Centre for Integrated Research in Biosafety

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Submission on the IAR for **APPLICATION A580 FOOD DERIVED FROM AMYLASE-MODIFIED CORN LINE 3272**

Submitted to Food Standards Australia/New Zealand (FSANZ)

by

Submitter: Centre for Integrated Research in Biosafety
July 12, 2006

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This submission from the Centre for Integrated Research in Biosafety (INBI) is prepared in response to an invitation from Food Standards Australia/New Zealand to comment on the Initial Assessment Report for Application A580.

A580 is an application to amend the Australia New Zealand Food Standards Code to allow foods derived from corn line 3272 to be sold in Australia and New Zealand. The corn has been modified by the insertion of the *amy797E* gene encoding a variant of alpha-amylase (the variant having been assembled from several species) and *pmi*, the *Escherichia coli* gene encoding phosphomannose isomerase. The former confers the commercial trait and the later was used to select transformed corn cells.

INBI has considered the scientific studies. INBI believes that the Authority should base its scientific risk evaluation on answers that address the risk issues behind the following questions.

1. How has the Applicant established the safety of exposure to the gene product at the concentrations that the Amy797E protein would be present in human food at normal levels of corn ingestion? The same question applies to PMI.
2. The broiler feeding study used corn contaminated with Amy797E in the negative control (presumably due to inadvertent mixing of grain). How has the applicant determined that the contamination of the control did not affect the measurement of effects on the broilers?
3. How has the Applicant determined that the contamination of the Line 3272 Negative was due to mixing of grain rather than a low level of hybridization between the Positive and Negative Lines?
4. Has the applicant conducted feeding, acute oral toxicity and allergenicity studies sourcing the protein from the grain of the modified corn line, and using whole corn or whole corn products after cooking and processing, to determine the effects of exposures as humans would be exposed? The same question applies for inhalation exposure.
5. How was the negative segregant, used as a control, derived? Were plants called the negative segregant ever derived from cells exposed to recombinant DNA? Why was a non-transgenic parental not used as a control?
6. How does PMI sourced from corn leaf tissue compare with PMI in grain?
7. A region of PMI predicted to be identical to the Per a 3 allergen of cockroach was excluded as a possible allergen because PMI did not have an epitope with strong IgE-binding potential. How was this determined, by assay or by folding prediction programs?
8. Were the ‘stability to degradation in simulated gastric and intestinal fluids’ studies conducted to FAO/WHO specifications? Why was only PMI subjected to SIF studies? Why was Amy797E not also digested with pepsin at the 0.0001X concentration?

Respectfully submitted on behalf of the Centre,

Dr. Jack A Heine

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