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From: [REDACTED]
Sent: Friday, 23 June 2017 2:49 PM
To: submissions
Subject: Submission on GE canola due 23/6/17

Categories: [REDACTED]

[REDACTED]

[REDACTED]

Dear FSANZ staff

I fully support the submission of the Auckland GE-Free coalition as written below, and would like this to be my individual submission as well.

Kind regards
[REDACTED]

BSc (Hons), PhD (genetic engineering)

Submission on Food derived from Herbicide-tolerant Canola Line MS11: to seek approval for food derived from herbicide-tolerant, male-sterile canola line MS11, genetically modified to provide tolerance to the herbicide glufosinate-ammonium.

Submission by The Auckland GE-free Coalition (AGEFC)

Contact:
[REDACTED]
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We submit that FSANZ should take Option 2 and reject the application.

The AGEFC is a network of concerned individuals and community groups representing the public concerns around the risks and regulation of GMOs since the early 2000's as industry and regulatory authorities have sought to push GMO foods into the New Zealand food chain.

We ask that the application not be approved.

The systems and processes currently used to approve this (and previous similar applications) are not fit for purpose as they lack the rigor and comprehensive data needed to make a genuine and credible safety assessment.

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:
As food from MS11 has been found to be as safe as food from conventional lines of canola, not preparing a draft variation offers little benefit to consumers, as approval of MS11 by other countries could limit the availability of imported canola products in the Australian and New Zealand market

(Reference source below)

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.

The techniques used in MS11 must be considered even less predictable.

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 or "omics"- transcriptomics — gene expression profiling, proteomics — protein composition profiling, metabolomics — profiling of metabolites, and miR-omics – microRNA profiling.

It is also 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 MS11.

Reference:

<http://www.foodstandards.gov.au/code/applications/Documents/A1140%20GM%20canola%20MS11%20CFS.pdf>

Option 2 – Reject application

Consumers:

Possible restriction in the availability of imported canola products which may be produced after co-mingling of seed from MS11.

No effect on consumers wishing to avoid GM foods, as food from MS11 is not currently permitted in the food supply.

Potential increase in price of imported canola food products due to requirement for segregation of MS11 seed.

Government:

Potential effect if considered inconsistent with WTO obligations but this would be in terms of trade policy rather than in government revenue.

Industry:

Possible restriction on imports of canola food products, if MS11 is commercialised overseas.

Without a food approval, it is unlikely a licence for the commercial growing of MS11 in Australia would be issued by the Gene Technology Regulator.

As food from MS11 has been found to be as safe as food from conventional lines of canola, not preparing a draft variation offers little benefit to consumers, as approval of MS11 by other countries could limit the availability of imported canola products in the Australian and New Zealand market