Patrick Schaub who has published before on Golden Rice, provided the long awaited but expected information **that the beta-carotene in this rice breaks down very quickly, with a half life of 25 days.** What this means is that after 25 days half of the beta carotene is no longer measurable, and after 75 days only 12.5% would remain. The rice was stored at ambient temperature, in the dark, and the supplementary data reported numbers for this line GR2E in a Kaybonnet germplasm. ***FSANZ did not mention nor allow for the rapid degradation of beta-carotene in it's safety/nutritional safety assessments, a feature expected by all familiar with the field, and this should trigger a Ministerial Review.***

FSANZ should have been very interested in this data because of the obvious question... **What happens to the beta carotene when it breaks down?** If FSANZ was a real food regulator for the people of Australia and New Zealand, and not just a gateway for the GM crop developers, FSANZ would be asking if there are other novel products in the GM crop that should be assessed for safety. In fact Schaub et al 2017 provided a lot of detail about the breakdown products of beta carotene in the rice. There were very high levels of the eccentric cleavage products of beta-carotene, "apo-carotenoids" in the Golden Rice, even at harvest. Thus it seems the beta carotene was breaking down even as it was being produced in the grain. ***FSANZ failed to consider the possibility of beta-carotene breakdown products in the rice, changing the nutritional qualities of the rice. This represents a scientific and regulatory failure, with potential to affect public health and safety, and this should trigger a Ministerial Review.***

Schaub et al 2017 analysed the beta carotene in Golden Rice, and found that it wasn't stored in crystallised form, as in carrots and orange fleshed sweet potatoes. Rather it was stored in lipids in the milled rice. As the rice aged after harvest the beta-carotene rapidly degraded and the apo-carotenoids continued to rise, until stabilizing. Schaub et al 2017 reported a number of studies making adverse findings for apo-carotenoids, particularly beta-apo-13-carotenone, the apo-carotenoid with the highest concentration in the GR2E rice. These apo-carotenoids were at far higher concentration than were found in foods like carrots and orange fleshed sweet potato, and the Golden Rice apo-carotenoid profile was very different. **This should have triggered an investigation by FSANZ. This represents a scientific and regulatory failure, with potential to affect public health and safety, and should trigger a Ministerial Review.**

The apo-carotenoids weren't the only novel products developing as the rice aged. Schaub et al 2017 further concluded that the beta-carotene was also degrading into highly oxidized polymers, and that a large amount of geronic acid was being produced.

If the Provitamin A Rice Line GR2E were placed in a more accommodating germplasm, grown in the field, and harvested, dried and stored according to local practices, how high would the concentrations of apocarotenoids reach?

**The presence of large quantities of novel products in the rice grain, obviously not present in the non-GM comparator, should have compelled FSANZ to collect full compositional data on the milled rice, to look for further unintended affects. *FSANZ failed in its primary obligation to protect public health and safety, and this should trigger a Ministerial Review.***

**The beta-carotene food value of this Provitamin A Rice Line GR2E germplasm is very weak**

IRRI said the average beta-carotene from the GR2E 2015 & 2016 trials was 3.57 ug/g dry weight of milled rice, when frozen immediately after harvest and measured under low light. [IRRI 2016]

With the degradation half-life reported by Schaub et al 2017 the concentration of beta-carotene after 25 days would be 1.79 ug/g, after 50 days would be 0.89 ug/g and after 75 days 0.45 ug/g dry weight.

In contrast, the US National Nutrient Database has the concentration of beta-carotene in carrots as 82.85 ug/g. [USDA 8/2/18] I weighed a medium carrot – it was 62 g. This medium carrot would thus have  $62 * 82.85 = 5134$  ug of beta-carotene.

To consume the same amount of beta-carotene as in a carrot, one would need to eat  $(5134/3.57)*1.122 = 1.6$  kg of raw rice, roughly 4 kg of cooked rice, adjusting for 12.2% to bring the cited 3.57 ug/g dry weight concentration to a fresh weight value, and then allowing for 150% water absorption during cooking.

After 75 days one would need to eat  $(5134/0.45)*1.122 = 13$ kg of raw rice, or roughly 32kg of cooked rice, using the same assumptions.

It is argued that the beta-carotene in “Golden Rice” is more bioavailable than in a cooked carrot, and that we should make some adjustments. However we haven't actually seen the bioavailability for the rice line in this germplasm, especially at these very low concentration values, and after time for degradation, with high concentrations of eccentric breakdown products in the rice. If we generously allowed for the bioavailability to be twice as high as well-chewed cooked carrots, that's still a lot of rice to eat.

The “3.57 ug/g” number was derived from rice that had been frozen at -20°C immediately after harvest. It’s to be wondered what the beta-carotene concentrations would be after being left out in full sun to dry for three days, as is a usual practice for farmers in South East Asia growing their own food. Beta-carotene breaks down in the presence of oxygen, light and heat.

Schaub et al 2017 did report that **the beta-carotene didn’t degrade if it was held in an environment devoid of oxygen** – presumably packaged in a vacuum and/or pumped with nitrogen. That however would make Golden Rice only valuable as a pharmaceutical product, certainly of no use to farmers growing their own food for storage.

This Provitamin A Rice Line GR2E clearly doesn’t have a practical value for the people it is supposed to benefit. Further, it could be harmful. Yet it could have a mild value as an extraction base for a glass-house grown single vitamin pharmaceutical, if the beta-carotenes could be extracted without the extremely high concentration of apocarotenoids, or after sufficient science on the apocarotenoids has determined their full effects. *Has this GM crop actually been assessed through the correct regulatory body? The Ministerial Forum should review whether this Provitamin A Rice Line should have been assessed under the TGA Standards.*

## Summary

If the Ministerial Forum seeks advice on any of the matters raised above, I would like to be given the opportunity to provide comment on such advice received.

**Yours faithfully**

**Madeleine Love**

As addressed above

## Attachments

- References
- Attached Studies:

Latham et al 2017; Latham J. R., Love M. & Hilbeck A. (2017) [The distinct properties of natural and GM cry insecticidal proteins](#). *Biotechnology and Genetic Engineering Reviews* 33:1, 62-96, DOI: 10.1080/02648725.2017.1357295. Attached

Latham 2017; Have Monsanto and the Biotech Industry Turned Natural Bt Pesticides into GMO “Super toxins”?  
<https://www.independentsciencenews.org/environment/have-monsanto-and-the-biotech-industry-turned-natural-bt-pesticides-into-gmo-super-toxins/> Attached.

Schaub et al 2017; Schaub P, Wust F, Julian K, Yu Q, Virk P, Tohme J, Beyer P (2017); Nonenzymatic  $\beta$ -Carotene Degradation in Provitamin A-Biofortified Crop Plants. *J. Agric. Food Chem.* 2017, 65, 6588–6598 DOI: 10.1021/acs.jafc.7b01693 + supplementary material – Attached.

## References

Aris and Leblanc 2011; Aris A, Leblanc S.; Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada; *Reprod Toxicol.* 2011 May;31(4):528-33. doi: 10.1016/j.reprotox.2011.02.004. Epub 2011 Feb 18.

Aris 2012a; Aris A; Response to comments from Monsanto scientists on our study showing detection of glyphosate and Cry1Ab in blood of women with and without pregnancy; *Reproductive Toxicology* 33 (2012) 122– 123;

Aris 2012b; Aris A; Response to “Food Standards Australia New Zealand’s” Comments; *Reproductive Toxicology* 33 (2012) 403– 404;

FSANZ 2011; FSANZ response to study linking Cry1Ab protein in blood to GM foods

<https://www.foodstandards.gov.au/consumer/gmfood/cry1ab/Pages/default.aspx>

FSANZ 2012; Mueller U, Gorst J.; Comment on "Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada" by A. Aris and S. Leblanc [*Reprod. Toxicol.* 31 (2011) 528-533]. *Reprod Toxicol.* 2012 Jun;33(3):401-2; author reply 403-4. doi: 10.1016/j.reprotox.2012.01.012. Epub 2012 Feb 21.

Guimaraes et al 2010; Guimaraes V, Drumare MF, Lereclus D, Gohar M, Lamourette P, Nevers MC, Vaisanen-Tunkelrott ML, Bernard H, Guillon B, Créminon C, Wal JM, Adel-Patient K; In vitro digestion of Cry1Ab proteins and analysis of the impact on their immunoreactivity; *J Agric Food Chem.* 2010 Mar 10;58(5):3222-31. doi: 10.1021/jf903189j.

IRRI 2016; International Rice Research Institute; 2016; Provitamin A Biofortified Rice Event GR2E; Application for Amendment to Standard 1.5.2 — Food Produced Using Gene Technology  
[https://www.foodstandards.gov.au/code/applications/Documents/A1138%20Application\\_Redacted.pdf](https://www.foodstandards.gov.au/code/applications/Documents/A1138%20Application_Redacted.pdf)

Latham et al 2017; Latham J. R., Love M. & Hilbeck A. (2017) [The distinct properties of natural and GM cry insecticidal proteins.](#) *Biotechnology and Genetic Engineering Reviews* 33:1, 62-96, DOI: 10.1080/02648725.2017.1357295. Attached

Latham 2017; Have Monsanto and the Biotech Industry Turned Natural Bt Pesticides into GMO “Super toxins”?

<https://www.independentsciencenews.org/environment/have-monsanto-and-the-biotech-industry-turned-natural-bt-pesticides-into-gmo-super-toxins/> Attached.

Monsanto 2012; Goldstein DA, Dubelman S, Grothaus D, Hammond BG.; Comment: Aris and Leblanc "Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada"; *Reprod Toxicol.* 2012 Jan;33(1):120-1; author reply 122-3. doi: 10.1016/j.reprotox.2011.10.007. Epub 2011 Oct 30.

Schaub et al 2017; Schaub P, Wust F, Julian K, Yu Q, Virk P, Tohme J, Beyer P (2017); Nonenzymatic  $\beta$ -Carotene Degradation in Provitamin A-Biofortified Crop Plants. J. Agric. Food Chem. 2017, 65, 6588–6598 DOI: 10.1021/acs.jafc.7b01693 + supplementary material – Attached.

Samia and Swamy 2016; Samia, M. and Swamy, M. (2016). Concentrations of beta-carotene and other carotenoids in grain samples from rice event IR-ØØGR2E-5. Technical report, IR2016-07004 (unpublished) International Rice Research Institute, Los Banos, Laguna, Philippines via GR2E-FFP-submitted-study-reports-PH.pdf

USDA 8/2/18; United States Department of Agriculture, Agricultural Research Service, National Nutrient Database for Standard Reference Release 28  
<https://ndb.nal.usda.gov/ndb/foods/show/2901?n1=%7BQv%3D1%7D&fgcd=&man=&lfacet=&count=&max=&sort=&qlookup=&offset=&format=Full&new=&measureby=&Qv=1&ds=Standard+Reference&qt=&qp=&qa=&qn=&q=&ing=>