Centre for Integrated Research in Biosafety

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Submission to Codex Alimentarius Commission of the United Nations on:
Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

The Centre for Integrated Research in Biosafety (INBI; the Centre) and the Sustainability Council of New Zealand wish to make a small number of points that we consider to be of high importance. Our submission is informed by recent experience comprehensively evaluating a variety of corn (LY038, Monsanto) modified for nutritional benefits. The corn was initially developed as an animal feed, but is now being considered for approval as a human food in many countries, including Australia, New Zealand, Canada, the EU and Japan. The complete evaluation is available in two large documents from http://www.inbi.canterbury.ac.nz/ly038.shtml.

In this submission, we draw attention to specific paragraphs in CX/FBT 06/6/5 and generic issues.

I. Scope of Coverage

The recommendation at paragraph 10 with respect to scope states:

"The following factors determine whether an rDNA plant is an rDNA Plant Modified for Nutritional or Health Benefit, and as such within the scope of the Annex:

a) the rDNA plant exhibits a particular trait in a portion of the plant intended for food use, and;

b) the trait aims to alter either the quantity or bioavailability of a nutrient or related substance, an anti-nutrient, a toxin or an allergen, or their interactions with other components of the plant, to achieve an intended nutritional or health benefit.

The Annex does not cover plants expressing pharmaceuticals or other substances that are not related to food."

It is important that the Commission formally recognize that rDNA plants modified for nutritional or health benefits may sometimes be developed for reasons other than use as a human food, but will either mix with human food or later be considered for use as a human food. This has been the lesson with LY038, a corn modified to produce high levels of lysine in free form (outside of protein) and which simultaneously accumulates potentially toxic breakdown products. To avoid trade disruptions caused by mixing LY038-derived material with other agricultural exports, the corn is also being considered for use in the

human food supply. Nevertheless, there has been and currently is discussion on the use of high lysine crops to supplement human feed, particularly in Africa.[1] So incentives other than those that guided development of an rDNA plant may be important for determining ultimate applications of the crop.

We therefore would prefer a modification to the text in CX/FBT 06/6/5 to language free of intent or stated intent of the use of the rDNA plant and that is more inclusive of plants with altered nutritional profiles regardless of the intention of the developer. It is effects that the Plant Guide must ultimately be attentive to and effects are not dependent on intent.

"*The following factors determine whether an rDNA plant is an rDNA Plant Modified for Nutritional or Health Benefit, and as such within the scope of the Annex:*

a) the rDNA plant exhibits a particular trait in a portion of the plant intended for food use, **and/or***;*

b) the trait alters either the quantity or bioavailability of a nutrient or related substance, an anti-nutrient, a toxin or an allergen, or their interactions with other components of the plant."

The next and last sentence of this recommendation [*"The Annex does not cover plants expressing pharmaceuticals or other substances that are not related to food."*] also covers a critical point of principle. We note that at the most recent meeting of the Task Force in July, the view was expressed by Norway that "contamination of food supply with plants producing pharmaceutical substances could be addressed by the Task Force with a view to assuring food safety and protecting consumers' health, if there was a slightest possibility for the plants to reach to food chain." That there was no agreement as to whether consideration of these substances was within the mandate of Codex does not absolve Codex from setting guidelines as to how regulators should respond to this scenario.

Given the lack of agreement as to the mandate of Codex, the Task Force should make clear that: In absence of a consensus as to how the safety of such substances should be assessed, these substances are for the time being not considered suitable for assessment as foods.

Failure to make such a clarification risks the interpretation that Codex has no position with respect to the assessment of such rDNA plants. Absence of a Codex position allows for statements to and by a food safety regulator that "approval of this variety as a food would not be inconsistent with Codex", or even that it would "meet Codex requirements."

If there is any doubt in the minds of parties that such an interpretation could subsequently be promoted and adopted, the experiences with LY038 applications are instructive. Note in particular, the clarifying footnote in the Plant Guideline with respect to what can be considered a conventional counterpart states that: "for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts". Instead, a GM variety was used as the counterpart for the evaluation of LY038. We therefore recommend the following amendment.

[1] "Africa needs lifesaving high-lysine corn." COPYRIGHT 1985 Saturday Evening Post Society. "Africa Harvest helping Africa fight hunger and malnutrition with biofortified sorghum." http://www.highbeam.com/doc/1G1-3660918.htmlhttp://72.14.203.104/search?q=cache:nWo4252MliAJ:www.supersorghum.org/frontNews/ABS%2520Feature.pdf+lysine+african&hl=en&ct=clnk&cd=7. Access date 30 September 2006.

"The Annex does not cover plants expressing pharmaceuticals or other substances that are not related to food. In the absence of a consensus as to how the safety of such substances should be assessed, they are for the time being not considered suitable for assessment as foods."

If such an amendment is not seen as suitable, then alternately and notwithstanding the lack of consensus as to mandate, the scope must be expanded to include plants expressing pharmaceuticals or other substances and the study of their effects provided for.

II. "Elements Considered for Inclusion"

We generally support inclusion of these passages. However, we caution the Commission with respect to language that can be used to undermine a precautionary approach to regulation. For example, while bioavailability and exposure estimates may be useful for hazard identification, both of these measures may change over time. This again can be illustrated by reference to LY038. Currently, it may be anticipated that LY038 will form a very small proportion of the corn supply. However, the average exposure based on the proportion of corn that is LY038 is not the same as the maximum possible acute exposure due to concentrations of the corn. Moreover, the market variables that determine how much LY038 corn is cultivated now may change, leading to more in the future. Finally, bioavailability of food hazards derived from cooking LY038 corn may vary depending on milieu conditions for preparation. These also may differ with time or by human practice. Therefore, we stress that the Commission should ensure its language is used to set a minimum standard for assessment and does not introduce caveats that can be used to undermine the spirit of the assessment.

III. Animal feeding studies

"Based on input from the Working Group this element does not appear to warrant further guidance in the Annex beyond that provided in the Plant Guideline. It is suggested, therefore, that the Annex do not elaborate on this element."

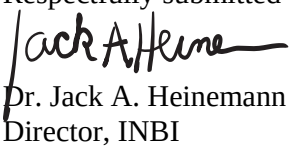
We do not generally agree that it is impossible to rule out the value of all animal studies or animal models that may be developed in the future. Nevertheless, should this language be adopted, then we believe that the Commission should set minimum requirements for post-market surveillance and pre-market human study trials.

IV. Generic issues with no corresponding text in CX/FBT 06/6/5

We recommend that the Commission reiterate in any new standard its commitment to the use of the conventional counterpart (usually the non-GM parental variety) as the necessary comparator in safety studies for rDNA plants. The Commission may wish to encourage developers to use other comparators in addition to the non-GM parental variety, but these should not substitute for the conventional counterpart. We note with concern that applications for allowing bio-industrial and feed rDNA plants as food that are now before food safety regulators do not uniformly use a conventional comparator. This again is illustrated by LY038 which used the sibling variety, also a product of gene technology and with no history of safe use, as the comparator.

We recommend that the Commission reiterate and strengthen its language about safety testing using material derived from the whole plant (and not surrogate sources of protein) and which has been cooked or processed in the representative ways relevant to its use in human food. This standard again was not met in applications for approval of LY038, or the proposed biofuel corn 3272 (Syngenta), as a human food.

Respectfully submitted



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1 October 2006

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