

7 July 2017

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To: Food Standards Australia and New Zealand (FSANZ)

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Subject: Application A 1139 Food derived from Potato Lines E56, F10, J3, W8, X17 & Y9.

Please note: **In any public hearing of this matter I wish to be notified and granted the opportunity to present my evidence.**

I strongly oppose the application and ask FSANZ to decline approval of A1139 - Food derived from Potato Lines E56, F10, J3, W8, X17 & Y9.

As industry and regulatory authorities have sought to push GMO foods into the New Zealand food chain I have supported consumer choice to avoid GM food, and proper independent testing and monitoring of novel foods.

The application fails on these and other counts and I demand that the application not be approved.

There is no comprehensive data showing evidence of unintended effects of the transgenic potato lines. It makes it mandatory for FSANZ to decline the approval.

Does FSANZ indemnify me and any one else who suffers as a result of the granting of this application? How much insurance do you carry?

It is necessary for FSANZ to require whole genome sequencing to identify off-target mutations and also essential to ascertain the effects of unintended changes on global patterns of gene function.

FSANZ must require sequencing using molecular profiling analyses or “omics”-

- transcriptomics — gene expression profiling,

- proteomics — protein composition profiling,
- metabolomics — profiling of metabolites,
- miR-omics – microRNA profiling

The best evidence available for effective safety assessment also requires long-term toxicity studies in established animal model systems. In the absence of these data to inform FSANZ, there can be no legal approval of A1139

The APHIS documentation shows that these GE potato lines offer no nutritional advantage, as there are non-GE potato varieties that are naturally low in the desired profiles. This demonstrates that there is no need for approval of the GE potatoes.

Instead of approving this application, FSANZ could instead recommend non-GE potato varieties that have naturally-occurring low levels of compounds responsible for acrylamide production. They could also educate food businesses on storing and cooking procedures that minimize acrylamide production.

The FSANZ assessment is compromised with respect to rigorous scientific procedure. These GE potato lines cannot be approved for the human or animal consumption, without the provision of comprehensive information regarding compositional differences to their non-GE counterparts. Compositional analyses are very limited in that they can only assay for known compounds. Any novel compounds would not be detected in such analyses.

FSANZ must provide evidence of safety, when eaten, in the lines that have significant variations in nutrients, or more importantly anti-nutrients. Anti nutrients such as glycoalkaloids can be highly toxic for consumers.

The afore-mentioned studies have not been carried out and in their absence, there should be no legal approval of the A1139 application.

In past studies, (2002) GM potatoes affected some of the male secondary sex organs in rats, similar studies also ought to be routinely performed with female small animals and extended to studies into the effects of GM foodstuffs on reproductive performance. Furthermore, as some of the potential effects of the consumption of GM foods is likely to be manifested in the long-term, these reproductive studies should be coupled to nutritional/ toxicological tests in which off springs of successive generations brought up on

GM food should be tested in comparison with those reared on comparable non-GM diets. I cannot find evidence that this has been done.

The systems and processes used to assess safety, and to approve and monitor labelling compliance of this (and previous similar applications) are failing or not fit for purpose.

Latest scientific understanding shows they lack the rigor and comprehensive data needed to make a genuine and credible safety assessment. To continue with an approval in knowledge of this would be unethical.

The lack of labeling requirements at likely sales channels for these GMO products, is a serious breach of choice for consumers.

The lack of mandatory labelling for food sold by restaurants is likely to lead to deception and unconsensual consumption of GE potatoes by consumers. The lack of enforcement and monitoring of compliance in GM food labelling by FSANZ is remiss and approval of the application would add to this, and be against the public interest.

In the absence of long term feeding studies and 'omic' analysis that have been identified as necessary and best practice by independent experts, to understand the changes and potential implications for food safety, FSANZ is erring by making a decision based on assumptions and inadequate data.

In the absence of full data it is not possible for FSANZ to support the claim made that:

“FSANZ know that there are unexpected off-target effects resulting from genetic engineering, including from much hyped 'accurate and precise' recent advances using CRISPR”

The complexity of unexpected risk is made clear by recent study in mice, which found that the large numbers of off-target mutations caused by CRISPR in mice could not be predicted by the usual computer algorithms.

Schaefer KA, Wu W-H, Colgan DF, Tsang SH, Bassuk AG, Mahajan VB. Unexpected mutations after CRISPR-Cas9 editing in vivo. Nat Methods. 2017;14(6):547-548.

doi:10.1038/nmeth.4293.

<https://www.nature.com/nmeth/journal/v14/n6/full/nmeth.4293.html>

FSANZ is in error by relying on the inadequate data and claims of the applicant. Independent scientific comment highlights that the data available for assessment by FSANZ is inadequate for any approval to be legitimate or to meet FSANZ's legislated responsibility.

It is necessary for FSANZ to require whole genome sequencing to identify off-target mutations and also essential to ascertain the effects of unintended changes on global patterns of gene function.

Also required is sequencing using other molecular profiling analyses : “omics”- transcriptomics — gene expression profiling, proteomics — protein composition profiling, metabolomics — profiling of metabolites, and miR-omics – microRNA profiling.

It is necessary for FSANZ to require long-term toxicity studies in established animal model systems. The compositional alterations in these and other food products produced with Genetic Engineering will not be fully revealed by the molecular profiling methods due to the current inherent limitations of these techniques.

In the absence of these data to inform FSANZ, there can be no legitimate approval of the application.

There is also a significant biosecurity risk and potential threat to local growers and exporters arising from these GMO potatoes.

Contamination of conventional food by GMO elements has led to loss of exports and economic harm in the past and continues to be an economic threat that FSANZ fail to properly address.

It is illegal to import viable genetically modified plants into New Zealand. Even parts of non-whole tubers can be viable and thus endanger the New Zealand biosecurity status. It would be illegal to approve these potatoes into the country.

I demand FSANZ to recognise and respond to the public concern and to support the public interest by not approving the application.

There is no consumer benefit or nutritional benefit from the GE potatoes listed in this application to outweigh known and unknown risks, compared to existing potato varieties that industry can use.

The possible lack of labelling requirements at sales channels, and the lack of labelling at

restaurants for these GMO products, would result in a serious breach of choice for consumers.

Please do not approve these GE potatoes.

Good now lets move to how we are going to ethically feed our growing populations.

Kind regards from greg