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Pending Approval of Substantially Different Form of GM Corn by FSANZ

This paper sets out the Centre for Integrated Research in Biosafety's position concerning an application from Monsanto to allow amounts of a variety of corn that has been genetically engineered to express high amounts of the amino acid lysine and other products, to enter the human food chain in New Zealand.

We have written a series of detailed critical reports to Food Standards Australia New Zealand (FSANZ), which persists in recommending "high lysine corn" (LY038) be routinely allowed into the human food chain. We argue that:

- It would be the first GM corn overtly designed to be substantially different in its nutritional profile and there are compelling reasons to believe that LY038 will produce a spectrum of food hazards.
- The product was never intended to be a human food. Permission is being sought for it to enter the human food supply simply to minimise legal and regulatory risks.
- The accepted international principles of safety testing have not been met in action or spirit. If safety testing as used in this application is accepted, this sets a precedent that can be cited for a stream of industrial GM varieties for which approval would be sought on the same basis.

1. **FSANZ has not met its "as safe as" requirement for approving high lysine corn.**
   "LY038 corn must be shown to be *as safe as* other varieties of corn currently available if it is to be approved by FSANZ" [quote from FSANZ, emphasis added].[1]

The high lysine corn is substantially *different* to conventional corn. All previous safety assessments have concerned GM corn intended to be substantially equivalent to conventional varieties. Yet this assessment has not included key tests required as a result of this unprecedented shift in product development.

We stated that LY038 cannot be expected to be as safe as conventional corn at least with respect to its profile of advanced glycation endproducts (AGEs). FSANZ has in turn conceded that "it is reasonable to assume that processed corn products containing LY038 may contain an altered profile of AGE/MRPs [Maillard reaction products] compared to conventional corn"[2]. This is very significant because there is ample evidence in the medical literature to suggest that some AGEs are threats to human health[3]. Their potential harm to human health cannot be dismissed because AGEs may arise at low concentrations compared to other kinds of foods, as FSANZ responds. Their chemical composition may be unique and therefore may still be a danger even at low levels.

[1] p. 13 FSANZ. 2006a. Draft Assessment Report Application 549 Food Derived from High Lysine Corn LY038. Food Standards Australia New Zealand, Canberra.
[2] p. 78 FSANZ. 2006b. Final Assessment Report Application A549 Food derived from high lysine corn LY038. Food Standards Australia New Zealand, Canberra.
[3] Negrean, M., A. Stirban, B. Stratmann, T. Gawlowski, T. Horstmann, C. Gotting, K. Kleesiek, M. Mueller-Roesel, T. Koschinsky, J. Uribarri, H. Vlassara, and D. Tschoepe. 2007. Effects of low- and high-advanced glycation endproduct meals on macro- and microvascular endothelial function and oxidative stress in patients with type 2 diabetes mellitus. Am J Clin Nutr 85:1236-1243, Uribarri, J., W. Cai, M. Peppa, S. Goodman, L. Ferrucci, G. Striker, and H. Vlassara. 2007. Circulating Glycotoxins and Dietary Advanced Glycation Endproducts: Two Links to Inflammatory Response, Oxidative Stress, and Aging. J Gerontol A Biol Sci Med Sci 62:427-433.

It is therefore reasonable and prudent for the Minister for Food Safety, Annette King, to ask FSANZ to review pertinent data on types and amounts of AGEs/MRPs arising, as compared to more closely related non-GM relatives of LY038 (such as line LH195), when LY038 is stored, cooked or processed.

2. **FSANZ has not viewed sufficient evidence to meet its requirement that high lysine corn be as safe or wholesome as "normally consumed food".**
   "The comparative approach allows for an evaluation of the important constituents of a new food in a systematic manner while recognizing that there is general acceptance that *normally consumed food* produced by conventional methods is regarded by the community as safe"[4] [quote from FSANZ, emphasis added].

FSANZ adopts an appropriately holistic approach to comparison of foods, but has not enforced the requirement in this case. The wholesomeness of LY038 when normally consumed by humans has not benefited from the comparative approach, because it has not been tested after cooking or processing. Raw corn is not a "normally consumed food" for human beings; cooked and processed corn is. Whether a food is to be eaten in a cooked or raw form can have a critical bearing on the ability for conventional foods to gain approval[5]. As we have previously stated, key safety concerns surrounding LY038 are the:

- unprecedented levels and potentially novel types of AGEs/MRPs components, including free lysine, saccharopine, α-aminoadipic acid and pipecolic acid;
- different types and amounts of AGEs/MRPs that may form in cooked or processed foods containing LY038.

It is therefore reasonable and prudent for the Minister to ask FSANZ to review pertinent animal feeding study data on cooked or processed LY038, as recommended by Codex Alimentarius (of the World Health Organisation).

3. **FSANZ has not followed international guidelines that require the Applicant to use the most suitable non-GM comparator for hazard identification.** These state that:
   "for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts"[6].

FSANZ has not consistently used a comparator that is free from genetic modification. It casts a misleading impression when stating that it has not relied on the GM-derived sibling [LY038(-)] as a comparator because it used conventional corn varieties to evaluate any differences between LY038 and LY038(-)[7]. LY038(-) was the only variety that could be consistently relied on as the comparator in the compositional studies because it was always grown at the same site and same time as LY038, and compared to LY038 over multiple years and sites. No other conventional corn compared to LY038 appears to have been used more than once. This is neither the standard used in previously approved applications (to the best of our knowledge) for a comparator, nor is it what would be understood as the comparator in a scientific sense. Codex states that "to *reduce any effect from naturally occurring genotypic variation* within a crop variety, each trial site should be replicated" [emphasis added][8].

It is therefore reasonable for the Minister to expect that a *replicated trial site would have the same conventional variety serving as the comparator* to LY038 in order to reduce the effects of genotypic variation. Codex has defined the comparator as the closest related non-GM parent (probably LH195) and especially not a product of gene technology [i.e. LY038(-)]. Not only has the use of LY038(-) been a variation on Codex with the potential to undermine future assessment standards, it also introduces unnecessary complications for safety assessment.

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[4] p. 413 Brent, P., D. Bittisnich, S. Brooke-Taylor, N. Galway, L. Graf, M. Healy, and L. Kelly. 2003. Regulation of genetically modified foods in Australia and New Zealand. Food Control 14:409-416. Note that this is an FSANZ-authored publication.

[5] The NZ Food Safety Authority includes cooking as part of their normal assessment of some foods. For example, NZFSA CEO Andrew McKenzie said (New Zealand National Radio interview 9 July 2007) that it would be illegal to sell cooked chicken that was contaminated with various kinds of bacteria (e.g. Campylobacter, Listeria, fecal coliforms) or contaminated with certain chemicals, but it is not illegal to sell raw meat with bacterial contaminants because "the thing is that meat is cooked". This case is pertinent because NZFSA would not condone a product with a post-cooking hazard to be sold when cooking is inseparable from the way it is consumed.

[6] p. 2 Codex. 2003. Codex Work on Foods Derived from Biotechnology CAC/GL 45-2003.

[7] FSANZ. 2007. First review report Application A549 food derived from high lysine corn. Food Standards Australia/New Zealand, Canberra.

[8] p. 18 Codex. 2003. Codex Work on Foods Derived from Biotechnology CAC/GL 45-2003.

We encourage the Minister to seek a second review that requires FSANZ to review new data as described above, or to exercise her option to decline to amend New Zealand food standards to allow LY038 into the food supply.

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