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24 July 2003

Mr. Andrew McKenzie, Executive Director
New Zealand Food Safety Authority
68-86 Jervois Quay
PO Box 2835
Wellington

Dear Mr. McKenzie

I wish to thank you, Paul Dansted, Sandra Daly, Tim Knox and Gerard Clover of MAF, for the prompt and helpful replies to my letter of 7 July. The Gisborne biosecurity breach has presented the NZFSA and MAF with a complicated task. We congratulate you on your quick action to secure the material.

We have drawn some preliminary conclusions from the email and verbal responses to my initial request for information. In light of this information, the Institute believes that it is within the public interest for the NZFSA to action the following requests:

1. publish not just the conclusions of the AgriQuality analysis, but the methodology of that and any other analysis on the Gisborne corn in sufficient detail for it to satisfy the requirements of standard scientific journals prior to peer review. The data ought to be made available to the competent and independent scientific community for inspection.
2. that until data that permits the identity of the modified corn to be determined with 'high confidence', the NZFSA treat the material as unclassified for impact on human health.

Whereas we understand that the contamination was under the prescribed limit of 1%, we have limited confidence in the methods used to conclude that the modified material is of the category approved for human consumption. Surely the 1% contamination threshold must be cautiously applied to include only material that has some regulatory history and a complete description, and not applied broadly to any genetic modification of any type. This conclusion is self-evident in that 1% levels of some gene products could be extremely toxic to humans. So until the source material can be reasonably well identified, it is premature to conclude that Bt11 is the only modification.

AgriQuality GMO Services also reports a variety of other events (and genes), known to be present in commercial 'varieties' of corn and maize, are absent from the

modified material grown in Gisborne. It is our assessment, however, that this characterisation falls short of a positive identification of the organism to the extent necessary to conclude that:

- the organism is one that has been trialled, reviewed and tested by either the Food Standards Australia New Zealand or any other regulatory agency in New Zealand or abroad;
- if a review of the type suggested above had been conducted, it would have cleared the organism for human consumption.

The evidence for the conclusion that the organism, still of unknown origin, can be considered known to a 'reasonable standard', is well short of what we deem prudent.

Furthermore, we are concerned with any interpretation of the Food Standards Code 1.5.2 that would allow food derived from any corn/maize bearing the Bt11 event to be considered as approved for use. Unless it were known that the Bt11 event was unaccompanied by any other modification (known or unknown), or could be identified with certainty to be derived from a stock whose breeding could be verified, the material should be treated as of unknown composition and risk. Any other course of action would fall below the stringency of risk assessment required even for some low-risk experiments conducted in a contained facility without intent for human consumption.

There are a variety of ways that the chromosome with the Bt11 event could be transmitted. The prevailing assumption in this matter appears to be that the modified organism arrived in New Zealand by chance and not by intent. We see no evidence as of yet to reassure us that the prevailing assumption is correct.

From the analysis commissioned by MAF, an independent reviewer would be unable to assert with confidence whether or not that organism was related to any other known commercially available 'variety'. Without such an analysis, the formal possibility remains that the corn in Gisborne was of a type that has not been approved for release or consumption.

Sincerely,

A handwritten signature in black ink that reads "Jack Heinemann". The signature is written in a cursive, slightly slanted style.

Assoc. Prof. Jack Heinemann
Director

copies to: Dr. Gerard Clover, MAF Biosecurity, Tim Knox, NZFSA, Sandra Daly, NZFSA, Paul Dansted, NZFSA