Lay summary

This contribution from the New Zealand Institute of Gene Ecology (NZIGE) is meant to support Food Standards Australia/New Zealand's preparation of a Draft Assessment on application A549. Our comments and wording are direct, but our spirit is constructive. The NZIGE is dedicated to the development for the public good of all responsible biotechnologies. We are an assemblage of serious researchers with independent credentials in the area of biotechnology and its social impact.

A549 is an application to amend the Australia New Zealand Food Standards Code to allow foods derived from corn line LY038 to be sold in Australia and New Zealand. "Corn line LY038 has been genetically modified to have higher than usual levels of the amino acid lysine," particularly in the corn grain.^{1[1]}

2[2]

Our submission begins with introductory material describing who we are and why we are involved. We then provide a summary of the major recommendations gathered from the detailed sections of our submission. These sections are organized into three main parts. In Part One, we undertake risk *forecasting*, an exercise at the leading edge of the research literature that serves to forewarn of risk where the science is not certain. Novel potential hazards of *C. glutamicum* Dihydordipicolinate Synthase (cDHDPS) protein, its metabolic products expressed in maize, and other side-effects of inserting DNA into the maize genome were identified to the best of our ability on the very tight timeframe available to us for this phase of consultation. Some of these properties, moreover, will be particularly influenced by the protein's environment and thus are even more important for assessments of food safety.

In Part Two, we review the scientific documents submitted by the Applicant in support of A549. We judged this material by two criteria: 1. Was the science at the best possible standard? and 2. Does the science add up to a package that is sufficient to assure the citizens of Australia and New Zealand that they may safely consume food derived from corn line LY038? In most cases we recommend how, why and when the Applicant should supplement their findings with additional data.

In Part Three, we comment upon the Impact Analysis contained in the Initial Assessment Report (IAR). We assess the costs and benefits listed and propose further costs and benefits of the options under consideration.

The Authority (FSANZ) has made plain "the need for standards to be based on risk analysis using the best available scientific evidence"

• The data comparing the composition of the transgenic lines to commercial reference lines of maize may be skewed by selective choice of commercial lines. The commercial reference lines chosen may inflate the 99% tolerance interval to more closely match the composition of LY038, thereby reducing the apparent number of significant compositional differences between the LY038 line and conventional corn.

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while the publication of a paper with a flaw generally has very little influence on the daily lives of most citizens, the change in the New Zealand and Australia Food Code has implications for tens of millions of people directly and, because it may be connected to