



GE Free New Zealand

In Food And Environment Inc.

PO Box 13402, Wellington, NZ

20/12/2017

Dear FSANZ,

We were totally unaware that the Provitamin A Rice GR2E line was up for submissions. Due to this our concerns could not be made. Please may we have this information under the Freedom of Information act (FOIA).

Please could you provide us with data on the Safety of the introduced proteins?

1. All data provided that you to assessed regarding the potential toxicity and allergenicity of the proteins expressed in GR2E.
2. Please could you provide the ingestion / feeding tests that showed safety for humans?

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
- c. A bioinformatics search using the endogenous rice phytoene desaturase (see discussion in Section 3.4.1.1 and Figure 6) also returned matches to LAAOs that aligned with sequences in the N-terminal region.
- d. The N-terminal region showing sequence similarity is a common feature of other flavoenzymes such as oxidoreductases, protoporphyrinogen oxidases and other phytoene desaturases which, in themselves, are not toxins.
- e. The FAD-binding domain is only one of the three domains required for a functional catalytic site of an LAAO (Mitra and Bhattacharyya 2013).

People in New Zealand do not commonly ingest snake venom and therefore find this supposition concerning. Just because something is not considered as sources for toxicity, FSANZ is a regulatory body reliant on scientific proof, it is important that you provide data to back up the allegation.

Please could you provide?

3. the comprehensive data and that shows ingestion of snake venom is non-toxic?
4. the published evidence that the PMI protein will not cause allergic or anaphylactic problems?
5. the published evidence that the CTRI protein will not cause allergic or

- anaphylactic problems?
- 6.
 7. All unpublished studies on the amino acid sequences that were provided for your assessment?

The bacterium *Pantoea ananatis* is disruptive to certain protein production pathways

Please could you provide

8. All data relating to *Pantoea ananatis* and its safety?

Were any published studies provided for your Assessment? If they did not go through a peer review process we consider this as industry verification and open to conflicts of interest regarding regulatory assessments.

9. Please could you provide all correspondance and emails between the applicant, submitters and FSANZ relating to A1138

We would be happy to have this information on a CD to save on printing.

Please could you advise us of the date that the Ministers have to appeal this decision?

Please may we have this information under the Freedom of Information act (FOIA).

Happy Christmas

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