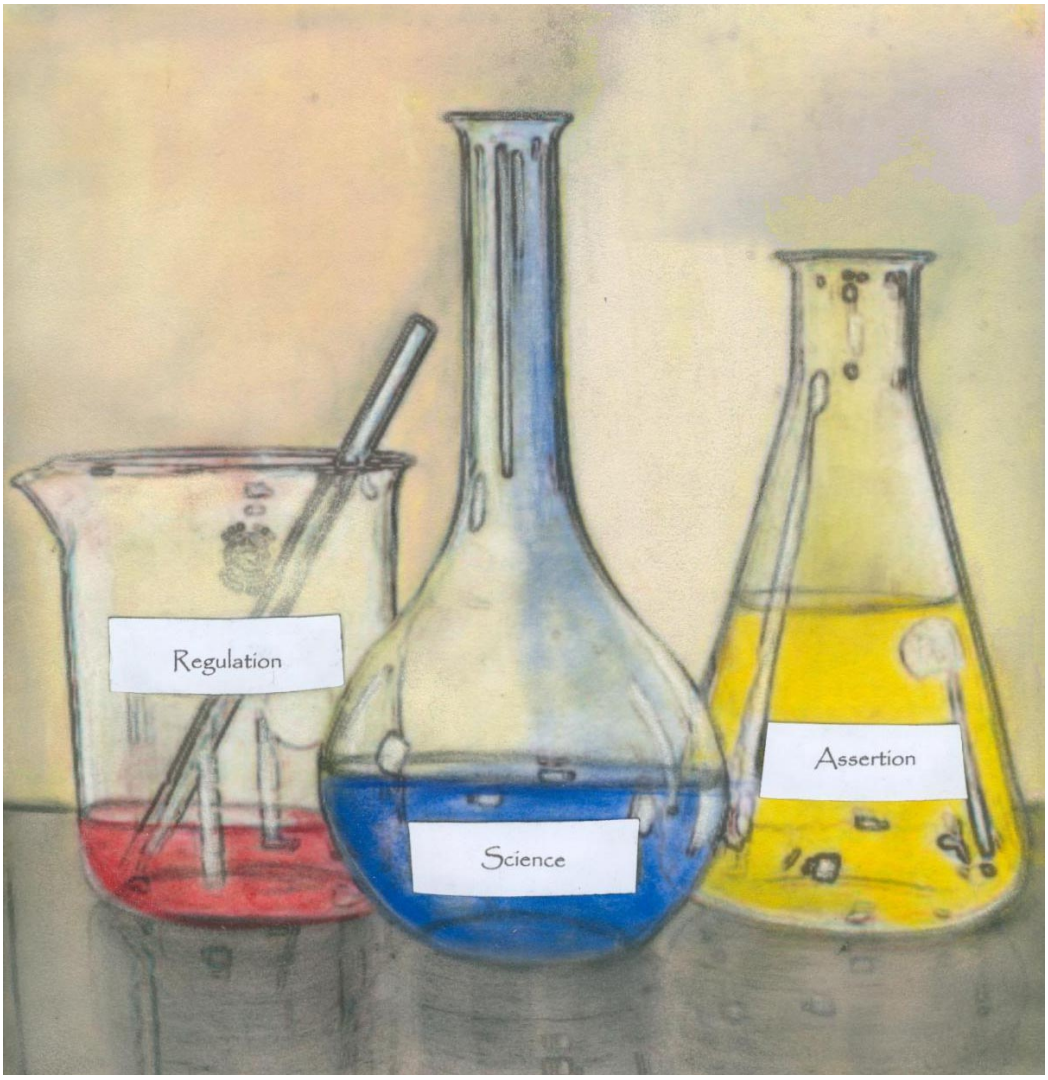
Food Safety Credibility

The Regulatory Response to GM Lysine Corn



SUSTAINABILITY
COUNCIL of NEW ZEALAND

Contents

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Summary

1. An important test case for food safety regulation has arisen through a request to approve a new form of genetically modified (GM) corn.

2. The Trans-Tasman food safety regulator, FSANZ, has recommended that an animal feed named LY038 be approved for human consumption. The variety's nutritional profile has been modified to a greater degree than previously approved GMOs so as to provide high levels of lysine to livestock. Approval for it as a human food would minimise the legal and financial risk for the developer and users if it enters the food supply.

3. This document reviews the Sustainability Council's concerns with an approval by New Zealand and presents the case for it standing aside from FSANZ's precedent-setting recommendation.

Untested Risks to Food Safety

4. While lysine is an essential amino acid, it is also very reactive. A series of risks arise from the products of reactions involving lysine and its breakdown products.

5. One of the classes of resulting products is Advanced Glycation Endproducts (AGEs). AGE's containing lysine have been implicated in the mechanisms that lead to a series of major and important human diseases (or their complications). There is also growing evidence that AGEs are harmful when present in food, and that food can be a significant source of AGEs.

6. While FSANZ examined the effect of a rise in absolute levels of lysine and its breakdown products available to humans, it did not investigate the compounds that could be expected to result from reactions involving lysine or its breakdown products when the corn is cooked or processed. FSANZ did not extend its investigations on the grounds that the proportion of AGEs resulting would be low. However, different AGEs or combinations of AGEs can have different physiological effects and the full spectrum of effects remains unknown. Therefore, the toxicity of AGEs cannot be assessed simply according to the proportions present.

7. Lysine and its breakdown products could also react with other substances to form toxic by-products. The potential for this and the severity of the effects was demonstrated by another similarly reactive amino acid, tryptophan. Experience from the synthetic production of tryptophan in 1989 under a particular set of conditions strongly suggests that even minor quantities of contaminants formed as by-products in such processes can have very significant public health consequences.

8. LY038 also introduces the risk of allergic reactions. It contains a protein that has a fundamentally different structure to the analogous protein found

naturally in corn. Existing data cannot therefore be relied on to predict its potential for allergenicity. Further, this protein can also react with sugars, creating an even more complex mixture of proteins and potential allergens with no history of safe use as a food.

Departures from the International Guidelines

9. A set of international guidelines has been devised for the assessment of foods from genetically modified plants. These guidelines, set under the Codex Alimentarius Commission, describe a process by which a new GM food is compared against the relevant conventional food that has a history of safe use – the "conventional counterpart". Any differences detected are then to be the subject of specific testing.

10. Yet FSANZ accepted an application for LY038 that uses a GM corn variety as the conventional counterpart in the safety studies submitted with it. This GM variety does not meet the relevant Codex standard that calls for a conventional counterpart that is both non-GM and has a history of safe use. Selection of such a variety reduces the scope for identification of differences in LY038.

11. FSANZ argues that its assessment is sound as it did not rely on the results of that comparison "to make a judgment about safety". It instead devised a two-stage process of comparison, relying on conventional varieties in the second stage of comparison. However, Codex guidelines clearly intend that the differences to be isolated are those that can be identified by *direct* comparison between the new GM food and the conventional counterpart.

12. A significant difference to conventional corn FSANZ does identify is that LY038 contains elevated levels of lysine and its breakdown products. Codex specifies that such differences "should be subjected to additional nutritional assessment to assess the consequences of the changes". In simply comparing the proportions of lysine and its breakdown products in common foods and in LY038, FSANZ does not identify or test the potential products of their reactions with one another or with sugars.

13. Similarly, if there is insufficient information, Codex suggests that animal feeding studies be required. Yet the feeding studies submitted with the application involve only uncooked corn when humans eat cooked corn. FSANZ states that it does not believe feeding studies are required at all to assess LY038.

14. The potential significance of such feeding studies was recently underlined by reanalysis of one undertaken in support of another form of GM corn - MON863. The peer-reviewed reanalysis stated that: "with the present data it cannot be concluded that GM corn MON863 is a safe product". In April, an evaluation of this study was commissioned by the New Zealand Food Safety Authority (NZFSA). However, NZFSA has refused access to the review on the basis that it has yet to be provided to the Minister of Food Safety.

15. The MON863 feeding study has direct implications for the LY038 application. For even though MON863 is a variety engineered to still be "substantially

equivalent", it caused statistically significant signs of organ damage during a relatively short feeding study. By comparison, LY038 was engineered to be substantially different to conventional corn. In consequence, it would be prudent to seek appropriate animal feeding trials before approving LY038.

16. While FSANZ states that it takes "an explicitly cautious approach" to food safety, the Sustainability Council does not consider this was the case for the assessment of LY038. There were a series of decision points at which a regulator acting with precautionary intent would have sought to investigate a risk, rather than assume this was not warranted. Yet FSANZ chose at these points to assert safety rather than reserve judgement or ask the applicant to provide further scientific evidence. This process and the outstanding issues of concern render unreliable FSANZ's assurance that: "food derived from corn line LY038 is as safe and wholesome as food derived from other corn varieties".

Absence of Public Benefits and Failure to Consider Alternatives

17. The information FSANZ has presented in its assessment report for LY038 does not meet a reasonable standard of cost benefit assessment. There is a complete absence of quantification and barely any indication of the magnitude of the costs or benefits identified.

18. Each of the three benefits claimed in support of approving LY038 is invalid, with two relying on circular logic. In particular, the claim that consumers will derive increased confidence in the food supply is a supposed outcome of the decision, and yet this is treated as an input to making the decision. On the costs side of the equation, FSANZ has not adequately documented these, and has not counted the public health risks that remain in absence of adequate safety investigations.

19. If a value were placed on the residual public health risks, and the absence of public benefits was acknowledged, the cost benefit analysis would necessarily conclude that an approval of LY038 would produce net costs to the public.

20. FSANZ rules out the option of not approving LY038 on the basis that this is likely to be inconsistent with WTO obligations. However, this judgement depends entirely on the assertion that LY038 is "as safe as food from other varieties of corn".

21. In contrast, there is a clear basis for rejection of LY038 under WTO rules as a result of important safety test data not conforming to the Codex guidelines. It is widely understood that inconsistencies with the guidelines provide a valid basis for defending a decision to reject an import.

22. FSANZ also has a statutory duty to consider alternatives to an approval that would be "more cost-effective", but there is no indication of such investigation. One alternative is for users of LY038 to adopt appropriately stringent segregation measures when cultivating the corn. An even simpler and more cost-effective alternative is the status quo. Lysine is currently fed to animals as a dietary supplement and this poses no significant risks to the

human food supply. Had FSANZ examined alternatives, this should have revealed that the most cost-effective option was not approving LY038 and allowing lysine to continue to be added separately to animal feed.

Opting Out

23. New Zealand has the right to stand aside from food safety decisions adopted in Australia. Relevant exceptional grounds for "opting out" include:

24. ***Risks from AGEs:*** Consumption of cooked LY038 is likely to result in the ingestion of novel AGEs or novel concentrations of AGEs. Due to the breadth and significance of their potential health effects, even if only small proportions of LY038 were consumed, the Sustainability Council believes avoidance of these risks is precautionary and warranted given the absence of any compensating consumer benefits or other public benefits.

25. ***Risks from Toxic Reaction By-products:*** As a class of reactive amino compounds, lysine and its breakdown products carry the demonstrated potential to react in ways that produce toxic reaction by-products. Due to their potential effects, the Sustainability Council believes avoidance of this risk is precautionary and warranted given the absence of any compensating consumer benefits or other public benefits.

26. ***Risks to Regulatory Credibility:*** FSANZ has put forward certain findings that cannot be deduced from the information presented in its assessment report, but are instead assertions. It has also conducted its assessment on a basis that does not consistently follow international guidelines. The Sustainability Council considers that a number of FSANZ's claims lack credibility and that they undermine trust and confidence not only in the LY038 decision but the regulatory system as a whole. The New Zealand economy's dependence on food export income and 'clean green' branding makes it unusually exposed to a lack of regulatory credibility. The health and safety of New Zealanders also depends on a credible regulatory structure.

27. ***Risks of a Precedent that Lowers Assessment Standards:*** Through not consistently following a precautionary interpretation of the international guidelines, FSANZ has presented a position that, if accepted by New Zealand, invites future applicants to seek a similarly less stringent basis for assessment on the grounds of consistency. To the extent this precedent can be used as an instrument to lower future assessment standards, or even forestall the rejection of an application, it represents a risk to health and safety.

28. It would be prudent for New Zealand to opt out of the Ministerial Council's decision on LY038, on the basis of the exceptional grounds identified. Issues documented in this report also provide grounds for New Zealand to seek changes to the way FSANZ responds to applications for novel foods in future. The reforms suggested are pre-conditions for regulatory credibility in light of the LY038 case.

1. Introduction

A form of corn, genetically modified to contain high levels of lysine, was presented for approval to the Trans-Tasman food safety regulator, FSANZ,[1] in 2004. The corn was developed as an animal feed, but if it is also approved for human consumption, this reduces the legal and financial risks to the developer should it be found in the food supply.[2]

FSANZ recommended approval of this corn, known as LY038, to the council of ministers representing each Australian state and New Zealand, which oversees FSANZ. On 23 July 2007, this Ministerial Council[3] agreed to LY038 becoming a legal food. Under the Trans-Tasman food safety arrangements, New Zealand is bound by this decision unless it formally "opts out".

FSANZ's assessment throws up a series of concerns about the evaluation process. They raise challenges to three overarching objectives held by the New Zealand Government:

- Ensure safe food for New Zealanders;
- Act consistently with international food safety guidelines and rules recognised by the WTO; and
- Avoid a loss of regulatory credibility.

This document reviews the Sustainability Council's concerns with the proposed approval by New Zealand of LY038 and presents the case for it standing aside from this precedent-setting decision.

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1 Food Standards Australia New Zealand (FSANZ).

2 FSANZ states: "Identity preservation methods will be used to segregate this product from conventional grain, however it is possible that a small percentage of LY038 grain will inadvertently be co-mingled with conventional corn and enter the human food supply. Monsanto Australia Limited has therefore applied to have Standard 1.5.2 amended". FSANZ, *Final Assessment Report, Application A549, Food Derived From High Lysine Corn LY038*, 13 December 2006, p 8.

3 The Australia and New Zealand Food Regulation Ministerial Council was established by the Food Regulation Agreement, 2000, and is roles are defined under an Australian Act of Parliament, the Food Standards Australia New Zealand Act 1991, which is in turn referred to in New Zealand's Food Act, 1981, Part 2A.

2. Significant Food Safety Risks Untested

LY038 has been engineered to produce high levels of lysine. While lysine is one of the nine amino acids that are generally considered to be essential for nutrition in humans and other mammals, it is also very reactive. Therefore, specific risks arise from the products of reactions involving lysine.

In addition, lysine breakdown products which normally do not accumulate in plants are found in exceptionally high concentrations in LY038. Each of these is also highly reactive and additional risk arises from products of reactions that involve these lysine derivatives.

2.1 Risks from Formation of AGEs

Lysine in proteins, free lysine and lysine breakdown products react with reducing sugars to form glycoconjugates, which are then amenable to further modification by oxidation, to yield so-called glycoxidation products, or Advanced Glycation Endproducts (AGEs).

The medical literature documents a series of AGEs as threats to human health.[4] Lysine-containing AGE products have been implicated in the mechanisms that lead to a series of major and important human diseases (or their complications), including atherosclerosis and coronary artery disease, hypertensive heart disease, the cardiovascular complications of diabetes mellitus, and chronic kidney failure, amongst others.

There is strong and increasing evidence that AGE products, when present in the tissues, lead to or cause many of the manifestations of these serious diseases. There is also growing evidence that such products are harmful when present in food, and that food can be a significant source of AGEs.[5]

The Central Chemical Differences in LY038

Lysine is an amino acid that is incorporated into protein.

Free lysine is rapidly converted by plants into safe compounds.

In LY038, still reactive lysine breakdown products tend to accumulate.

The breakdown products include: saccharopine, α-aminoadipic acid, pipecolic acid and possibly cadaverine.

[4] See INBI submission to FSANZ, 2 June 2006, for a comprehensive review of medical implications of AGEs. Also see: Negrean, M., Stirban, A., Stratmann, B., Gawlowski, T., Horstmann, T., Gotting, C., Kleesiek, K., Mueller-Roesel, M., Koschinsky, T., Uribarri, J., et al. (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, and, Uribarri J, Cai W, Peppa M, Goodman S, Ferrucci L, Striker G and Vlassara H. "Circulating Glycotoxins and Dietary Advanced Glycation Endproducts: Two Links to Inflammatory Response, Oxidative Stress, and Aging." J Gerontol A Biol Sci Med Sci 62 (2007), 427-433. See also Appendix 2.

[5] Goldberg T, Cai W, Peppa M, Dardaine V, Baliga B S, Uribarri J and Vlassara H. "Advanced glycoxidation end products in commonly consumed foods." *J. Am. Diet. Assoc. 104* (2004), p. 1877.

FSANZ states, and we agree 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"[6] (Figure 1).

However, FSANZ excludes the high level of lysine in LY038 corn as a dietary risk to humans on the basis that "when compared to lysine from other dietary sources this is not a large amount of lysine"[7]. FSANZ has further stated that: "We have considered the potential for production of AGEs, but have no concerns"[8]. Yet the potential for AGEs from LY038 to harm human health cannot be excluded simply because they may arise at low concentrations compared to other kinds of foods.

The comparison FSANZ made was to eggs, red meat, chicken, fish, lentils, rolled oats and broccoli. However, these foods are uniformly much lower than LY038 in reducing sugars, which are the other component in the formation of AGEs. The combination and concentration of sugar and lysine in LY038 appears to be unique. In a review of the literature, we could find no food (including high AGE sources such as red meat[9]) with higher levels of sugar and elevated levels of lysine.

FSANZ also compared the proportion of known lysine breakdown products in LY038 against other foods.[10] However, in each case it has simply set out the comparison without analysing the types or concentrations of AGEs that would arise from these breakdown products.

Further, of themselves, such comparisons cannot yield reliable conclusions as to the safety of LY038 because:

- none of these foods is corn;
- they are not eaten in the same proportions or cooked and processed in the same way with the same combination of other ingredients; and
- they are not consumed in the same proportions by particular groups, such as infants and heart patients.

Finally, FSANZ has not characterised the allergenic potential of the recombinant protein, cDHDPS, in LY038 after this has reacted with the sugars found in this corn. The protein introduced into LY038, cDHDPS, has a fundamentally different structure to the analogous protein found naturally in corn. This structural difference means that

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6 FSANZ, *Final Assessment Report, Application A549, Food Derived From High Lysine Corn LY038*, 13 December 2006.

7 FSANZ, *Final Assessment Report, Application A549, Food Derived From High Lysine Corn LY038*, 13 December 2006.

8 Catherine Clifford, *Food regulator amends code for GM corn*, Australian Broadcasting Corporation, 3 August 2007.

9 These foods included: cheese, tuna, lentil, flatfish, chicken, red meat, fish, eggs, oats, sweet corn, and broccoli.

10 High levels of the lysine catabolite saccharopine were dismissed as a food hazard by saying that "[t]he levels of saccharopine found in LY038 corn grain (499 – 818 μg/g dwt, mean 650 μg/g) are substantially higher than those found in broccoli or cauliflower, but similar to the level in button mushrooms". High levels of the lysine catabolite α-aminoadipic acid, which has a known neurotoxic activity (Rozan P, Kuo Y H and Lambein F. Nonprotein amino acids in edible lentil and garden pea. Amino Acids *20* (2001), 319-324 were dismissed as a human food hazard because "[c]ompared to the levels found in other common plant foods, [e.g. lentils, mushrooms, cauliflower, green beans and broccoli] this level is not a cause for concern". FSANZ, *Draft Assessment Report Application 549 Food Derived from High Lysine Corn LY038*, 2006.

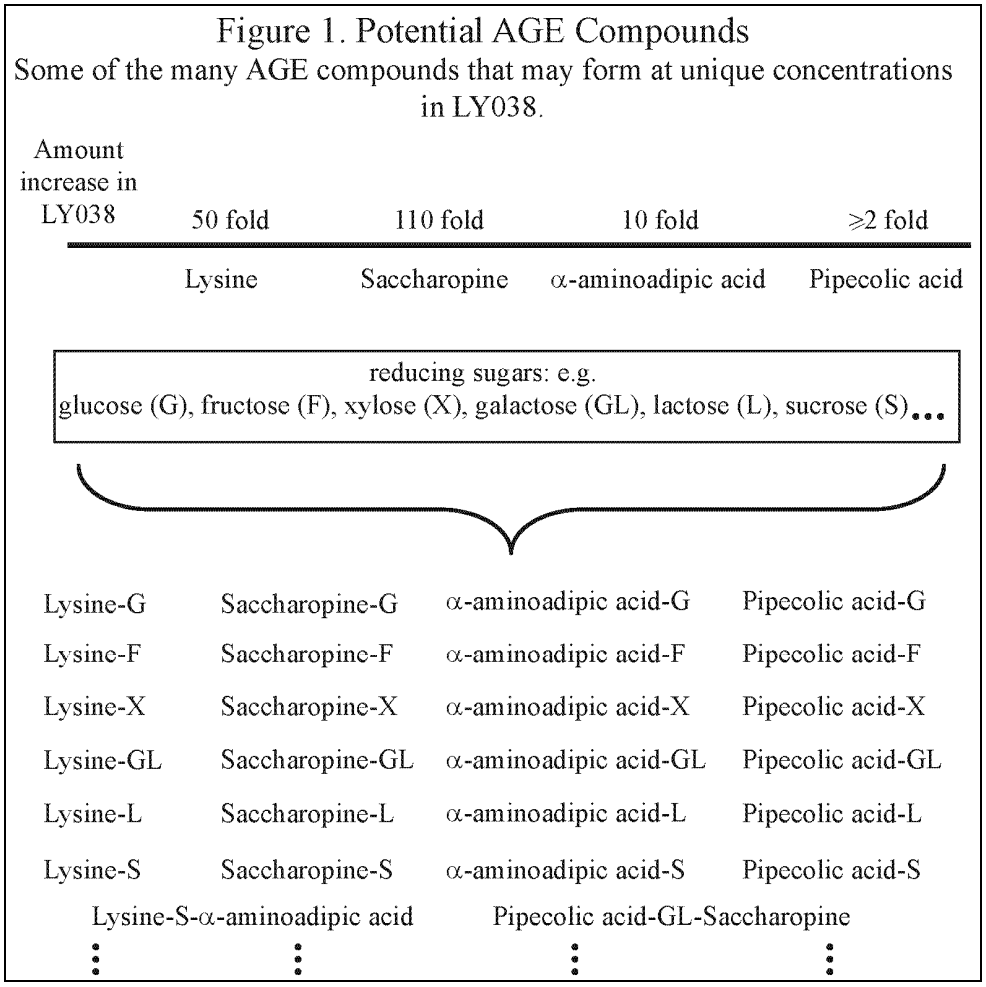
existing chemical profiles, as used by FSANZ, cannot be relied on to predict the potential for cDHDPS to be an allergen. The source of this protein, a soil bacterium, is not understood to have reached significant levels in human food and its history as a safe organism can therefore not be extrapolated to provide assurance about the safety of this protein.[11] Finally, this protein can also react with sugars, creating an even more complex mixture of proteins with no history of safe use as a food.

In summary, cDHDPS, lysine and its many breakdown products produced in LY038 can react with each other and different sugars to produce a spectrum of AGEs (Figure 1).

Different AGEs or combinations of AGEs can have different physiological effects and the full spectrum of effects remains unknown. Therefore, the toxicity of AGEs cannot be assessed according to absolute proportions.

Figure 1. Potential AGE Compounds

Some of the many AGE compounds that may form at unique concentrations in LY038.



[11] With respect to invoking an immune response in humans.

Particular Risk Groups

Codex states that:

> Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems.[12]

Infants: Corn is used in infant formulae, unlike some of the non-corn foods FSANZ has used to make comparisons with LY038.[13] Infant formulae (e.g. "Enfamil") can contain corn and corn-derived products and are already known to be much higher in AGE content than human or bovine milk.[14] There is no indication in FSANZ's reporting that it has considered this important group. An approval of LY038 would effectively raise the concentration of glycation reactants in infant formula with no compensating health benefits.

Food allergies: How and why some people mount an immune reaction to proteins in foods[15] is a developing area of science and medicine. However, it is clear that those with a tendency to develop such reactions can be further sensitised to AGEs from repeated consumption of the same foods. In a study of the minor allergens of peanuts, researchers found that indicator immune reactions were much stronger if the natural allergen was converted into an AGE.[16] There may be groups of individuals prone to developing allergies to AGEs unique to LY038, such as AGEs derived from the novel recombinant protein cDHDPS, or found at unique concentrations in this corn.

2.2 Potential Toxic Products

Separate to the risks arising from AGEs is the potential for lysine and its breakdown products to react with other substances and generate toxic by-products.

Another essential amino acid – tryptophan – provides a useful case study to illustrate the potential scale of health effects. Tryptophan is similarly reactive and is sometimes taken as a dietary supplement. The presence of elevated concentrations of a reactive substance can lead to the formation of products not usually present in human tissues, or present only in minute amounts. It is likely that this was the process that was responsible for the generation of highly toxic by-products arising through a particular synthesis of tryptophan.[17]

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12 Codex Alimentarius Commission, *Foods Derived from Biotechnology*, p 19, paragraph 49.

13 For example, button mushrooms.

14 Goldberg T, Cai W, Peppa M, Dardaine V, Baliga B S, Uribarri J and Vlassara H. "Advanced glycoxidation end products in commonly consumed foods." J. Am. Diet. Assoc. 104 (2004), 1287-1291.

15 Such as in coeliac disease.

16 Gruber P, Becker W M and Hofmann T. "Influence of the Maillard Reaction on the Allergenicity of rAra h 2, a Recombinant Major Allergen from Peanut Arachis hypogaea, Its Major Epitopes, and Peanut Agglutinin." *J. Agric. Food Chem. 53* (2005), p 1876.

17 A report by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment - an advisory body of independent experts that provides advice to the UK Food Standards Agency, the UK Department of Health - forms the basis of the following description.

In late 1989, the synthetic production of tryptophan under an altered set of conditions was associated with hundreds of hospitalisations and at least 37 deaths in the United States.[18] Between 97% and 100% of the cases of a previously unrecognised epidemic illness, termed the eosinophilia-myalgia syndrome (EMS), were linked to the tryptophan produced by one manufacturer using the altered production conditions. Of the survivors, 28% reported long term cognitive changes (impaired memory, impaired concentration or mood change).[19]

The altered conditions included the use of a new form of a genetically modified organism to produce the tryptophan along with less stringent purification, and the EMS epidemic was statistically associated with these two factors.[20] Of the more than 60 contaminants found in low levels in the relevant batches, 6 were subsequently associated with the causation of EMS.[21]

> On the balance of evidence, it is likely that … EMS was due to one or more contaminants. Changes to the manufacturing and purification process by one particular manufacturer may have increased levels of these contaminants to harmful levels.[22]

The lesson this case study offers is that even minor quantities of contaminants formed as by-products of processes involving reactive amino acids can lead to very significant consequences for public health. Thus, characterisation of the spectrum of products that could be produced through reactions involving lysine and its breakdown products in LY038, and assessment of their potential effects, should be required.

This report, attached as Appendix 5, provides a detailed account of an event that has only recently received the scrutiny warranted. The references citing in this report have in most cases been individually accessed and the interpretation checked for accuracy.

18 Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, *COT Statement on Tryptophan and the Eosinophilia-Myalgia Syndrome*, August 2004, p 1. http://www.food.gov.uk/science/ouradvisors/toxicity/statements/cotstatements2004/cotstatements2004tryptophan

19 Ibid, p 2.

20 "Statistical analysis showed significant associations between batches of L-tryptophan associated with EMS and the use of Strain V *Bacillus amyloliquefaciens* and the reduction in the amount of activated carbon used". Ibid, p 3.

21 Ibid, p 4.

22 Ibid, p 8.

3. Departures from the International Guidelines

International guidelines for food safety testing have been laid down by a joint WHO/FAO body - the Codex Alimentarius Commission.

Codex guidelines devised especially for the assessment of foods from genetically modified plants do not purport to be a comprehensive or "bottom up" safety assessment. They are an abridged set of procedures designed to identify hazards through detecting differences between new GM plants and foods with a history of safe use.

Codex, and the comparative approach to safety assessment generally,[23] set the minimum requirements for identifying potential hazards that then can be further evaluated.[24]

3.1 A Comparator Without a History of Safe Use

The Codex test protocol for biotech foods specifies that testing be carried out by comparing characteristics of the new GM food with a "conventional counterpart". The 2003 guidelines define this as follows:

> ***"Conventional Counterpart***" - means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food.

A footnote to the definition states:

> It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.[25]

A conventional counterpart must therefore:

- Be a single plant variety, in common use as a food;[26]
- Have a history of safe use; and
- Not be a product of modern biotechnology (defined to include genetic modification).[27]

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23 This relies on the concept of "substantial equivalence".

24 "The concept of substantial equivalence is thus the starting point and guiding concept for the safety assessment, not its conclusion." (König A, Cockburn A, Crevel R W R, Debruyne E, Grafstroem R, Hammerling U, Kimber I, Knudsen I, Kuiper H A, Peijnenburg A A C M, et al. "Assessment of the safety of foods derived from genetically modified (GM) crops." Food Chem. Toxicol. 42 (2004), 1047-1088.)

25 Codex Alimentarius Commission, *Foods Derived from Biotechnology*, standards CAC/GL 44-2003 and CAC/GL 45-2003, p 8.

26 Note that the specification of the counterpart being a single variety is not exclusive to the definition but is reinforced throughout the guideline – for examples pages 10 and 12.

27 ***"Modern Biotechnology"*** means the application of:
i) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection."
Footnote: "This Codex definition is taken from the Cartagena Biosafety Protocol under the

The conventional counterpart used for the safety studies submitted in support of the LY038 application, is a related corn line known as LY038(-). This plant variety is the only one to have been grown alongside LY038 in each year and in each plot where the trial data was gathered (as the control). However, it meets none of the three requirements listed above. LY038(-) is not in common use as a food, and therefore has no history of safe use, and is unambiguously a product of modern (gene) biotechnology. We provide the history of LY038(**-**) in Appendix 1, showing that both of LY038(-)'s parental lines were the products of genetic modification.

When asked to comment on the appropriateness of the comparator, Environmental Science and Research (ESR) stated "The parent corn line H99 would be the closest non-transgenic line to use as a comparator. Why the Applicant did not use it is unclear".[28]

FSANZ also initially questioned the use of LY038(-) as an appropriate comparator.[29] A FSANZ representative stated to the applicant that: "Unfortunately, I am still concerned about whether LY038(-) is a suitable control line as it could be considered to be a product of gene technology itself".[30] A further letter from FSANZ stated that Codex Guidelines indicate that "an appropriate comparator is the conventional counterpart…for the foreseeable future, food derived from modern biotechnology will not be used as the comparator." [31]

Pre-Market Assessment

Two kinds of pre-market assessments are: 1. molecular characterisation and 2. composition.

The former generally uses techniques, such as Southern blotting (which reveals changes to the genome as a result of the transformation process) and techniques that evaluate any anticipated new proteins (e.g. cDHDPS).

Compositional assessments provide a comprehensive description of the chemical components of the comparator and the commercial product, after growing the two side-by-side in multiple different environments and seasons.

In consequence, FSANZ required the applicant, Monsanto, to conduct a new series of experiments that partly replaced LY038(-) with conventional parents of LY038.[32] These replaced some of the experiments used to undertake the molecular comparisons, but FSANZ did not require that the compositional experiments also be redone. It is unclear why FSANZ would enforce the use of a conventional counterpart for the genomic comparisons but not the chemical composition comparisons, and this represents an inconsistency in enforcement of standards.

Convention on Biological Diversity. (Codex Alimentarius Commission, *Foods Derived from Biotechnology*, standards CAC/GL 44-2003 and CAC/GL 45-2003, p 2.)

28 ESR is retained advisor to the New Zealand Food Safety Authority, NZFSA. Memo from ESR to NZFSA, commenting on submission from the Centre for Integrated Research in Biosafety with respect to FSANZ's Draft Assessment report, 2006.

29 "Our process for assessing the safety of GM foods is based on concepts and principles developed by international organisations that **focus on a comparison of the GM food with the commonly eaten conventional form**, from a molecular, toxicological, nutritional and compositional point of view." (Emphasis added) (FSANZ, *FSANZ reaffirms its risk assessment of genetically modified corn MON 863*, 25 July 2007).

30 FSANZ to Monsanto, 11 March 2005.

31 FSANZ to Monsanto, 17 March 2005.

32 These new experiments were conducted between the Initial Assessment and the Draft Assessment.

Even if FSANZ believed a GM variety could be used instead of a conventional variety, it has indicated that this should be a GM variety that had already been approved and had a history of safe use.

> In general, FSANZ would expect to receive information relating to the non-GM counterpart food, however the guidelines are sufficiently broad to encompass a comparison with other lines, including…**previously approved GM lines with a safe history of use**…it may be appropriate for the new GM food to also be compared with **an approved GM variety.**[33] (Emphasis added)

LY038(-) is not approved anywhere in the world and has no history of safe use as it was created concurrently with LY038.

Following the FSANZ recommendation to approve LY038 in December 2006, New Zealand expressed concern over this issue. Food Safety Minister Annette King requested a review of the FSANZ recommendation on the basis that: "there were inconsistencies between the processes described in the domestic and international standards, in particular, the choice of comparator".[34] Tasmania also sought a review on related grounds and the Ministerial Council that oversees FSANZ in turn suggested that: "the Applicant be required to undertake additional comparative studies using a comparator or comparators that clearly satisfy current, relevant definitions, prior to any decision to approve LY038".[35]

In response, FSANZ rejected the call for further research and presented a two-stage justification for the approach it had adopted. It first argued that the assessment was still sound as it "did not rely on comparison with [LY038(-)] in order to make a judgment about safety".[36]

> Rather, [LY038(-)] was used to aid in the identification of any differences, which were then further evaluated by comparison with conventional corn varieties.[37]

Codex makes no exception for such use of a mixture of lines as comparators, especially when a single conventional line is not consistently used throughout all comparisons. More importantly, the Codex guideline clearly intends that the differences to be isolated are those that can be identified by **direct** comparison with a non-GM variety that has a history of safe use. The core logic for this testing methodology, specifically devised for genetically modified plants, is that the comparison can be relied on to identify the differences that matter.[38] If the only differences to be studied are those arising from comparison of a novel GM variety with another closely related GM plant that does not even have a history of safe use,

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33 FSANZ letter to Sustainability Council, 20 December 2006.

34 Annette King, *King seeks a Ministerial Council review of GM corn approval*, 21 February 2007.

35 FSANZ, *First Review Report Application A549 Food Derived From High Lysine Corn LY038*, 23 May 2007, p 4.

36 FSANZ, *First Review Report Application A549 Food Derived From High Lysine Corn LY038*, 23 May 2007, p 4.

37 Ibid, p 4.

38 "The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value." Codex Alimentarius Commission, *Foods Derived from Biotechnology*, standards CAC/GL 44-2003 and CAC/GL 45-2003, p 12.

then the fundamental rationale for the methodology is undercut. What Codex requires is that differences between LY038 and a non-GM counterpart are indeed used to "make a judgment about safety", contrary to the approach FSANZ adopted.

Having circumscribed the scope for differences to those between two closely related GM varieties, the second stage of the FSANZ's justification for departing from Codex is that 20 conventional corn varieties can be used as comparators. While the greater number of comparators used might superficially indicate a more robust level of testing, this is not the case, for none of the 20 were consistently tested alongside LY038 in all trials over all years. This undermines the explicit Codex requirement that the trials be replicated using a consistent conventional comparator "to reduce any effect from naturally occurring genotypic variation within a crop variety", a requirement repeatedly stated throughout the guideline.[39]

FSANZ states that its "approach is consistent with both the FSANZ and Codex guidelines".[40] When reporting to its minister on this interpretation, it is significant that NZFSA notes only that: "FSANZ **claims** that this approach is consistent with both the FSANZ Guidelines and Codex Guidelines" (emphasis added).[41] The claim is not explicable on the basis of information provided to date.

3.2 Inadequate Investigation of Identified Differences

FSANZ is nonetheless clear that there are significant differences between high lysine and conventional corn. It states: "food produced from LY038 corn has been significantly changed with respect to its lysine content" and lysine breakdown products.[42] In this regard, LY038 is not "substantially equivalent" to conventional corn and therefore cannot be evaluated as other GM food products have been by FSANZ to date. The Codex guidelines spell out what is expected in this case:

> [F]oods derived from recombinant-DNA plants that have undergone modification to intentionally alter nutritional quality or functionality **should be subjected to additional nutritional assessment to assess the consequences of the changes** and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.[43] (Emphasis added)

As noted above, comparing the proportions of lysine and its breakdown products in common foods to those in LY038 does not begin to identify, let alone test,[44] the

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39 Codex Alimentarius Commission. Codex Work on Foods Derived from Biotechnology. In CAC/GL 45-2003, p. 18. In particular, none were subjected to particular tests, Southerns, that are critical to identifying variations of special concern. The use of 20 one-off comparisons actually reduces the power of statistics to reveal differences of importance.

40 FSANZ, *First Review Report Application A549 Food Derived From High Lysine Corn LY038*, 23 May 2007, p 5.

41 NZFSA, Briefing Note 06/125, 28 June 2007, p 4.

42 FSANZ, *Final Assessment Report, Application A549, Food Derived From High Lysine Corn LY038*, 13 December 2006.

43 Codex Alimentarius Commission, *Foods Derived from Biotechnology*, CAC/GL 44, p. 19, para 48.

44 The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant or the bioavailability of a nutrient after processing.

potential products of their reactions with sugars, with each other, or the novel form of the protein introduced into the high lysine corn (cDHDPS) before and after it has reacted with sugars in corn.[45]

Codex again specifies what could be expected in cases such as this where there are many potential substances and complex interactions to assess.

> Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, **properly designed animal studies could be requested on the whole foods.**[46] (Emphasis added)
>
> …
>
> [The] potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered.[47]

FSANZ acknowledges that in "cases where the composition of food has been significantly changed, as is the case with high-lysine corn, feeding studies with suitable livestock species may be useful to confirm the wholesomeness of the food".[48]

Feeding studies with rats and chickens had been submitted by the applicant to FSANZ. However, the animals were fed uncooked corn, when humans eat cooked corn. In its review of the FSANZ report, ESR states:

> the assertion that "LY038 corn, cooked as part of a normal diet, would not make a substantial change to dietary AGE intake" is unsupported.[49]

ESR also notes FSANZ's statement that the technology is not yet available to analyse the production of AGEs.[50] However our understanding is that the technical capacity to carry out such work is rare but not absent. Ample evidence for this capacity appears in our references. In any case, the inability to perform an analysis important to evaluating safety is not a justification for approval when there is evidence to suggest it could be unsafe.

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45 The safe use of the plant enzyme (mDHDPS) does not extend to the recombinant bacterial enzyme used in LY038 because the cDHDPS differs structurally from the plant version. This difference in molecular architecture means that different faces of the protein are presented to the solution, with a different direct allergenic potential and different indirect allergenic potential through Maillard reaction products. Gruber P, Becker W M and Hofmann T. *Influence of the Maillard Reaction on the Allergenicity of rAra h 2, a Recombinant Major Allergen from Peanut Arachis hypogaea, Its Major Epitopes, and Peanut Agglutinin*. J. Agric. Food Chem. 53 (2005), p 2289-2296.

46 Codex Alimentarius Commission, *Foods Derived from Biotechnology*, standards CAC/GL 44-2003 and CAC/GL 45-2003, s 11, p 9.

47 Codex Alimentarius Commission, *Foods Derived from Biotechnology*, standards CAC/GL 44-2003 and CAC/GL 45-2003, s 47, p 18.

48 FSANZ, *Final Assessment Report, Application A549, Food Derived From High Lysine Corn LY038*, 13 December 2006.

49 ESR, *FSANZ Final Risk Assessment Report: Application A549 Food Derived from High Lysine Corn LY038*, January 2007, p 3.

50 Ibid.

The potential impact of cooking is an issue clearly identified in the Codex guidelines[51] and it is known that cooking and processing stimulates the production of AGEs. Thus a feeding study that has not made use of cooked or processed corn is an unreliable basis for assessment of this product as a human food.

Other shortcomings with the feeding studies are:

- the choice of livestock species, such as chickens, does not provide a good model for testing the safety of this food for human consumption;
- in the case of the chicken study, a statistically significant growth inhibition was detected among chickens fed high lysine corn during the first 21 days but not investigated further;
- only one mammalian species, rats, was tested. At least two different species, one non-rodent, should be used, and for longer than 90 days; and
- in the case of the rat study, no raw data or pathological description of organs was made available for inspection.

FSANZ responds to the suggestion that new feeding trials be completed by stating that it does not believe feeding studies are required to assess LY038.[52] It further states that it does not require feeding studies to be submitted as part of an application for a GM food. This is because:

> Where GM varieties have been shown to be compositionally equivalent to conventional varieties, feeding studies using target livestock species will add little to a safety assessment and are generally not warranted.[53]

Yet, in the case of LY038, FSANZ has acknowledged it is not "compositionally equivalent" to a conventional variety, and that feeding studies "may be useful to confirm the wholesomeness of the food". Its subsequent rejection of the need for revised feeding studies is contrary to normal scientific practice (the appropriate application of substantial equivalence as the **starting point** of a safety assessment), and leaves unchecked an important exposure.

3.3 Lessons from MON863 and the Role of Feeding Studies

Another form of GM corn approved by FSANZ provides an interesting case study for comparison to testing conducted on LY038.

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51 "In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as **stability to heat** or processing and to degradation in appropriate representative gastric and intestinal model systems." (Emphasis added) Codex Alimentarius Guidelines, p 16, paragraph 38. FSANZ acknowledges this but states that: "Codex only asks regulators to *consider* testing heated or processed GM foods" (Emphasis as per original). Catherine Clifford, *Food regulator amends code for GM corn*, Australian Broadcasting Corporation, 3 August 2007.

52 Radio New Zealand "Nine to Noon", 19 July 2007. Note that FSANZ does not deny that there exists no compositional or feeding study data comparing cooked and processed food derived from LY038 and conventional corn.

53 FSANZ, *FSANZ reaffirms its risk assessment of genetically modified corn MON 863*, 25 July 2007.

When FSANZ considered the MON863 corn in 2003,[54] it viewed the results of two animal studies – a toxicity study using mice, and a feeding study using chickens. "No studies on rats were made available to FSANZ" the regulator states.

However, in 2005 a German appeal court required the developer, Monsanto, to release a further animal study – this time, a 90 day feeding study undertaken with rats. In March this year, three independent researchers based at French scientific institutions[55] produced a peer-reviewed re-analysis of the raw data underlying the Monsanto-commissioned study.[56] As rather few studies of mammals fed on GM plants have been undertaken,[57] the research team argues that careful analysis, and re-analysis, of the relatively short length studies that are available is important.[58]

The researchers, led by Professor Séralini, concluded that there were signs of toxicity and that longer experiments were essential to identify the real nature and extent of the risk the corn posed. Significantly, this study concluded overall that:

> … with the present data it cannot be concluded that GM corn MON863 is a safe product.[59]

Despite the FSANZ policy that it does not require feeding studies for assessment of GM food applications, it requested from Monsanto the same raw data that was reassessed by Séralini, but returned it to the company when Monsanto insisted on commercial confidentiality. FSANZ then instead reviewed Séralini's work and stated that:[60]

> FSANZ concludes that the use of alternative statistical tests did not identify any new safety concerns.[61]

The Seralini study identified potential hazards that could be used as a basis for requesting more targeted and effective testing of MON863. Instead, FSANZ

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54 FSANZ, *Final Assessment Report. Application A484. Food derived from insect-protected MON863 corn,* 8 October 2003.

55 All were also part of the Committee for Independent Information and Research on Genetic Engineering CRIIGEN, Paris, France.

56 Séralini G-E, Cellier D and J S de Vendomois. "New Analysis of a Rat Feeding Study with a Genetically Modified Maize Reveals Signs of Hepatorenal Toxicity", *Archives of Environmental Contamination and Toxicology*, March 2007.

57 Séralini *et al*: "Very little data have been published on mid- or long-term feeding studies with genetically modified plants, approved and commercialized, in equilibrated diets, given to mammals, with numerous blood and organs parameters measured", p 2.

58 Séralini et al: "Regulatory rules do not require 3-month tests with three mammalian species, then with a mammal for 1 year and yet another for 2 years, such as those employed for the testing of pesticides or drugs. This is why it appears crucial to analyze carefully the longest toxicity tests available only in one mammalian species".

59 Ibid, p 2.

60 Recently the European Food Safety Authority has also reviewed the Séralini work and concluded that that differences identified were not significant.

61 FSANZ, *FSANZ reaffirms its risk assessment of genetically modified corn MON 863*, 25 July 2007, p 21. Note also FSANZ states in the full report: "In conclusion, the observed differences are consistent with normal physiologic variation and are not related to the consumption of MON863 corn. The observed histopathological changes are similarly unremarkable for rats of this strain and age. Therefore, the results of this study do not indicate adverse effects from the consumption of MON 863 corn." (FSANZ, *Review of 13-Week Rat Feeding Study with MON863 Corn*, July 2007, p 9.)

concluded that while the harmful effects identified were indeed statistically significant, they were not considered by FSANZ to be proof of biologically significant effects as it believed these to be within normal biological variability.[62]

NZFSA has also sought a review of the Séralini study and commissioned ESR to undertake this work in April 2007. However, NZFSA has denied access under the Official Information Act to what we understand to be this report in order "to protect the confidentiality of advice tendered Ministers of the Crown and officials", and in particular because:

> The report was commissioned by NZFSA for the specific purposes of providing advice to the Minister, and that advice has yet to be provided.[63]

NZFSA will not confirm when the ESR report was completed and the degree of sensitivity surrounding this document suggests it could be a significant input to the LY038 decision.

The lesson, and link to LY038, is that if a trial as short as 90 days can show signs of organ damage through toxicity, and this is for a GM variety that was not intended to be different in its nutritional profile, then considerably more rigorous investigation is justified for LY038. It requires adherence to the highest precautionary standards and at least the use of feedings studies involving two mammalian species, one or more non-rodent, fed cooked and processed corn.

When the intended difference in this case is elevated levels of a highly reactive amino acid, the absence of appropriate additional scientific testing means FSANZ lacks the information to deduce that the required level of safety - that of equivalence to a similar conventional food - has been achieved. This is the standard FSANZ itself sets as the test for appropriate precaution. Significantly, although ESR rarely raised points of contention, it was only prepared to conclude that "the data is consistent with the conclusion that … LY038 is as safe and wholesome", not that this is the case.[64]

Inconsistent Application of Confidentiality to Feeding Studies

A related concern is the differing standards for treatment of information in the MON863 case and for the LY038 assessment. FSANZ did not believe the MON863 feeding studies warranted confidentiality, so it did not retain them when this was requested. In contrast, FSANZ did consider that the LY038 feeding studies warranted confidentiality. FSANZ has not clearly indicated, on the one hand, what aspects of LY038 testing provided grounds for granting confidentiality, while on the other hand not relying on them for its assessment (as it states was the case). Further, even if FSANZ did not consider the studies were required to assess LY038, if they were not confidential, at least independent parties could then assess the results.

62 "The observed differences are consistent with normal physiologic variation and are not related to the consumption of MON863 corn". FSANZ, *Review of 13-Week Rat Feeding Study with MON863 Corn*, 2007, p 3, 4, and 9.

63 NZFSA letter to the Sustainability Council, 10 August 2007, p 2.

64 ESR. *FSANZ Draft Risk Assessment Report, Application A549 Food derived from high lysine corn LY038*, April 2006, p9.

3.4 Whither Precaution?

FSANZ has outlined its underlying philosophy to food safety assessment in the following terms:

> **An explicitly cautious approach is applied** to foods and food ingredients that do not have a history of safe human use.
> …
> due to potential health concerns about their use, they should be prohibited unless expressly permitted. The basis for permitting substances with no prior history of safe use is that: the relevant and appropriate scientific data indicate that the **foods are as safe as their conventional counterpart**.[65] (Emphasis added)

In other words, there is a clear test to be satisfied before approval so that a precautionary approach to health risks is observed. Further, section 10(2) of the FSANZ Act specifies that the assessment be "based on risk analysis using the best available scientific evidence".[66]

The LY038 case raises a series of decision points at which a regulator acting with precautionary intent would have sought to investigate a risk, rather than assume this was not warranted. Each of the attendant risks is potentially significant or very significant. Most were also fully identified to FSANZ during the assessment process. Yet the regulator chose to assert safety rather than reserve judgement or ask the applicant to provide further scientific evidence. This includes the following instances:

- The safety testing did not employ a comparator with a history of safe use to make direct comparisons with LY038.
- A related GMO was used to detect differences in the GM lysine corn, so one cannot expect to find differences specific to genetic modification.
- FSANZ has nonetheless identified intended differences but has not advanced analysis of these to a sufficient level.
- Feeding (and allergenicity) studies that Codex suggest be used to assess complex risks arising from unintended changes following cooking or processing have not been undertaken using corn in its cooked state.

This catalogue of identified risks and absence of appropriate responses that would seek to address them renders unreliable FSANZ's assurance that: "food derived from corn line LY038 is as safe and wholesome as food derived from other corn varieties".[67]

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65 ANZFA, *ANZFA's Standards Decision Making Framework: A Report to ANZFSC*, 2001, p 6.

66 10 (2) "In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following: (a) the need for standards to be based on risk analysis using the best available scientific evidence"

67 FSANZ, *Final Assessment Report Application A549 Food derived from high lysine corn LY038*, 13 December 2006.

4. Cost Benefit Analysis Unsound

As a part of assessing a new food, FSANZ has a statutory obligation to undertake an analysis of costs and benefits arising.[68] This must count only public benefits, and so exclude private benefits.

The information FSANZ has presented in its assessment report for LY038 does not meet a reasonable standard of cost benefit assessment.

4.1 Absence of Public Benefits

FSANZ presents the following as benefits to be counted in favour of an LY038 approval:

- *Consumers* - "consumers can maintain confidence in the food supply if LY038 becomes co-mingled with other corn varieties".
- *Government* - "if LY038 corn were to inadvertently enter the human food supply, this … would ensure that there is no potential for trade disruption on regulatory grounds".
- *Industry* – "Possible benefit if LY038 is commingled with other corn varieties as no regulatory action would need to be taken and so costs from this (e.g. product recall) are likely to be negligible".[69]

Yet none is a valid public benefit:

- The claimed **consumer benefit** is justified on circular logic. It does not arise from the nature of the product. It is entirely a result of the decision, and yet is treated as an input to the decision. In any case, the reverse outcome seems more likely. That is, rather than an approval allowing "consumers to maintain confidence in the food supply", public confidence in the wider regulatory structure will be reduced once the public comes to appreciate the inadequate nature of the assessment process for LY038.

- The claimed benefit to **government** is also circular. The freedom to trade a product is a consequence of an approval, not a reason to approve. Otherwise all products would deserve such a credit, no matter how unsafe.

- The claimed benefit with respect to the **industry** category confuses public and private benefits. It is a private benefit if no "product recall" is required and

[68] Section 15(3)(c) specifies that "In making a draft assessment of the application, the Authority must have regard to: …
(c) whether costs that would arise to bodies or persons from a food regulatory measure developed or varied as a result of the application outweigh benefits that would arise to the public from the measure or variation;

[69] FSANZ, *Final Assessment Report Application A549 Food derived from high lysine corn LY038*, 2006, p 18 and 19.

only public benefits can be counted.[70] To the extent that regulatory action is required to cause the private party to conduct the recall, any such action readily falls within the standing functions of the regulator, such that no cost savings would be expected from avoiding this action.

FSANZ's decision to count any of the above claimed benefits is a clear departure from FSANZ's earlier draft report for LY038 when for each of the above three categories, no benefits were identified.[71] The later 'discovery' of invalid benefits raises questions about FSANZ's processes of investigation.

Equally concerning is the thinness of the documentation of cost and benefit issues. Less than two pages of a 97 page document is devoted to cost and benefit assessment and each of the six costs or benefits identified in the favoured scenario is generally described in a single sentence.

Further, there is a complete absence of quantification. In spite of a statement on the FSANZ's website that such analysis "wherever possible, includes factual quantitative information",[72] of the six elements described in the favoured scenario, only one carries any indication whatsoever of the magnitude of the cost or benefit.[73]

4.2 Inadequate Scoping of Costs

FSANZ has not adequately documented the scope and scale of the costs associated with approving LY038 which include the following:

Risks to Public Health: FSANZ has asserted the safety of LY038, rather than demonstrated this, and has not counted the residual public health risks.

The product was never intended to be a human food. However, if permission were obtained for it to enter the human food supply, this would minimise legal and regulatory risks for the developer and users of the GM corn. Such risks were clearly demonstrated by another GM corn variety called StarLink that was also intended only as an animal feed, was not approved as a human food, and was supposed to be strictly segregated when grown. However, segregation proved ineffective and it contaminated

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70 This is not simply a requirement of the FSANZ Act, it is a fundamental requirement of the economic theory that provides the context for regulatory intervention. While the public may indeed suffer inconvenience in any recall, it would not be called for unless the risks outweighed the benefits to consumers, so there is no net benefit to this group.

71 The term "no direct impact" was used to summarise the position in each case, although in apparent contradiction, under the "Government" category, a similar potential benefit regarding lack of trade disruption was noted. FSANZ, Draft Assessment Report, p 6 and 7.

72 FSANZ, *Application Handbook*, August 2007, p 35 states: "FSANZ is required to prepare a Regulatory Impact Statement (RIS), which includes an analysis of potential costs and benefits both economically and socially of the regulatory options available. The RIS, wherever possible, includes factual quantitative information."

73 FSANZ, *Final Assessment Report Application A549 Food derived from high lysine corn LY038*, 2006, p 18 and 19.

a significant proportion of US corn production,[74] triggering the most costly food product recall in US history.

Approval of LY038 as a legal food would transfer risk and cost from the developer and seed users to consumers of food. Instead of seed users facing the cost of effective segregation, consumers face the residual health risks that have been identified but remain untested. The normal incentive for due care on the part of the user is eroded to the extent that the burden of proof lies with the consumer, and is also weakened because New Zealand's relevant liability law is thoroughly inadequate.[75] Further, to the extent that a health effect can be proven, and compensation can be claimed under the Accident Compensation Commission (ACC) Act, the Act prevents the agent responsible for the harm from being sued. As a result, the Crown is liable for these costs rather than the agent causing harm.

Restricted Consumer Choice: Consumers who believe the safety of LY038 is unproven, and seek to take a precautionary approach as a result, may suffer through having to avoid a wide range of products of which LY038 may potentially form a part. FSANZ has provided a long list of such processed food, including basic foodstuffs such as corn flakes.

4.3 The WTO Dimension

FSANZ's conclusion to its cost benefit assessment begins by ruling out the option of declining the application:

> As food from LY038 corn has been found to be as safe as food from other varieties of corn, [rejection of the application] is likely to be inconsistent with Australia and New Zealand's WTO obligations.[76]

This statement is entirely dependent on the assertion that LY038 is "as safe as food from other varieties of corn", yet FSANZ has not proven this. An appropriate casting of the current state of knowledge is a statement of the form that "it has yet to be shown that LY038 is as safe as food from other varieties of corn as testing to date has been inadequate to explore issues for which it is reasonable to hold concerns".

The question of whether rejection of the LY038 application is consistent with WTO obligations can, however, be settled more easily - by reference to the Codex guidelines.

The chief WTO obligation FSANZ alludes to is the Sanitary and Phytosanitary Measures (SPS) Agreement. This sets standards that may legitimately be invoked to reject a product. While there is very little relevant case law, it is widely understood

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74 William Lin, Gregory K. Price, and Edward Allen, *Impacts on the U.S. Corn Market and World Trade*, US Department of Agriculture's Feed Yearbook, 2001, pages 40-48.

75 See Chen Palmer & Partners and Simon Terry Associates, (2001) *Who Bears the Risk,* and Sustainability Council, *The New Frontiers: Biotechnology Liability Law Reform*, paper to the Biotechnology Law Conference, 20 February 2003.

76 FSANZ, *Final Assessment Report Application A549 Food derived from high lysine corn LY038*, 2006, p 19.

that citing the absence of conformance to Codex guidelines will provide a clear defence against legal action under the SPS agreement.[77]

As documented in the preceding section, there are a number of instances in which the existing safety test data is either inconsistent with Codex guidelines, or at very least, interpretations of the guidelines can be confidently presented as valid grounds for rejection.

Deeper consideration suggests the risk is the reverse to that FSANZ presents. The LY038 decision raises concerns with respect to the precedent it sets - for the assessment of GM food generally and bio-industrial crops in particular. This is because the SPS agreement and Codex place emphasis on consistency.[78]

If New Zealand permits a GMO without a history of safe use to be the conventional counterpart in an assessment, this could weaken the nation's ability to refuse the use of such a comparator in future. This is not so much because the guidelines would prevent the return to a standard requiring a comparator with a history of safe use. It is more that it provides plausible grounds for a WTO action against New Zealand, where one would not previously exist. While in theory, New Zealand might have a good basis for believing it could win such an action, the decision whether or not to make such stands is as much a question of politics as international law. (New Zealand's decades of prior reluctance to press a WTO case against Australia with respect to its resistance to apples exported from this country is a case in point.)

New Zealand has been rigorous in complying with international law surrounding food trade in order to be on high ground when challenging other countries that inappropriately block access for its food exports. While the departure from Codex guidelines in this case operates in the other direction (undermining the testing standard locally rather than permitting an unduly high testing standard offshore), the same principle is at stake. Resistance of equal strength is therefore merited, only this time with the health of New Zealand consumers (rather than trade access) as the driver.

Returning to FSANZ's conclusion to its cost benefit work, the second leg of this states:

> [Approval] is the preferred option as LY038 has been found to be safe for human consumption, and provides the benefit that approval of this line may prevent problems in the future if LY038 were to enter the food supply.[79]

In other words, in weighing the total costs and benefits it has counted no public health risks, but has apparently counted as public benefits:

a) the avoidance of a cost a private agent may face from product recall and the cost to a regulator of enforcing this; and

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77 Personal Communication, MFAT representative, 8 August 2007.

78 The Codex guidelines state: This should include consistency of data requirements, assessment frameworks, the acceptable level of risk, communication and consultation mechanisms and timely decision processes. Codex Alimentarius Commission, *Foods Derived from Biotechnology*, standards CAC/GL 44-2003 and CAC/GL 45-2003, p 5.

79 FSANZ, *Final Assessment Report Application A549 Food derived from high lysine corn LY038*, 2006, p 19.

b) the avoidance of trade disruption;

Yet (a) should not involve any discernable public cost, and (b) is only a cost to a particular set of trade policy objectives, and thus essentially a political cost, rather than an economic one (as FSANZ has previously acknowledged).[80]

In summary, were a value placed on the residual public health risks and the absence of public benefits was acknowledged, the analysis would necessarily conclude that an approval of LY038 would produce net costs to the public.

The significance of this is that if the LY038 application had been assessed after October 1 2007, it would have been subject to new clauses in the FSANZ Act. One providing for rejection of any application that fails the cost benefit test.

> The grounds for rejection are:
> **whether costs** that would arise from a food regulatory measure developed or varied as a result of the application **outweigh the direct and indirect benefits to the community**, Government or industry that would arise from the development or variation of the food regulatory measure. (Emphasis added)[81]

The change elevates net public benefits from a consideration to a *de facto* requirement.

4.4 Failure to Examine Alternatives

In addition to undertaking a cost benefit analysis, FSANZ also has a statutory duty to consider alternatives to an approval, and in particular:

> whether there are any alternatives (available to the Authority or not) **which are more cost-effective** than a food regulatory measure developed or varied as a result of the application.[82]

There is no evidence in FSANZ's assessment that it has considered such alternatives.[83]

Appropriately Stringent Segregation

One alternative is for those who grow, transport and process LY038 to adopt appropriately stringent segregation measures. FSANZ states that the motive for the application is the risk of LY038 entering the human food chain.[84] Having the

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80 FSANZ states on p 19 of its draft assessment report : "Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue".

81 FSANZ website, http://www.foodstandards.gov.au/standardsdevelopment/newamendmentstothefsanzact/rejectionofanapplica3612.cfm

82 FSANZ Act, section 15(3)(d).

83 The declining of an approval is not taken to be an alternative. Also, the defence that there is no need to consider alternatives, as there are no costs, is not available to FSANZ.

84 "Identity preservation methods will be used to segregate this product from conventional grain, however it is possible that a small percentage of LY038 grain will inadvertently be co-mingled with conventional corn and enter the human food supply. Monsanto Australia Limited has

developer (and thus users of its seed) internalise the risk through appropriate segregation is a "more cost-effective" solution than approval, and so meets the statutory test. For while it may well be privately profitable to transfer risk and cost, the regulator may only count public costs and benefits.

Separate Feeding of Lysine Supplements to Animals

An even simpler and more cost-effective alternative is the status quo. Lysine is currently given to animals as a dietary supplement to assist with their growth. In feedlots, it is mixed in with animal food provided to the trough.

LY038 is presented as a convenient means of providing the two in one. However, this convenience carries with it a series of disadvantages:

a) The feed additive approach allows for accuracy in achieving optimal supplementation. By contrast, the LY038 corn is a transgenic line. In this transgenic, the amount of extra lysine cannot be controlled and may well vary by time and hybrid.[85]

b) The feed additive approach poses no significant risks to the environment or human health; it has no major consequences beyond the feedlot.[86] In particular, it minimises the risk of elevated levels of lysine directly entering the human food chain. By contrast, with LY038 corn, the extra lysine, breakdown products and potential allergens are present in the plant, thus introducing downstream effects, as described elsewhere.

c) The feed additive approach is simple and relatively inexpensive. By contrast, appropriate segregation and/or the risk-weighted costs associated with human ingestion are likely to be significant.

In summary, had FSANZ examined alternatives, this should have revealed that the most cost-effective option was not approving LY038 and allowing lysine to continue to be added as a separate supplement.

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therefore applied to have Standard 1.5.2 amended to include food derived from corn line LY038." FSANZ, *Final Assessment Report Application A549 Food derived from high lysine corn LY038*, 2006, p 8.

85 This is not a theoretical possibility. To illustrate, a Monsanto study found that crosses of high lysine varieties produced even higher levels of lysine than predicted from each line separately. Huang, S., Kruger, D. E., Frizzi, A., D'Ordine, R. L., Florida, C. A., Adams, W. R., Brown, W. E. and Luethy, M. H. (2005). High-lysine corn produced by the combination of enhanced lysine biosynthesis and reduced zein accumulation. Pl. Biotechnol. J. 3, 555-569.

86 This is in part because the lysine is not cooked or processed when fed to animals and because it does not include toxic lysine breakdown products.

5. The Case for Opting Out

5.1 Grounds for Concern

The Sustainability Council believes FSANZ's assessment of the LY038 application raises a series of grounds for concern. These can be summarised as follows:

- FSANZ accepted an application that uses an unapproved GM corn variety as the conventional counterpart for safety studies submitted with the application. Such a variety does not meet the relevant Codex standard that calls for a comparator that has a history of safe use and is non-GM. The use of a GM comparator reduces the scope for identifying differences in LY038 to be subjected to detailed study.

- FSANZ nonetheless identified a significant difference: the levels of free lysine and lysine breakdown products. In the presence of reducing sugars, lysine, protein and lysine breakdown products form AGEs. FSANZ implicitly confirmed that eating LY038 would lead to an increase in the amounts and types of dietary AGEs, but did not assess the potential impact of this on the grounds that their proportions were small. However, AGEs can have significant effects in small proportions, particularly with respect to vulnerable sub-groups of the population.

- The reactivity of lysine[87] also implies the formation of a series of by-products, some of which, experience suggests, may well be of concern in even very small proportions. FSANZ has not investigated the scope or potential effects of such reaction by-products.

- FSANZ acknowledges that "where the composition of food has been significantly changed, as is the case with high-lysine corn, feeding studies … may be useful". However the studies made available to it involved the feeding of uncooked corn to animals, whereas humans eat cooked and processed corn. The submitted studies are thus an inadequate basis for such assessment. Further, FSANZ has stated that it does not believe feeding studies are required when Codex guidelines recommend their use under these circumstances.

- At a series of critical decision-making points in the assessment process, FSANZ has concluded that a risk lacked significance without providing adequate evidence that it was not worthy of further investigation or requiring the applicant to provide additional information targeted at resolving the risk issue. Rather than adhere to the "explicitly cautionary approach"[88] it proclaims, at a number of points FSANZ has failed to apply precaution in practice.

[87] And certain breakdown products.

[88] ANZFA, *ANZFA's Standards Decision Making Framework: A Report to ANZFSC*, 2001, p 6.

- NZFSA's reviews of the FSANZ assessments have not identified to its minister the reasons why further investigation and precaution would be warranted at these decision points.

- FSANZ's conclusion to its assessment - that LY038 is as safe as conventional corn - cannot be deduced on the basis of the assessment carried out. It stands as an assertion, insufficiently supported by appropriate science.

- Similarly, the cost benefit analysis inadequately scopes risks and costs. The single consumer benefit identified - that "consumers can maintain confidence in the food supply" - is based on circular logic. Given the absence of valid public benefits, were any allowance made for the health risks that remain unexplored, the cost benefit assessment would show a net cost to society.

- Further, had FSANZ examined alternatives, it should have revealed that the most cost effective option was not approving LY038 and allowing lysine to continue to be added as a separate supplement.

- Regulatory institutions depend on trust and confidence in their processes and findings. A decision that asserts safety beyond the capacity of the information available to support this undermines not just the credibility of the decision at hand, but also the credibility of the regulatory structure in general.

- New Zealand's need for trust and confidence in the regulator is even greater than Australia's due to New Zealand's very high level of reliance on food products for its export earnings. Annette King has noted that: "New Zealand and international consumers are increasingly aware of and concerned about what is in the food they eat. And in a world that is rapidly changing in respect of food production and consumption, New Zealand needs a food regulatory programme that enhances consumer protection and ensures the continued health of our trade in food and food-related products." [89]

- New Zealand has been an ardent champion of countries consistently adhering to international standards in food matters, so as to minimise its exposure to counter example when calling on importing countries to not adopt discriminatory practices, so inconsistencies are also important in this context.

- Finally, the New Zealand public has demonstrated a relatively high resistance to the consumption of GM foods of all forms and consequently seeks a high level of assurance with respect to the safety of any GM foods gaining approval. FSANZ did not deliver an assessment that undertook the extra levels of investigation justified by the significantly different LY038 nutritional profile.

[89] Annette King, *New Zealand Food Safety Authority briefing to Minister*, media statement, 30 August 2002.

5.2 Grounds for Opting Out

5.2.1 The Treaty Provisions

New Zealand has the right to stand aside from decisions adopted by the Ministerial Council under specified conditions. These are set out in the treaty governing the system of joint food standards, signed in 1995.[90] In particular:

> Where the New Zealand Minister considers that an approved food standard … would be inappropriate for New Zealand, the New Zealand Minister may inform the Council in a timely manner that New Zealand needs to vary from the food standard and shall also inform the Council of the relevant grounds for the variation.[91]

On 23 July 2007, the Ministerial Council determined by majority to approve LY038. (At least one Council member, Western Australia, opposed this.) A food standard for LY038 was duly gazetted in Australia on 2 August 2007. On the same day, New Zealand announced that it was not keeping to the normal timetable for adopting a Council decision. Food Safety Minister Annette King stated she had asked NZFSA to "provide her with more advice as to the appropriateness" of New Zealand accepting the Council decision when it was for a plant variety intended as an animal feed.[92]

In a letter to Canberra, the minister stated she wanted to examine whether the approval of LY038 was within the scope of the treaty and New Zealand's Food Act 1981.[93] Notwithstanding the intended role of the high lysine corn as a feed, if the law does in fact allow it to be approved as a food in New Zealand,[94] then concerns about LY038 itself need to be addressed and a decision made whether to "opt out" of the Ministerial Council decision.

While technically New Zealand could decline to approve LY038 by invoking the Food Act instead (which provides for a wide range of grounds),[95] it seems important in this instance to formally opt out so as to provide a direct signal to FSANZ, as further described in Section 6.2 below.

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90 Australian and New Zealand Governments, *Agreement Between the Government of Australia and the Government of New Zealand establishing a System for the Development of Joint Food Standards System,* 5 December 1995 (and since amended).

91 Annex D to the treaty, section 2 states (as per the ANZFA 2002 version):

> "(2) Where the New Zealand Minister considers that an approved food standard for which any reviews requested by the Council pursuant to Annex C have been completed would be inappropriate for New Zealand, the New Zealand Minister may inform the Council in a timely manner that New Zealand needs to vary from the food standard and shall also inform the Council of the relevant grounds for the variation."

92 Annette King, NZ Minister of Food Safety, *Pause on High Lysine Corn*, 3 August 2007.

93 "I intend to seek advice from my officials as to whether it is appropriate for New Zealand to proceed with the approvals of varieties intended for use as animal feed as joint standards under the Food Treaty. The New Zealand Food Act also covers only food intended for human consumption and I will also need to seek advice as to whether these approvals are within the scope of the Act. … The question as to whether these approvals are within the scope of the Treaty (and the Act) is such a matter." Annette King, to Senator the Hon Brett Mason, 27 July, 2007.

94 The concern appears to be interactions with other legislation, rather than the ability to consider a feed as a food *per se*. Personal communication, Bruce Burdon, NZFSA, 10 August 2007.

95 Part 2A, section 11E, provides that "In issuing any food standard, the Minister shall take into account the following: … (e) Such other matters as the Minister considers appropriate".

5.2.2 Specific Grounds

While the first part of this section has outlined a string of grounds for concern, the treaty provides a more limited scope for opting out.

> A standard may be inappropriate for New Zealand on one or more of the following grounds: exceptional health, safety, third country trade, environmental, or cultural factors.[96]

Relevant exceptional grounds are as follows:

> ***Risks from AGEs***
> Consumption of cooked LY038 is likely to result in the ingestion of novel AGEs or novel concentrations of AGEs. While the scope of AGE products that will result from the elevated levels of lysine, its breakdown products, and cDHDPS in LY038 is unclear, the best science available implicates AGEs in a range of serious diseases, directly or indirectly. Due to the breadth and significance of their potential effects, even in the small proportions expected from consumption of LY038, the Sustainability Council believes avoidance of these risks is precautionary and warranted given the complete absence of any compensating consumer benefits or other public benefits.
>
> ***Risks from Toxic Reaction By-products***
> As one of a group of reactive amino acids, lysine and its breakdown products carry the demonstrated potential to react in ways that produce toxic by-products. While the type and concentration of toxic reaction by-products that may result from the elevated levels of lysine in LY038 is unclear, due to their potential effects, the Sustainability Council believes that avoidance of this risk is precautionary and warranted given the complete absence of any compensating consumer benefits or other public benefits.
>
> ***Risks to Regulatory Credibility***
> FSANZ has put forward findings that cannot be deduced from the information presented in its assessment report, but are instead assertions. In particular, it has stated that LY038 has met the assurance standard of being as safe as conventional corn without having the evidence to sustain this. FSANZ has also conducted its assessment on a basis that does not consistently follow international guidelines. The Sustainability Council considers that a number of FSANZ's claims lack credibility and that this undermines trust and confidence not only in the LY038 decision but the regulatory system as a whole. When seeking a first review of FSANZ's assessment report, Annette King stated "The process may, as a result, need revisiting in order to ensure consumer confidence is maintained."[97] The New Zealand economy's dependence on food export income and 'clean green' branding makes it unusually exposed to a lack of regulatory credibility. The health and safety of New Zealanders also depends on a credible regulatory structure.

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[96] Annex D to the treaty, section 4 (as per the ANZFA 2002 version)
[97] Annette King, *King seeks a Ministerial Council review of GM corn approval*, 21 February 2007.

Risks of a Precedent that Lowers Assessment Standards

Through not following a precautionary interpretation of the international guidelines, FSANZ has presented a position that, if accepted by New Zealand, invites future applicants to seek a similarly less stringent basis for assessment on the grounds of consistency. Consistency is stressed as important in the Codex guidelines. To the extent that this precedent can be used as an instrument to lower future assessment standards or even forestall the rejection of an application, it represents a risk to health and safety.

Collectively, these grounds would appear more than adequate to satisfy the opt out conditions – including conformance to New Zealand's WTO obligations,[98] as discussed in Section 4.3 above. As they are unlikely to be subject to any formal legal test, it is essentially a question of the extent to which they satisfy the treaty partners' interpretation in terms of the political aspiration for common food standards in absence of good reason.

New Zealand has once previously exercised the opt out provisions when in November 2005 it elected to stand aside from the FSANZ recommendation that country of origin labelling for food products be mandatory. The Cabinet paper prepared by NZFSA in support of opting out stated that "this action would set a precedent" in terms of the treaty relationship with Australia.[99]

New Zealand advised Canberra of its concerns regarding the inconsistency of the assessment with Codex guidelines in its first response to the FSANZ assessment report. All other members of the Ministerial Council have been informed in general terms of most of the risks identified above prior to making their individual responses to the Ministerial Council.[100] Thus the Australian treaty partners have had sufficient warning and opportunity to seek a different outcome if they sought to avoid the prospect that New Zealand would opt out on this decision.

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98 The treaty requires that any food standards (and hence the absence of approving a food standard) is consistent with WTO agreements, and states.

> "(2) In addition, food standards developed under the Australia New Zealand Food Standards System shall be: …
> (c) consistent with the obligations of both Member States under the Agreement establishing the World Trade Organization done at Marrakesh on 15 April 1994." (Annex A, section 2 (c) to: Australian and New Zealand Governments, *Agreement Between the Government of Australia and the Government of New Zealand establishing a System for the Development of Joint Food Standards System,* 5 December 1995 (and as since amended)

99 Office of the Minister of Food Safety, *Country of Origin Labelling: Proposed Joint Australia/New Zealand Food Labelling Standard*, CBC (05) 214, 28 October 2005, p 6.

100 FSANZ reported on its responses to submissions raising these issues.

6. Recommendations

6.1 Responding to the FSANZ Approval of LY038

6.1.1 Opting Out

In light of the wide-ranging concerns identified above, it would be prudent for New Zealand to opt out of the Ministerial Council's decision on LY038 on the basis of the exceptional grounds outlined above.

6.1.2 In the Case of Further Investigations by New Zealand

At the point New Zealand opts out of a FSANZ decision regarding a food standard, we understand there is no process remaining under New Zealand law that would allow an applicant to reapply for approval. Equally, there is nothing stopping New Zealand undertaking its own subsequent evaluation and determining whether to decline or approve LY038 as a food.[101]

If New Zealand authorities do wish to further consider LY038 after opting out, they may wish to pursue more thorough and comprehensive testing of LY038 under arrangement with an independent laboratory or the developer. In the latter case, we recommend that an expert and independent panel be established to oversee the design and interpretation of the scientific experiments conducted to test LY038 as a human food. The panel would consider the need for additional molecular and compositional studies, including the use of a conventional comparator, and appropriate feeding studies.

The panel should consist of members with food safety and human medicine expertise and not plant breeding per se (which is not sufficient for comprehensive identification of human risks). The results of this investigation should be made public, both to ensure transparency and to reassure New Zealanders that LY038 has benefited from a robust evaluation using the best available science of the day.

6.2 Proposals to the Ministerial Council

The issues identified in this report make clear that changes are required in the way FSANZ responds to future applications for novel foods. Section 11 of the FSANZ Act provides for the Ministerial Council (by way of the relevant Australian minister) to give written direction to FSANZ on matters of policy.[102]

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[101] Personal Communication, NZFSA representative, 14 August 2007.

[102] Section 11 provides that:

> "(1) Subject to subsection (3), the Minister may give written directions to the Authority as to the performance of its functions and the exercise of its powers and the Authority must comply with those directions. …
>
> (3) The Minister must consult with the Council before he or she gives a direction under subsection (1)."

The following are proposed as a basis for directions to be provided to FSANZ. Each could be given effect though a variation to the FSANZ Applications Handbook.

1. **An application for a novel GM food must be backed by safety assessment information that uses as the conventional counterpart a plant variety that (1) is not itself a GMO, (2) has a history of safe use, and (3) is the closest possible parental variety**.
   This would ensure that any application is processed in accordance with the expectations set by the Codex guidelines, with non-conforming applications being rejected prior to any assessment. While the draft Applications Handbook made frequent reference to the standard being a "non-GM counterpart",[103] the recently issued version of the handbook refers only to "an appropriate comparator (usually the non-GM counterpart)".[104]

2. **An application for a novel GM food must explain as a part of that application why any variation from the maximum standard of safety testing permitted under the Codex guidelines (including the types of studies allowable) has not been followed, such information to be appended to the assessment.**
   While it is quite conceivable that there will be novel foods for which the maximum standard of safety testing permitted under Codex is either redundant or inappropriate, the burden should be placed on the applicant to fully explain any such departure at the outset so that FSANZ may elect to accept the application in light of the explanation, or specify the further information required before it would be accepted. This practice would also underscore an expectation of adherence to a precautionary approach and incentivise developers to incorporate precaution into their development plans.

3. **All information FSANZ relies upon for the determination of an application shall be made publicly available, including the raw data underlying any study.**
   At present, an applicant can interpret raw data from a study in a way that favours approval and then seek confidentiality for that study. The practical effect of this is to foreclose the opportunity for independent scrutiny that, as the Séralini study shows, can identify issues that have not been picked up by regulatory authorities.

   A requirement to provide the raw data and agree to public disclosure provides a positive incentive for applicants to develop cutting-edge safety testing and statistical techniques. Naturally, information that is legitimately confidential but not required for safety testing can be excerpted from the public version. However, as a matter of principle and as a necessary means to audit the regulator, all information FSANZ relies upon for the determination of an application must be made publicly available.

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103 FSANZ, Draft *Application Handbook,* October 2006. Section 3.5.1 C 5 p 58, 59, refers three times to "the non-GM counterpart".

104 FSANZ, *Application Handbook*, August 2007, s 3.5.1 C 5 P 97.

4. **An application to FSANZ must be accompanied by all relevant and associated studies conducted by or on behalf of the applicant, reported to the applicant in some way, or held by the applicant. If a failure to conform to this is subsequently discovered, this shall result in immediate withdrawal of the relevant food standard and a fresh application being required.**

   FSANZ states that at present: "there is a requirement for *all* applicants seeking amendment to the *Food Standards Code*, irrespective of the nature of the application, **not** to withhold information that could impact the regulatory decision taken in respect of their application" [105] (emphasis as per original). However, this leaves open the ability for the applicant to have commissioned, or be aware of, other studies and yet not be bound to provide such information to the regulator. Moreover, it does not define what kind of studies would be relevant to a regulatory decision and thus leaves the applicant to make a decision that cannot be reviewed by the regulator or the public.[106] Further, there appears to be no sanction should an applicant fail to comply with even the existing scope of the rule. In order to rectify the incentive structure, the appropriate response is that if an applicant withholds relevant studies from the regulator, and thus biases the range of scientific information from which it can make its assessment, this should trigger immediate revocation of the relevant food standard.

5. **An application for a novel GM food must provide for public disclosure sufficient information about the GM food to allow for its independent third party detection and identification, as is the case in Europe.**

   At present, it is up to applicants to voluntarily make commercial arrangements with selected laboratories for the provision of the information required to determine whether or not a GM construct detected is one for which a food standard has been issued. A requirement to provide the relevant information for public disclosure, as is mandated by the European Commission,[107] allows for testing to be undertaken by any third party.

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[105] FSANZ, Letter to the Sustainability Council, 19 December 2006. The specific declaration required of an applicant in the handbook is that "No information has been withheld that might prejudice this application, to the best of my knowledge and belief". See section 3.1.10 p 47.

[106] What science would be relevant is also not a settled issue as a recent debate in the Australian Environmental and Law Planning Journal illustrates. Heinemann, J.A, Letter to the Editor, Environmental Planning Law, J. 24 p.157-160.

[107] The European Commission requires that:

> "A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Annex III:
>
> …..
>
> 7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,"

(Directive 2001/18/EC of the European Parliament and of the Council, 12 March 2001, on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Annex IV, p 32.)

6 An application for a novel GM food shall include a feeding study with that food over the period of rapid growth of the animal, using at least two animal species (one non-rodent) that would represent a good model for human ingestion.

This is effectively the standard that was proposed in the draft Applications Handbook (although then with only one animal type).[108] The current version of the handbook states instead that "There is no requirement for an animal feeding study to be conducted on the GM food, however, such a study may provide additional re-assurance that the GM food is at least nutritionally equivalent to the non-GM counterpart food".[109]

As New Zealand has just one vote of nine on the Ministerial Council, should it believe such proposals are important to advance and finds any are not supported through to a change in assessment practice, New Zealand then has the option to communicate to the Council its unwillingness to accept a future food standard that was assessed on a basis contrary to the proposals is has put forward.

[108] FSANZ, Draft *Application Handbook*, October 2006. It stated "This part shall include a feeding study with the GM food over the period of rapid growth of the animal, using an animal species that would normally consume the non-GM counterpart food"..

[109] FSANZ, *Application Handbook*, August 2007, s 3.5.1 D 2.

List of Appendices

1. Parental Lineage: LY038 and LY038(-) Relatedness

2. *The risks of foods that have been genetically engineered to produce high concentrations of Lysine*, Dr Garth Cooper.

3. *The risks of corn that has been genetically engineered to produce high concentrations of lysine and a number of its breakdown products,* Dr Jack Heinemann.

4. Letter from Food Standards Australia New Zealand to Sustainability Council, 19 December 2006.

5. *COT Statement on Tryptophan and the Eosinophilia-Myalgia Syndrome,* UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment.

These are set out in a separate volume