ANZFA

TE MANA WHAKARITE KAI
MO AHITEREIRIA ME AOTEAROA

FULL ASSESSMENT REPORT AND REGULATORY IMPACT ASSESSMENT

SUBJECT: A338 û FOOD DERIVED FROM GLYPHOSATEûTOLERANT SOYBEANS

EXECUTIVE SUMMARY

ò The Australia New Zealand Food Authority (ANZFA) received an application from Monsanto Australia Ltd on 24 March 1997 to amend the *Food Standards Code* to include food derived from glyphosateûtolerant soybean line 40û3û2 in the Table to clause 2 of Standard A18 û Food Produced Using Gene Technology;

ò Standard A18 was adopted as a joint Australia New Zealand standard in July 1998 and is due to come into effect on 13 May 1999. After that time, the sale of food produced using gene technology will be prohibited unless the food is listed in the Table to the Standard;

ò Glyphosate is the active ingredient of the proprietary herbicide Roundup which is used widely as a nonûselective agent for the control of weeds in crops. It acts by inhibiting an enzyme called 5ûenolpyruvyl shikimateû3ûphosphate synthase (EPSPS), an essential enzyme involved in the biosynthesis of aromatic amino acids in all plants, bacteria and fungi. Animals, including humans, do not produce EPSPS as they obtain aromatic amino acids from dietary sources;

ò Glyphosate tolerance has been achieved in soybean line 40û3û2 by the transfer of a bacterial EPSPS gene (known commercially as the Roundup Ready gene) to the plant. The bacterial enzyme, encoded by the transferred gene, is not inhibited to the same degree as the soybean EPSPS. Hence, the activity of the bacterial EPSPS is sufficient to sustain the metabolic functions of the plant in the presence of the herbicide;

ò Soybean plants containing the EPSPS gene have been grown without restriction in the United States for several years, with the first commercial crops harvested in late 1996 when they constituted around 1û2% of the total US crop. Since that time, a proportion of glyphosateûtolerant soybeans have been entering commercial markets, including Australia, without differentiation from conventional soybeans;

- ò Soybeans imported from the US are mainly processed into vegetable oil, which is supplied to the food industry for a variety of uses, and protein meal which is mainly supplied to animal feed manufacturers. Potentially, a small amount of the protein meal (~ 3%) may also be used in products destined for human consumption;

- ò A full data package for glyphosateûtolerant soybean line 40û3û2 was submitted by the applicant for assessment. Quality Assurance certification was provided that the studies were done in accordance with Good Laboratory Practice and that the information presented in the application accurately reflects the raw data generated during the studies.

- ò The submitted data has been evaluated according to ANZFAÆs safety assessment guidelines for foods produced using gene technology. This assessment found the following:

    - û the only new gene which has been transferred to glyphosateûtolerant soybean line 40û3û2 is that which codes for the bacterial EPSPS;

    - û the bacterial EPSPS gene has been stably integrated into the soybean genome and is stably inherited from one generation to the next;

    - û the bacterial EPSPS is functionally and structurally similar to plant EPSPSs and other EPSPSs present in the food supply;

    - û data from acute toxicity tests in mice, and comparative analyses with known toxins, combined with the knowledge that the bacterial EPSPS is closely related to plant EPSPSs already in the food supply, does not indicate that there is any potential for the bacterial EPSPS to be toxic to humans;

    - û the bacterial EPSPS does not have characteristics that are typical of known food allergens and there is no history that this family of EPSPS proteins are allergenic;

    - û there is no evidence, from tests with human sera, that glyphosateûtolerant soybean line 40û3-2 has increased allergenicity in comparison to conventional soybeans;

    - û there are no significant differences in the levels of major constituents, nutrients, antiûnutritional factors or natural toxicants between glyphosateûtolerant soybean line 40û3û2 and conventional soybeans in either whole soybeans or any of the processed fractions; and

    - û glyphosateûtolerant soybean line 40û3û2 provides a nutritive and wholesome diet which is equal to that of conventional soybeans;

- ò Therefore, no potential public health and safety concerns were identified in the assessment. Food derived from glyphosateûtolerant soybean line 40û3û2 can be regarded as substantially equivalent to food from conventional soybeans in respect of its composition, safety, wholesomeness and end use:

- ò Under Standard A18, as currently drafted, food derived from glyphosateûtolerant soybean line 40û3û2 would not require labelling as it can be regarded as substantially equivalent to food from conventional soybeans. However, under proposed amendments to Standard A18, as a result of a recent decision of the Australia New Zealand Food Standards Council (ANZFSC), it is likely that certain soybean products may require labelling once these amended provisions take effect. It is proposed that interim labelling requirements not be recommended at this stage. The labelling requirements will be resolved and put into effect, when the labelling amendments to Standard A18 are decided;

- ò The regulatory impact analysis concluded that, as glyphosateûtolerant soybeans do not pose any greater risk to public health and safety than conventional soybeans, an amendment to the *Food Standards Code* to list food derived from glyphosateûtolerant soybean line 40û3û2 in the Table to Standard A18 is necessary, cost effective and of benefit to both industry, government and consumers.

BACKGROUND

Standard A18

On 30 July 1998, the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt Standard A18 for the regulation of foods produced using gene technology.

In Australia, the Standard was gazetted on 13 August 1998. In New Zealand, the decision was gazetted, as a mandatory standard, on 20 August 1998. The Standard will come into effect in both countries on 13 May 1999, nine months after the Australian gazettal date, to allow the Australia New Zealand Food Authority (ANZFA) time to consider applications for food already in the market place, prior to implementation of Standard A18.

Under Standard A18, the sale of food produced using gene technology is prohibited unless they are included in the Table to clause 2 of the Standard and comply with any special conditions so listed in the table. Inclusion in the table is contingent on satisfying a preûmarket safety assessment by ANZFA. The standard also contains a provision for labelling of food that contains new or altered genetic material and which is no longer substantially equivalent to its conventional counterpart. Specifically, the standard will require labelling of food where the nature of the food has been significantly changed with respect to its nutritional quality, composition, allergenicity, or end use.

On 17 December 1998, ANZFSC decided that the mandatory labelling requirements should be extended to foods produced using gene technology that are also substantially equivalent. Specifically it was decided that an amendment to the *Food Standards Code* should be developed which takes into account the need to:

(a) label if the manufacturer knows the food contains genetically modified material; and

(b) if the manufacturer is uncertain about the foods contents, they must indicate that the food may contain genetically modified material.

ANZFSC recognised that there are many foods, such as oils and sugars which can be made from genetically modified crops but which can be virtually identical to their conventional counterparts. ANZFSC has agreed that these products should be exempted from a labelling requirement. ANZFA is in the process of developing an appropriate amendment to Standard A18. A timetable for the implementation of these new provisions has yet to be determined.

Application A338

On 24 March 1997, the Authority received an application from Monsanto Australia Limited to amend the *Food Standards Code* to include food derived from glyphosateûtolerant soybean line 40û3û2 in the Table to clause 2 of Standard A18 û Food Produced Using Gene Technology. As this application was received prior to the adoption of Standard A18, its assessment could not proceed until the standard had been agreed to by ANZFSC. Assessment of this application did not recommence until 10 September 1998.

Soybeans are a traditional source of protein and oil for human consumption. Foods that contain soybean protein include bakery products, confections, meat products, textured foods and nutritional supplements. Soybean protein isolate is also the protein source for soyûbased infant formula. The oil is typically used in margarine, shortening, cooking oil, salad oil and mayonnaise. Lecithin, derived from crude soybean oil, is used as a natural emulsifier, lubricant and stabilising agent.

Glyphosateûtolerant soybean plants have been grown without restriction in the United States for several years, with the first commercial crops harvested in late 1996 when they constituted around 1û2% of the total US crop. Consequently, a proportion of glyphosateûtolerant soybeans enter commercial markets, including Australia, without differentiation from conventional soybeans. Bulk consignments of soybeans from the US, containing a proportion of glyphosateûtolerant soybeans, currently enter Australian markets because, as yet, there is no legal requirement for their preûmarket approval. The implementation of Standard A18 will require these glyphosateûtolerant soybeans to have undergone an approval process for use in food.

The imported soybeans are mainly processed into vegetable oil, which is supplied to the food industry for a variety of uses, and protein meal which is mainly supplied to animal feed manufacturers, although a small proportion (~ 3%) may also potentially be used in products destined for human consumption.

Glyphosate is the active ingredient of the proprietary herbicide Roundup which is used widely as a nonûselective agent for the control of weeds in crops. The use of Roundup is reported to provide soybean growers with an alternative weed management option, in place of other herbicides, while maintaining optimal yields of highûquality harvest, essentially free of weed seeds.

The mode of action of glyphosate is to specifically inhibit the activity of 5ûenolpyruvyl shikimateû3ûphosphate synthase (EPSPS), an essential enzyme involved in the biosynthesis of aromatic amino acids in all plants, bacteria and fungi. Animals do not produce EPSPS as they obtain their aromatic amino acids from dietary sources.

Glyphosate tolerance has been achieved in soybean line 40û3û2 by the transfer of a bacterial gene derived from *Agrobacterium* species strain CP4, which produces an EPSPS enzyme (CP4 EPSPS). The bacterial enzyme is not inhibited to the same degree as the soybean EPSPS and its activity is sufficient to sustain the metabolic functions of the plant in the presence of the herbicide.

The purpose of the genetic modification is primarily to assist in agricultural production only, with no intention to alter any characteristic or property of the foods derived from the soybean. The applicant claims that the use of glyphosateûtolerant soybeans is expected to reduce overall agrochemical usage, maximise yield and reduce production costs.

OBJECTIVE

The objective, in addressing the issue of permitting the sale of food derived from glyphosateûtolerant soybeans, is to allow innovation in the food industry without compromising public health and safety or the provision of information to consumers to enable informed choice.

RELEVANT PROVISIONS

Australian *Food Standards Code*

Food produced using gene technology is currently provided for in Standard A18. This Standard will come into effect on 13 May 1999. Following a decision of the ANZFSC in December 1998, amendments to the labelling provisions of Standard A18 are proposed. The procedure and timing for implementation of these new provisions has yet to be determined.

New Zealand *Food Regulations*

As a result of the Agreement in 1995 between the Governments of Australia and New Zealand, a joint *Australia New Zealand Food Standards Code* is being developed by the Authority. The decision of ANZFSC to adopt Standard A18 was gazetted in New Zealand, as a mandatory standard, on 20 August 1998 and will apply in both countries on the same day, that is 13 May 1999.

Codex Standards

There are currently no Codex provisions relating to the preûmarket assessment or labelling of foods produced using gene technology. Draft Codex recommendations for the Labelling of Food Obtained through Biotechnology (proposed draft amendment to the General Standard for the Labelling of Prepackaged Foods) are at Steps 3 and 5 of the Codex process[1].

PUBLIC CONSULTATION

The Authority has received a total of six applications from Monsanto Australia Ltd for a variety of foods produced using gene technology. Due to commonalities in these applications, a combined preliminary assessment report was prepared. The Authority released the combined preliminary assessment report for public comment on 28 October 1998 and submissions were accepted until 23 December 1998. Each application, however, is to be assessed individually at Full Assessment. A total of 58 submissions were received by the closing date of 23 December 1998. These submissions are primarily from individuals, consumer organisations and special interest groups from both New Zealand and Australia.

OPTIONS including alternatives to regulation

As Standard A18 requires preûmarket assessment of foods produced using gene technology it is not appropriate to consider nonûregulatory options. Only two regulatory options will be considered.

Option 1 û no approval

The status quo would be maintained and no specific approval would be given in the *Food Standards Code* for food derived from glyphosateûtolerant soybean line 40û3û2. This would need to be based on an identified public health and safety concern.

[1] Δυε το λαχκ οφ χονσενσυσ οπερ δραφτ προπισιονσ ρελατινγ το τηε λαβελλινγ οφ φοοδσ τηατ αρε συ βσταντιαλλψ εθυιπαλεντ, ωηιχη ρεμαινσ ατ Στεπ 3, ονλψ τηε προπισιονσ φορ α δεφινιτιον ανδ λαβελ λινγ φορ τηε πρεσενχε οφ αλλεργενσ ηαπε αδπανχεδ το Στεπ 5

Option 2 û approval

The *Food Standards Code* would be amended to include food derived from glyphosateûtolerant soybean line 40û3û2 in the Table to clause 2 of Standard A18.

IDENTIFICATION OF AFFECTED PARTIES

Parties affected by the options listed above include:

- consumers
- State, Territory and New Zealand Health Departments
- Australian Quarantine and Inspection Service
- manufacturers and producers of food products that are likely to be derived from glyphosateûtolerant soybeans
- suppliers of soybeans and soybean products to manufacturers

ASSESSMENT

1. Summary and Conclusions of the Safety Assessment (see Attachment 3)

Glyphosateûtolerant soybean line 40û3û2 contains a single new gene derived from the bacterium *Agrobacterium* sp. strain CP4. This gene encodes the protein enolpyruvyl shikimateû3ûphosphate synthase (EPSPS) which is an essential enzyme involved in the synthesis of aromatic amino acids. Soybeans naturally contain an enzyme of this type, however, the plant EPSPS is inhibited by the herbicide glyphosate, whereas the bacterial EPSPS is not. Therefore, the transfer of the bacterial EPSPS to soybean enables the plant to withstand applications of the herbicide. This would allow postûemergent use of glyphosate on soybean crops.

Considerable data has been presented by the applicant to establish that food derived from glyphosateûtolerant soybean line 40û3û2 is equivalent to the parental soybean, line A5403, as well as other commercial varieties of soybeans, in all respects apart from the expression of the CP4 EPSPS gene. This data included molecular and genetic analyses of the new soybean line, an examination of the potential for the newly expressed protein to be toxic or allergenic to humans, compositional analyses of the soybeans, and animal feeding studies to establish the wholesomeness of the glyphosateûtolerant soybean line in comparison to conventional soybeans.

The molecular and genetic analyses provided by the applicant indicate that the introduced gene for CP4 EPSPS has been stably integrated into the plant genome and is stably inherited from one generation to the next.

The applicant submitted data which shows that the newly expressed protein, CP4 EPSPS, has been evaluated for its potential to be toxic or allergenic to humans. This included acute toxicity tests using mice, comparison of the amino acid sequence of the protein with known toxins and allergens, examination of digestion of the protein in simulated mammalian digestive systems, and testing against human sera taken from individuals known to be allergic to soybeans. The evidence does not indicate that there is any potential for the CP4 EPSPS protein to produce adverse effects in humans. The CP4 EPSPS protein also does not have characteristics that are typical of known food allergens and there is no indication, from tests with human sera, that glyphosateûtolerant soybean line 40û3-2 has increased allergenicity in comparison to conventional soybeans.

The compositional analyses were comprehensive and indicate that there are no significant differences in the levels of major constituents, nutrients, anti-nutritional factors or natural toxicants between glyphosateûtolerant soybean line 40û3û2 and the parental soybeans for either whole soybeans or any of the processed fractions. The animal feeding studies presented by the applicant indicate that glyphosateûtolerant soybeans provide a nutritive and wholesome diet which is equal to that of the parental line of soybeans.

In conclusion, no potential public health and safety concerns have been identified in the assessment. Food derived from glyphosateûtolerant soybean line 40û3û2 can be regarded as substantially equivalent to food derived from conventional soybeans in respect of its composition, safety, wholesomeness and end use.

2. Issues Raised by Public Submissions

A total of 58 submissions in relation to the combined preliminary assessment were received by the closing date of 23 December 1998 in response to the section 14 Gazette Notice. Very few of the submissions specifically addressed any of the details of the individual applications or provided the Authority with any additional information. Rather, the majority of submissions made statements against the use of the technology, asserted that food produced using this technology is unsafe for human consumption and expressed opposition to any amendment to Standard A18 to permit the sale of such food. A summary of the submissions is attached (Attachment 4). An evaluation of the issues raised by the submissions appears below. Where possible, individual submitters or organisations are identified, however, where a large number of submissions addressed the same issue it was not possible to list the submitters individually.

GENERAL ISSUES RAISED BY SUBMISSIONS

1. The safety of genetically modified foods for human consumption

A majority of submitters raised the issue of public health and safety in relation to food produced using gene technology. In particular, it was stated that there has been inadequate testing of genetically modified foods, that there is limited knowledge concerning the risks associated with the technology and that there may be potential longûterm risks associated with the consumption of such foods.

Evaluation

It is a reasonable expectation of the community that foods offered for sale are safe and wholesome. In this context, æsafeÆ means that there is a reasonable certainty of no harm. As with other aspects of human behaviour, the absolute safety of food cannot be guaranteed. Conventionally produced foods, while having a long history of being considered as safe, are associated with human disease and carry a level of risk which must be balanced against the health benefits which they contribute as part of a nutritious and varied diet.

Because the use of gene technology in food production is relatively new, and a long history of safe use of these foods has yet to be established, it is appropriate that a cautious approach is taken to the introduction of these foods onto the market. The purpose of the preûmarket assessment of a food produced using gene technology under Standard A18 is to establish that the new food is at least as safe as existing foods.

New technologies, including gene technology, are, therefore, assessed, in part, by a comparison to the benchmark of commonly consumed foods which are already regarded as safe. This concept has been adopted by both the World Health Organisation (WHO)/Food and Agriculture Organisation (FAO) and the Organisation for Economic Cooperation and Development (OECD). The Authority has developed detailed procedures for the safety assessment of foods produced using gene technology that are consistent with international protocols developed by these bodies. The data available indicate that food from the glyphosateûtolerant soybean line 40û3û2 is equivalent to the other commercial varieties of soybeans in all aspects apart from the expression of the protein from the EPSPS gene which is not associated with any acute toxicity in mice and furthermore, does not have any characteristics which indicate it may have potential as either a toxin or allergen in humans. In addition, the applicant tested extracts of the glyphosateûtolerant soybean and determined that this plant line does not demonstrate any increase in allergenicity when compared to conventional soybeans. The protein is very similar to a protein which is already present naturally in soybeans. In addition, the soybeans were found to be equivalent to conventional soybeans in terms of their ability to support typical growth and well being in animals. Overall, the data indicate that the glyphosateûtolerant soybeans are as safe and wholesome for human consumption as conventional soybeans.

2. Substantial equivalence

J. Chapple (NZ) and N. Green (NZ) objected to the use of æsubstantial equivalenceÆ as a means of establishing the safety or otherwise of foods produced using gene technology. The Natural Law Party (NZ) submitted that they reject the premise of substantial equivalence on the grounds that differences at the DNA level make foods substantially different.

Evaluation

The concept of æsubstantial equivalenceÆ has been internationally recognised and embraced as a valuable tool in the safety assessment of foods produced using gene technology. This concept was first espoused by a Joint Consultation of the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) in 1991 where it was established that the *comparison of a final product with one having an acceptable standard of safety provides an important element of safety assessment.*

Since the establishment of that principle, work by the OECD on food safety and biotechnology has also focussed on this concept. The OECD advocates an approach to safety assessment based on substantial equivalence as being ôthe most practical to address the safety of foods and food components derived through modern biotechnologyö.

Substantial equivalence embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety as its traditional counterpart. Substantial equivalence encompasses both phenotypic[2] characteristics and compositional comparisons. Genotypic differences (ie differences at the DNA level) are not normally considered in a determination of substantial equivalence if that difference does not significantly change the composition of the new food relative to the conventional food.

The concept of substantial equivalence provides a commonsense approach to the evaluation of a food produced using gene technology. It allows the evaluator to determine in a systematic fashion if there have been any significant changes to important constituents of a new food. It is also important to note that, although a particular food or food component may be found to be not substantially equivalent to an existing food or food component, this does not necessarily mean that it is unsafe. Such a food will need to be evaluated on the basis of its composition and properties.

[2] characteristics that are visible

3. Labelling of foods produced using gene technology

A majority of submissions focussed on this issue. Specifically, the submitters expressed a desire that all foods produced using gene technology be labelled, regardless of whether or not they are substantially equivalent to conventional foods. The submitters based their demands for full labelling on the presumption that all foods produced using gene technology are unsafe and on consumer ôright to knowö arguments. It was stated that full labelling will enable identification and possible avoidance of such foods in the market place.

Evaluation

In the development of Standard A18, the Authority recommended that foods produced using gene technology, that are no longer substantially equivalent to their conventional counterparts, be labelled. This recommendation was adopted by ANZFSC and Standard A18 was gazetted in August 1998, to come into effect in May 1999. In December 1998, ANZFSC decided that foods produced using gene technology that are substantially equivalent should also be subject to mandatory labelling, with the exception of certain products that are highly refined and purified and contain no new or altered genetic material, such as oils and sugars. The Authority is currently preparing an amendment to Standard A18 to this effect.

4. Timing of assessment of applications

C. Elwell (NZ), Berylla (NZ), Friends of the Earth (NZ), the Consumers' Federation of Australia Inc. and the National Council of Women of Australia suggested in their submissions that genetically modified foods should not be introduced until the recent labelling decision of Health Ministers is implemented. The Australian GeneEthics Network submitted that all approved foods should be labelled in keeping with the ANZFSC decision.

Evaluation

The implementation timetable for the new labelling provisions agreed to by ANZFSC on 17 December 1998 has yet to be determined. Standard A18 comes into effect on 13 May 1999 from which point on food derived from glyphosateûtolerant soybeans will be prohibited unless it is listed in the table to the standard. Currently, Standard A18 only provides for mandatory labelling in circumstances where the food is not substantially equivalent to its conventional counterpart. Therefore, as currently drafted, it is likely the food derived from glyphosateûtolerant soybeans will not require labelling. Standard A18 does allow for the imposition of special conditions. This could be used to impose interim labelling conditions on soybean products. However, this would entail drafting special requirements into Standard A18 ahead of resolution of the labelling amendments to the standard. This could prove problematic and would be inappropriate. Therefore, it is proposed that interim labelling requirements not be recommended at this stage. The labelling requirements will be

resolved and put into effect, when the labelling amendments to Standard A18 are decided.

5. The nutritional value of food produced using gene technology

C. Kell (NZ) submitted that the genetic alteration of food decreases its nutritional value. No supporting information was provided by the submitter.

Evaluation

The assessment of food produced using gene technology by ANZFA entails an assessment of any intentional or unintentional compositional changes that have occurred to the food. This assessment will take into account the major constituents of the food (fat, protein, carbohydrate, fibre) as well as the key nutrients (amino acids, vitamins, fatty acids). There is no evidence to suggest that genetic modification per se reduces the nutritional value of food and there are examples where genetic modification is being used to improve the nutritional value of food. Therefore, it does not necessarily follow that genetically modified foods will have reduced nutritional value. This will be assessed by ANZFA on a caseûbyûcase basis.

6. Public consultation and information about gene technology

M. and J. Gregory (NZ) submitted that the public has not been properly consulted or informed by government or ANZFA on the introduction of foods produced using gene technology. J. Adams (Aust), R. Anderson (NZ), N. Green (NZ), C. Elwell (NZ), Berylla (NZ) and Friends of the Earth (NZ) also submitted that there has been very little opportunity for public debate on the issue of genetically modified foods. The Natural Law Party (NZ) submitted that no further applications should be considered until there has been proper public debate.

A submission from Goodman Fielder (Aust) stated that it is fully supportive of developments in the agriûfood industry through the application of gene technologies provided that consumer benefits are clearly defined and communicated. They urged ANZFA to undertake wider consultation with all affected parties including growers, crushers (in the case of oilseeds), food industry users and consumers before these modified plants are introduced. They appreciate that regulation of markets is not within ANZFAÆs area of responsibility, but would like ANZFA to at least ensure that adequate consultation is undertaken as part of its assessment process.

Evaluation

The issue of gene technology and its use in food has been under consideration in Australia since 1992. The Agreement between the Governments of Australia and New Zealand for a joint food standard setting system, however, did not occur until 1995, therefore, the New Zealand community had not been consulted on this matter by the Authority until after that time. Consequently, Standard A18 only underwent

one round of public comment in New Zealand at which time significant objections were raised by the New Zealand community to the use of gene technology in food production.

Many New Zealand consumers, both in these submissions, and in previous submissions to the Authority, have expressed the view that there has been insufficient consultation and a consistent lack of information about gene technology.

Although ANZFA only undertook one round of public comment in New Zealand for the development of Standard A18, there is further opportunity for public consultation in the context of the current applications to vary Standard A18. This will involve two rounds of public comment. Furthermore, all the documentation (except for commercial in confidence information) relating to these applications will be available in the public domain, including the safety assessment reports. There is ample evidence that the provision of such information by ANZFA has already significantly stimulated public debate on this matter.

In addition, other potential sources of information about gene technology are available to consumers in New Zealand. These include:

ò The æGene PoolÆ which is an information resource established by the Gene Technology Information Trust, with initial funding from the Association of Crown Research Institutes in New Zealand. The function of the Gene Pool is ôto ensure the widespread dissemination of balanced, accurate, credible and timely information about gene technologyö. The Gene PoolÆs information resources include a website, a repository of publications, regular newsletter, fact sheets about various issues, a list of professionals available for public speaking engagements, and resources for schools and other learning institutions; and

ò The Environmental Risk Management Authority (ERMA), which is a statutory authority set up by the New Zealand Government to administer the *Hazardous Substances and New Organisms (HSNO) Act 1996*. It is the body that has responsibility for assessing the risks to the environment from genetically modified organisms. This body has been assessing applications for the approval of genetically modified organisms since July 1998 and this has involved a number of public meetings.

7. Maori beliefs and values

C. Elwell (NZ), Berylla (NZ) and Friends of the Earth (NZ) submitted that Maori people find genetic engineering in conflict with their beliefs and values and that out of respect to Maori, no genetically modified foods should be allowed into New Zealand until a wider discussion, both within Maori and nonûMaori, is held. In support, C. Elwell provided a copy of a report to the ERMA from a Maori advisory committee (Nga Kaihautu Tikanga Taiao) formally established under the *Hazardous Substances and New Organisms (HSNO) Act 1996* to advise on how to take account of issues of concern to Maori.

Evaluation

This is an issue that was also raised in a consideration of a proposal for the development of Standard A18. Then it was stated that the likely implications for Maori regarding genetically modified organisms surround the issues of the rights of Maori to the genetic material from flora and fauna indigenous to New Zealand and the release into the environment of genetically modified organisms. The *HSNO Act 1996* requires that these matters be considered by ERMA.

The report provided by C. Elwell indicates that the Nga Kaihautu is opposed, in principle, to any research that seeks to artificially modify the genome of an individual organism or species.

This issue appears to be of importance to the Maori. This, however, raises the question of the appropriate means of giving consideration to such issues. Both New Zealand and Australia have established mechanisms for the scrutiny of proposals to introduce viable new genetic material into the respective countries. As indicated above, this is the role of ERMA in New Zealand (and the Genetic Manipulation Advisory Committee and the associated arrangements to establish a Gene Technology Office in Australia). Issues of cultural belief and values concerning the use of genetically modified organisms should be dealt with in that context rather than through ANZFA processes given the statutory requirement that ANZFA focus upon the protection of public health and safety, consumer information, fair trading, industry development and international trade considerations. It would be inconsistent with the objectives of good government, administrative efficiency and clarity over responsibilities for two agencies to have overlapping responsibilities for this (or any other) matter.

8. Sources of genes being used to modify the crops

C. Kell (NZ) submitted that the applicant has failed to disclose the source of genes being used to modify the crops in question and goes on to state that ôit is a known fact that genes from animals and fish are being used.ö

Evaluation

The applications carry full details of the source of all the genes used in the modifications. None of the genetically modified plants in question have had either animal or fish genes transferred into them.

9. Environmental concerns

A number of submitters (N. Mc Rae *et al*, M. Rouse, C. Taylor, M. Karas, S. Parsons, J. Adams, W. Borst and B. Thrussell) have raised concerns that genetically modified crops may pose a risk to the environment. The Australian GeneEthics Network submitted that ôall proposals should be submitted for Genetic Manipulation Advisory

Committee (GMAC) assessment and recommendation including an updated and public review of Roundup Ready soy for environmental and health impacts.

Evaluation

These issues are considered in the assessment processes of GMAC in Australia and ERMA in New Zealand. The Authority has neither the expertise nor the mandate to assess matters relating to environmental risks resulting from the release of food produced using gene technology into the environment.

The glyphosateûtolerant soybeans are not grown in Australia or New Zealand, but rather are imported in Australia as whole seeds for processing. In 1996, GMAC undertook an assessment of this importation and found that it does not represent a significant biosafety risk, provided the soybeans remain physically contained during all stages of their transport and handling. The Australian Quarantine and Inspection Service (AQIS) controls and monitors all movement of imported soybean and trash remaining after processing. Any changes to the handling procedures or AQIS requirements would be notified to GMAC. GMAC further advised AQIS that particular attention should be paid to monitoring of movements of the imported soybeans to ensure that any escape of seed is minimised.

Currently, there are no formal mechanisms in place for the coordination of assessments and approvals of gene technology products by the various regulatory agencies in Australia. ANZFA, at this stage, also has no formal links with ERMA. However, informal links exist between ANZFA and other regulatory agencies and a large degree of information sharing occurs. It is highly unlikely that the Authority would make a recommendation for the approval of a food produced using gene technology if the genetically modified organism from which it was derived did not have the appropriate clearance for general release from either GMAC (or its successor) or ERMA, as appropriate.

10. Creation of market monopoly

J. Chapple (NZ) submitted that he is strongly opposed to the application on the grounds that approval of these foods may create a market monopoly for the applicant in the supply of agrochemicals. The Commerce Commission of NZ, on the other hand, stated that the applications do not raise any issues on which they would wish to comment.

Evaluation

The AuthorityÆs role is to develop and vary food standards and in so doing to ensure that public health and safety is protected and that consumers are provided with sufficient information to make informed choices about that food. It is not appropriate for the Authority to influence the market in these matters. Allegations of antiûcompetitive practice are more appropriately dealt with by other government bodies.

11. Toxins and allergens

R. Anderson (NZ), Consumers' Federation of Australia Inc. and N. Gannaway (NZ) expressed concerns about the risks of the introduction of new toxins or allergens.

Evaluation

It is possible to develop foods containing new toxins or allergens by gene technology or by traditional breeding techniques. It is also possible to use these techniques to develop foods specifically lacking such compounds. The advantage of gene technology is that the transferred genes are well characterised and defined, thus the possibility of developing a food with a new toxic or allergenic compound is likely to be reduced.

12. Antibiotic resistance

W. Borst (NZ), R. Anderson (NZ), F. Davies (NZ), O. Jones (NZ) and B. Thrussell (NZ) raised concerns about increased antibiotic resistance resulting from the use of gene technology. InforMed Systems Ltd (NZ) and the New Zealand Nutrition Foundation stated that it would be reassuring if independent biomedical advice were available to reassure us that the use of antibiotic resistance markers does not pose a risk to the future use of antibiotics in the management of human disease.

Evaluation

This issue arises because of the use of antibiotic resistance marker genes in the generation of genetically modified plants. Antibiotic resistance genes are often linked to the gene of interest which is being transferred. They enable the initial selection of the engineered cells by exposing them to antibiotic selection. Those cells that contain the antibiotic resistance marker gene will be able to survive and divide in the presence of the antibiotic. Those cells that do not contain the antibiotic resistance marker gene, and hence do not contain the gene of interest, will die in the presence of the antibiotic.

Concern has arisen that ingestion of food containing copies of antibiotic resistance genes could facilitate the transfer of the gene to bacteria inhabiting the gut of animals and humans. It is argued that these genes may then be transferred to disease causing bacteria and that this would compromise the therapeutic use of these antibiotics.

The World Health Organisation considered this issue in 1993 at a Workshop on the health aspects of marker genes in genetically modified plants. It was concluded at that Workshop that there is no recorded evidence of transfer of genes from plants to microorganisms in the gut and also that such transfers would be extremely unlikely given the complexity of the steps required. Antibiotic resistant bacteria are ubiquitous and normally inhabit the gut of animals and humans.

The transfer of antibiotic resistance genes is much more likely to arise from this source rather than from ingested genetically modified food.

13. Viral recombination

W. Borst (NZ), F. Davies (NZ) and O. Jones (NZ) all expressed concern about the long term effects of transferring viral sequences to plants.

Evaluation

The issue is one which is commonly raised as many of the genes that are transferred to plants are linked to a plant virus promoter. Promoters are controlling DNA sequences which act like a switch and enable the transferred genes to be expressed (ie to give rise to a protein product) in a plant cell. The routine use of these viral promoters is often confused with research which has shown that plant virus genes, which have been transferred into plants to render them virusûresistant, may recombine with related plant viruses that subsequently infect the plant, creating new viral variants. This research demonstrates that there may be a greater risk to the environment if viral genes are transferred to plants because it may lead to the generation of new plant virus variants capable of infecting a broader range of plants. This is a matter that will be addressed by the Genetic Manipulation Advisory Committee (GMAC) on a caseûbyûcase basis when it assesses such plants.

However, the presence of plant viruses, plant virus genes or plant virus segments in food is not considered to pose any greater risk to human health as plant viruses are ubiquitous in nature and are commonly found in food eaten by animals and humans. Plant viruses are also biologically incapable of naturally infecting human or animal cells.

SPECIFIC ISSUES RAISED BY SUBMISSIONS

1. Glyphosate residues

A large number of submitters expressed concerns about the presence of glyphosate residues on the glyphosateûtolerant soybeans. E. Attwood, the Consumers' Association of South Australia, the Consumers' Federation of Australia Inc, Mahikari Australia, the Natural Law Party, the Australian GeneEthics Network, the Pacific Institute of Resource Management/Revolt Against Genetic Engineering and the National Council of Women of Australia noted that no data was submitted by the applicant on the levels of glyphosate on imported soybeans. E. Phimister (NZ) submitted that the increased glyphosate residues on the glyphosateûtolerant soybeans should make them not substantially equivalent. The Australian GeneEthics Network added that the environmental and public health impacts of glyphosate should be assessed as part of the applications.

Background

The risk associated with the presence of chemical residues in food is managed through the establishment of maximum residue limits (MRLs).

The setting of MRLs is outside the Agreement between Australia and New Zealand for the development of a joint *Food Standards Code*. The TransûTasman Mutual Recognition Arrangement, which came into effect between Australia and New Zealand in July 1998, however, allows for the mutual recognition of MRLs between the two countries. That is, if MRLs differ, products imported from New Zealand into Australia need only comply with the New Zealand MRLs and vice versa. In New Zealand, there is also recognition of Codex MRLs for imported foods.

In Australia, MRLs are recommended by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) following an evaluation of actual field trials. In addition, an evaluation of toxicological and other safety data is undertaken by the Chemicals and Nonûprescription Drugs Branch of the Commonwealth Department of Health and Aged Care to determine that likely human levels of exposure will not result in adverse health effects.

ANZFA is responsible for incorporating Australian MRLs into the *Food Standards Code* and, in cooperation with these other government bodies, for ensuring that food containing such residues is safe for human consumption under foreseeable dietary conditions. The values set for MRLs define a legal limit above which residues should not occur if the chemical is used according to good agricultural practice. The MRLs set for chemical residues in the *Food Standards Code* are set well below the level at which adverse health effects may occur.

Evaluation

This issue has arisen because of an application that had been received by ANZFA from the NRA for an increase to the MRL for glyphosate on imported soybeans from 0.1 mg/kg to 20 mg/kg. This application was being assessed according to ANZFAÆs statutory processes but has subsequently been deemed to be withdrawn. The matter is now being considered as part of the review of Standard A14 û Maximum Residue Limits in the Review of the *Food Standards Code*.

The issue of glyphosate residues on glyphosateûtolerant soybeans is not considered to be relevant to a consideration of their safety as a food produced using gene technology under Standard A18 or a consideration of whether or not they are substantially equivalent. This is because residue levels are more appropriately addressed under Standard A14 when changes to MRLs are considered. Therefore, the applicant would not be required to submit such information for an assessment under Standard A18.

The glyphosateûtolerant soybeans are not segregated from conventional soybeans at source and are, therefore, imported into Australia and New Zealand in bulk,

nonûsegregated consignments.
All soybeans imported into Australia must comply with the current MRL for glyphosate in soybeans of 0.1 mg/kg and all soybeans imported into New Zealand must comply with the Codex MRL of 20 mg/kg. Both levels are considered to be well within the safe limits for this herbicide which is considered to pose very little risk to public health and safety because of its relatively low toxicity at the levels used in agricultural practice.

2. Animal testing

E. Attwood (Aust), the Consumers' Association of South Australia and the National Council of Women of Australia submitted that the animal testing done by the applicant in relation to glyphosateûtolerant soybean line 40û3û2 is inadequate to be assured of long term safety. R. James (NZ) submitted that the animals studies were too short in duration. The Australian GeneEthics Network submitted that no human and few animal tests have been done.

Evaluation

E. Attwood, the National Council of Women of Australia and R. James appear to be concerned with the fact that the animal feeding studies done by the applicant are of relatively short duration.

The animal feeding studies using glyphosateûtolerant line 40û3û2 were done to establish the wholesomeness of soybean meal and whole soybeans derived from this line. They were not designed specifically as toxicity tests but only to serve as indicators of whether there are unknown factors present in soybeans which affect animal growth and wellûbeing. Such feeding studies are typically of short duration because of the difficulties with interpreting the results of longûterm whole food animal feeding studies. This arises because of nutritional imbalances that result in the animals when their normal diets are heavily substituted with the test material.

Various international bodies (WHO/FAO, International Food Biotechnology Council), in fact, have recommended against the use of longûterm whole food animal feeding studies in the safety assessment of genetically modified foods as they are typically insensitive and beset with confounding factors, such as the nutritional imbalances referred to above. They recommend that detailed molecular, biological, and chemical analyses should always be done first before the need for animal testing is assessed. The nature and extent of such testing must then be carefully assessed in relation to the need to provide additional assurances of safety.

Assurances of longûterm safety cannot be categorically given for food, regardless of whether it is produced using gene technology or not. Detailed molecular, biological and chemical analyses are the best indicators of any unintended adverse effects and this information must be submitted to the Authority for preûmarket assessment.

The Australian GeneEthics Network is correct that very few animal toxicity tests were done by the applicant and no human studies. The animal toxicity tests done by the applicant are considered to be adequate and were only to provide additional assurances of safety. The comparative studies with other EPSPSs and the simulated digestion studies had already showed that there was very little potential for the bacterial EPSPS to be toxic to humans. Human studies can play an important role in the assessment of the safety of foods in that they too can provide additional assurances of safety. This is particularly the case for novel foods, provided animal studies have demonstrated no adverse effects. However, if the food in question is very similar to its conventional counterpart, as the glyphosateûtolerant soybeans are, then they would offer very little additional information. Therefore, the absence of human studies or additional animal studies for glyphosateûtolerant soybeans is not a concern.

3. Toxicity and allergenicity testing of bacterial EPSPS

A joint submission from the Pacific Institute of Resource Management (NZ) and Revolt Against Genetic Engineering (NZ) stated that the bacterial EPSPS protein is unlike any protein that humans have eaten and that there is no reliable method for predicting its allergenic potential. In addition, a submission from the National Council of Women of Australia said that although the bacterial EPSPS may be heat inactivated on processing, the application did not take account of the use of raw soybeans to grow sprouts. V. James (NZ) submitted that EPSPS had not been subjected to longûterm allergenicity testing. C. Elwell (NZ), Berylla (NZ) and Friends of the Earth (NZ) also stated that genetically engineered soybeans have been found to cause allergic reactions.

The Australian GeneEthics Network submitted that the toxicological studies provided by the applicant for the glyphosateûtolerant soybeans are ôbrief and insufficientö as they only checked the bacterial EPSPS against known protein toxins and allergens, and the simulated gastric and intestinal systems were only used on isolated EPSPS, not whole soybeans.

Evaluation

It is correct that there are no predictive assays available to assess the allergic potential of proteins, however, food allergens tend to have a number of characteristics in common. New proteins in the food supply can, therefore, be evaluated to determine if they share any characteristics of known allergens. One component of this analysis is to compare the amino acid sequence of the protein in question with the amino acid sequence of known allergens (and toxins). Significant homology to a known allergen (or toxin) could indicate that there may be cause for concern and would indicate that more extensive testing, including toxicity testing, is warranted. It would not be meaningful to search data bases of proteins, that have unknown allergenicity or toxicity, as any identified homology would not be helpful in determining whether there may be a public health and safety concern.

It is not correct to say that the bacterial EPSPS protein is unlike any protein that humans have eaten. All plant, microbial and fungal food sources contain EPSPSs, therefore, this type of enzyme is not novel to the human food supply. Furthermore, the bacterial EPSPS transferred to soybeans is functionally and structurally similar to the EPSPSs typically found in food. This family of proteins are not known to be either toxic or allergenic to humans.

The applicant, using a series of analyses, was able to demonstrate that the bacterial EPSPS does not have characteristics that are common to known allergens. One of these analyses used a simulated mammalian digestive system to show that the bacterial EPSPS is rapidly digested. The Australian GeneEthics Network is correct that this test was done on purified protein only, not on extracts of whole soybeans. Despite the fact that there may be technical limitations to doing such a test, there is no reason to suspect, from the way the purified protein behaved in these tests, that the bacterial EPSPS would be digested differently to other EPSPSs, or not at all, if it was consumed as part of soybean extract as opposed to pure protein. Therefore, testing of whole soybean extracts in the simulated digestion system is not considered to be necessary.

The knowledge that bacterial EPSPS does not have characteristics that are common to known allergens, combined with the fact that EPSPSs are not novel to the human food supply, indicates that the risk is no greater that bacterial EPSPS would be allergenic to humans, when other EPSPSs are not.

Furthermore, there have been no documented reports, of which ANZFA is aware, that indicate or suggest that the glyphosateûtolerant soybeans have thus far proved to be allergenic to humans. The anecdotal report provided by C. Elwell as evidence of allergenicity appears to refer to research in which a gene from brazil nut encoding an allergen was transferred to soybeans. These soybeans, which never progressed beyond the research stage, are not connected in any way to the glyphosateûtolerant soybeans, which are the subject of this application.

Allergenicity is not an issue which is peculiar to foods produced using gene technology. Foods produced using conventional breeding can also have new allergens transferred into them. The advantage of gene technology is that the genes being transferred are well characterised and defined beforehand. The possibility of developing food with allergenic compounds can be better recognised than is possible using conventional plant breeding.

The issue of raw sprouts is not relevant to this application as the soybeans are not imported into Australia for this purpose. Nevertheless, given the findings of the safety evaluation, the consumption of raw sprouts grown from glyphosateûtolerant soybeans would not be considered to pose any additional public health and safety risk.

4. Phytoestrogens

A joint submission from the Pacific Institute of Resource Management (NZ) and Revolt Against Genetic Engineering (NZ) stated that the comparative analyses submitted by the applicant were inadequate because they were done on ôtransgenic soybeans that have not been sprayed with glyphosate, and therefore can reveal nothing about the actual levels of phytoestrogens in the products that are sold.ö The submitter further stated that applications of glyphosate have been shown to induce the biosynthesis of phytoestrogens in broadbeans and possibly also soybeans. This issue was also raised by the Natural Law Party (NZ) and A. Ward (Aust) in their submissions.

Evaluation

The submitters are correct that the comparative analyses were done on plants that had not been treated with glyphosate. The applicantÆs stated reason for this was to focus the analysis on any effects of the introduced gene and protein.

The concern of the submitters appears to relate mainly to the issue of phytoestrogens and their potential for being associated with adverse effects if there are significant increases to their concentration in soybeans.

It should be noted that the concentrations reported for phytoestrogens in plants are very variable, not only between species but also between different samples from the same species. Data for a given species may vary as a result of the part of the plant that is sampled, growth, location, temperature, humidity and degree of environmental stress, among other factors. This is also supported by data submitted by the applicant which showed that there was large siteûtoûsite variability in the concentrations of phytoestrogens for both the control and glyphosateûtolerant soybeans. Therefore, it can be logically assumed that human beings are already exposed to soy products which vary widely in their phytoestrogen content. A variation in the concentration of phytoestrogens in response to the application of glyphosate and other herbicides would be an expected effect. This would be a normal physiological or stress response of the plant to the deleterious metabolic action of the herbicide. Furthermore, the glyphosateûtolerant soybeans may be less susceptible to this effect as they are able to withstand applications of the herbicide.

5. Compositional analyses

A joint submission from the Pacific Institute of Resource Management (NZ) and Revolt Against Genetic Engineering (NZ) stated that ôa major allergen, trypsinûinhibitor, was found to be 26.7% higher in transgenic soybeans.ö R. James (NZ) submitted that the applicant's compositional analyses for toxicants omits many of the well known toxic factors of soybeans. The Consumers' Federation of Australia Inc. submitted that the application does not provide sufficient evidence of antiûnutrients to prove that the soybeans are safe for processing into infant formula.

Evaluation

The data submitted by the applicant does not indicate that there are any significant differences in the levels of trypsin inhibitor between glyphosateûtolerant soybean line 40û3û2 and conventional soybeans. In addition, the applicant also made comparative analyses of the other major antiûnutritional factors present in soybean. These were lectins, phytate, isoflavones, raffinose and stachyose. There were no significant differences between the glyphosateûtolerant soybeans and the control soybeans with respect to any of these constituents. These analyses are considered to be sufficient.

6. Wholesomeness studies

A joint submission from the Pacific Institute of Resource Management (NZ) and Revolt Against Genetic Engineering (NZ) stated that feeding studies with dairy cows ôrevealed significant increases in milk fat in cows fed transgenic soybeans compared to control.ö

Evaluation

The feeding study with dairy cows showed that there was a small but statistically significant increase in the 3.5% fat corrected milk (FCM) production for cows fed glyphosateûtolerant line 40û3û2 in comparison to the control. Cows fed on glyphosateûtolerant line 40û3û2 were also shown to have an increased (nonûsignificant) net energy (NE_L) intake. It is considered likely that the small increase in the NE_L intake of the cows fed on glyphosateûtolerant soybeans is responsible for the small increase in the FCM production. When the ratio of FCM production to NE_L is calculated there is no significant difference between cows fed the test material and the control cows. Therefore, the small but statistically significant increase in the 3.5% fat corrected milk (FCM) production is not considered to be of concern.

7. Conventional soybeans do not have a history of safe use

D. Mclaughlin (NZ), R. Parsons (NZ), R. James (NZ) and D. Chapman (NZ) all submitted that conventional soybeans do not have a history of safe use and therefore challenged the inclusion of glyphosateûtolerant soybeans in the Table to clause 2 of Standard A18. Some submitters were solely concerned with the presence of phytoestrogens in soybeans. D. Mclaughlin (NZ) was specifically concerned about the presence of phytoestrogens in soy infant formula. Whereas, other submitters were more concerned with some of the natural toxicants and antiûnutritional factors in soybeans.

Evaluation

The purpose of an assessment of glyphosateûtolerant soybean line 40û3û2 is to establish that it is equivalent with conventional soybeans in terms of its safety for human consumption. The purpose of the assessment is not to evaluate the safety for human consumption of conventional soybeans, which have had a long history of safe use by human beings. ANZFA is aware that some members of the community have developed allergies to certain soybean proteins and concerns have also been raised about the widespread use of soy for infant formulas because of its high phytoestrogen content. While these issues are of concern, it is not appropriate for them to be considered in the context of this application. Concerns in relation to the use of soyûbased infant formulas are already being addressed by ANZFA in relation to its review of infant formulas.

3. ANZFA Section 10 Objectives

Protection of public health and safety

A safety assessment of the glyphosateûtolerant soybean line 40û3û2 has been done according to ANZFAÆs safety assessment guidelines using data submitted by the applicant. This assessment concluded that there would be no additional public health and safety concerns associated with the consumption of food derived from glyphosateûtolerant soybean line 40û3û2. Food derived from this line can be regarded as substantially equivalent to food derived from conventional soybeans in respect of its composition, safety, wholesomeness and end use.

Provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception

Under the current provisions, which do not mandate the labelling of foods that are deemed to be substantially equivalent (such as the glyphosateûtolerant soybeans), the onus is very much on the consumer to seek out additional information about these products. Much of this information is available in the public domain and can be readily obtained from ANZFA, government information programs such as Gene Pool in New Zealand, and from the food industry. In addition, the use of negative claims is not prohibited by Standard A18 provided such claims are not false, misleading or deceptive. Therefore, those in the community wishing to avoid these products altogether will be able to do so by accessing the alternative products that have been produced without the use of gene technology, eg organic foods.

The recent decision by ANZFSC to amend the current labelling requirements to include mandatory provisions for substantially equivalent foods will most likely result in some foods from glyphosateûtolerant soybean line 40û3û2 being labelled.

Promotion of fair trading in food

Approval for the sale of food derived from glyphosateûtolerant soybean line 40û3û2 will mean that all manufacturers and food producers are free to use such products should they wish to do so. Therefore, the proposed amendment should not impact on fair trading in food.

Promotion of trade and commerce in the food industry

The glyphosateûtolerant soybeans represent a technological advance in agricultural cropping systems which enables the grower to use more amenable herbicide regimes for the control of weeds inûcrop. The glyphosateûtolerant soybeans do not offer any technological advantage to the food industry as their processing, storage, and nutritional characteristics, are unchanged, therefore, they are grown on a nonûsegregated basis. Consequently, this objective is not directly relevant to this application. However, the approval of foods that have been produced using new technologies will indirectly lead to the promotion of trade and commerce in the food industry by encouraging innovation.

Promotion of consistency between domestic and international food standards

There are no international (ie., Codex) food standards for foods produced using gene technology, therefore an amendment to the *Food Standards Code* will not contribute to the promotion of consistency between domestic and international standards. However, the glyphosateûtolerant soybeans have already been permitted for use by AustraliaÆs and New ZealandÆs major trading partners (eg., United States, European Union, Canada). Approval in Australia and New Zealand will lead to harmonisation with our trading partners and will facilitate trade in this commodity.

4. Regulatory Impact Analysis

Option 1ûnot permit the sale of food derived from glyphosateûtolerant soybean line 40û3û2 from 13 May 1999.

GOVERNMENT Commonwealth, New Zealand Health Departments, State/Territory Health Departments local government, Australian Quarantine and Inspection Service	**Benefits** ò no benefits were identified	**Costs** ò the governments may be open to challenge under WTO as a prohibition on the sale of foods derived from glyphosateûtolerant soybeans could interfere with the trade in soybeans between the United States and Australia ò there may be technical and resource implications for enforcement agencies in enforcing a prohibition.

INDUSTRY manufacturers and producers of foods from glyphosateûtolerant soybeans, food importers, suppliers of soybeans and soybean products	**Benefits** ò no benefits were identified	**Costs** ò food manufacturers and producers will be unable to use the processed fractions of imported soybeans from the US in their products as glyphosateûtolerant soybeans are not segregated from conventional soybeans at source ò suppliers of US soybeans to manufacturers will have to source their soybeans from elsewhere

CONSUMERS	**Benefits** **ò** no benefits were identified	**Costs** **ò** a prohibition on the sale of foods containing the products of glyphosateûtolerant soybeans could lead to decreased availability of certain food products. **ò** increased costs to consumers because manufacturers and producers

		may have to source their raw commodities from other suppliers

Option 2ûamend the Food Standards Code to permit the sale of food derived from glyphosateûtolerant soybeans

GOVERNMENT Commonwealth, New Zealand Health Departments, State/Territory Health Departments local government Australian Quarantine and Inspection Service	**Benefits** ò increased innovation and competitiveness by the food industry has the potential to benefit the economy	**Costs** ò minor costs associated with amending the *Food Standards Code*

INDUSTRY manufacturers and producers of foods from glyphosateûtolerant soybeans, food importers, suppliers of soybeans and soybean products	**Benefits** ò manufacturers and producers will have continued access to the same soybean markets	**Costs** ò there may be increased costs associated with complying with the any labelling conditions that may be imposed in the future
CONSUMERS	**Benefits** **ò** consumers can be assured that the glyphosateûtolerant soybeans have been through a preûmarket assessment and found to be as safe for human consumption as conventional soybeans	**Costs** **ò** consumers wishing to avoid consuming foods produced using gene technology may have reduced choice in the market place ò costs associated with labelling may be passed on to consumers

Evaluation of the regulatory impact

<u>Option 1</u>

This option will result in the prohibition of foods derived from glyphosate tolerant soybeans from 13 May 1999. That is, the sale of such food would be illegal after that

date. A recommendation by ANZFA against inclusion of food derived from glyphosateûtolerant soybeans would need to be based on an identified public health and safety concern. A large number of submissions were received in support of this option on the grounds that the glyphosateûtolerant soybeans are unsafe for human consumption. However, the safety assessment has found that the glyphosateûtolerant soybeans are equivalent in terms of their composition, safety, wholesomeness and end use to conventional soybeans. Therefore, there would be no public health and safety benefit to be derived from this option.

The costs of this option are considerable. A prohibition on foods derived from glyphosateûtolerant soybeans will mean that importers of soybeans into Australia from the US will have to source soybeans from elsewhere as glyphosateûtolerant soybeans are coûmingled with conventional soybeans in the US. This is likely to result in severe disruptions to the market and could lead to a challenge under WTO. This could result in considerable expense to the Australian and New Zealand Governments. Furthermore, this prohibition will have to be enforced by enforcement agencies making considerable demands on resources. Food manufacturers that have to source their soybeans from elsewhere could be faced with increased costs. These costs are likely to be passed on to consumers.

Therefore, this option is not considered to be a viable option as the benefit would only accrue to those people wishing to avoid eating food produced using gene technology. The potential costs identified for government, industry and consumers, outweigh any benefit to those consumers wishing to avoid these products.

Option 2

This option will result in permitting the sale of food derived from glyphosateûtolerant soybeans. The safety assessment has concluded that glyphosateûtolerant soybeans do not pose any greater risk to public health and safety than conventional soybeans, therefore this is the preferred option.

The benefits of this option primarily accrue to the food industry and government. The government will benefit because this decision will serve to give encouragement to the food industry that technological innovations will be accepted by the government. This could lead to greater certainty in the food industry, and greater competition and investment in agriûfood businesses. The food industry will benefit because there will be very little disruption to their businesses and they can continue to access their soybeans from their usual suppliers. Consumers will benefit in so far that they can be assured that the glyphosateûtolerant soybeans have been through a safety assessment and found to be as safe for human consumption as conventional soybeans.

There are also costs associated with this option. The costs that would accrue to the food industry are associated primarily with compliance with any interim labelling conditions that may be imposed. For some manufacturers the costs could be

considerable, however, these costs would not be expected to be any greater than those that will be associated with the proposed new labelling amendments to Standard A18.

This option could also result in some cost to consumers. Firstly, costs associated with compliance with any interim labelling requirements are likely to be passed on to consumers. Secondly, consumers wishing to avoid eating food produced using gene technology will be restricted to alternative markets, such as organic foods, which have reduced variety and tend to be more expensive.

Conclusion of the regulatory impact analysis

Consideration of the regulatory impact for this application concludes that, as the consumption of foods derived from glyphosateûtolerant soybeans does not pose any greater risk to public health and safety than conventional soybeans, Option 1, to maintain the status quo and not permit their sale, is not a viable option. Therefore, the preferred option is to amend the *Food Standards Code* to permit the sale of foods derived from glyphosateûtolerant soybean line 40û3û2. In addition, the potential costs associated with Option 1 exceed any potential benefit that may accrue to consumers.

It is concluded from the regulatory impact analysis that the amendments to the *Food Standard Code* are necessary and cost effective in that the potential benefits for industry, government and consumers, outweigh the potential costs.

CONCLUSIONS OF THE FULL ASSESSMENT

It is concluded that:

- food derived from glyphosateûtolerant soybean line 40û3û2 can be regarded as substantially equivalent to food derived from conventional soybeans in respect of its composition, safety, wholesomeness and end use. There are no additional public health and safety concerns associated with the use of these soybeans;

- the concerns raised in public submissions have been adequately addressed by the safety assessment conducted by ANZFA or by the processes of other regulatory agencies involved in the assessment of genetically modified organisms;

- food derived from glyphosateûtolerant soybean line 40û3û2 will not require labelling as it can be regarded as substantially equivalent to food derived from conventional soybeans. Proposed amendments to the labelling provision of Standard A18 could result in some food products from glyphosateûtolerant soybeans being labelled in the future;

- ò the proposed amendment to list food derived from glyphosateûtolerant soybean line 40û3û2 in the Table to Standard A18 is consistent with ANZFAÆs section 10 objectives;

- ò the benefits of the proposed amendment primarily accrue to the food industry and government, with potentially a small benefit to the consumer. These benefits outweigh the costs associated with recommending against the amendment.

WORLD TRADE ORGANISATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFAáis required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter does not need to be notified to the WTO as an Sanitary and Phytosanitary (SPS) notification or a Technical Barriers to Trade (TBT) notification because the proposed variation to the *Food Standards Code* constitutes a minor technical change and will have no effect on trade issues for either technical or sanitary reasons.

Attachments to the Report:

1. Draft Variation to the Australian *Food Standards Code*
2. Explanatory Notes
3. Safety Assessment
4. Public Comment Received

Attachment 1

DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE

A338 - FOODS FROM GLYPHOSATEûTOLERANT SOYBEANS

Standard A18 *is varied by inserting into Column 1 of the Table to clause 2 -*

Food derived from glyphosate-tolerant soybean line 40-3-2.

Attachment 2

DRAFT EXPLANATORY NOTES

DOCUMENT AVAILABLE SEPARATELY

SAFETY ASSESSMENT
A338 û FOOD DERIVED FROM GLYPHOSATEûTOLERANT SOYBEANS

BACKGROUND

Monsanto Australia Ltd have made an application to ANZFA to vary Standard A18 to include food derived from glyphosateûtolerant soybeans in the Table to the standard.

Glyphosateûtolerant soybean plants are known commercially as Roundup Ready soybeans as they are tolerant to the proprietary herbicide, Roundup. The soybeans were developed by Monsanto Ltd for cultivation in the United States. Soybeans harvested from these plants have been imported into Australia, and presumably New Zealand, since December 1996.

Soybeans are imported for processing into vegetable oil, which is supplied to the food industry, and protein meal, which is supplied to animal feed manufacturers and, potentially, a small amount to the food industry. Local production of soybean currently falls short of demand by approximately 50%.

DESCRIPTION OF THE MODIFICATION

The parental soybean line A5403 was transformed with plasmid PVûGMGTO4 using particle bombardment. Glyphosateûtolerant soybean line 40û3û2, which is the subject of this application, was derived from the original transformant. This transformation resulted in the transfer of the following genes: two CP4 5ûenolpyruvyl shikimateû3ûphosphate synthase (EPSPS) genes fused to a petunia EPSPS chloroplast transit peptide (CTP), the *uidA* gene and the *nptII* gene. The origin and purpose of these genes is described below.

The CP4 EPSPS gene is derived from *Agrobacterium* sp. strain CP4. EPSPS is an essential enzyme involved in the biosynthesis of the aromatic amino acids by the shikimate metabolic pathway. This metabolic pathway is present in all plants, bacteria and fungi. The mechanism of action of glyphosate is to inhibit this enzyme. The *Agrobacterium*ûderived CP4 EPSPS has a reduced affinity for glyphosate, therefore, its expression in the soybean is sufficient to compensate for the inhibition of the endogenous EPSPS by glyphosate. The two CP4 EPSPS genes are under the control of the cauliflower mosaic virus 35S promoter and the figwort mosaic virus 35S promoter, therefore, both copies of the gene would be expected to be expressed in plant cells.

The *uidA* gene encodes the bacterial enzyme β-glucuronidase (GUS) and is under the control of the mannopine synthase promoter. This enzyme is used as a marker of plant cell transformation. It converts the exogenously applied substrate, 5ûbromoû4ûchloroû3ûindolyl βûDûglucuronide, into a blue precipitate in the plant cells in which the enzyme is expressed.

The *nptII* gene encodes the enzyme, neomycin phosphotransferase II and confers resistance to the aminoglycoside antibiotics. This gene was used as a bacterial selectable marker. The *nptII* gene is under the control of a bacterial promoter, therefore, would not be expected to be expressed in the transformed plant cells.

The techniques of Southern blotting and polymerase chain reaction (PCR) were used to demonstrate that, although the original transformant contained both the *uidA* gene and the *nptII* gene, these sequences are no longer present in glyphosateûtolerant line 40û3û2. This line was shown to contain a single insertion of DNA which consists of the cauliflower mosaic virus 35S promoter, the petunia EPSPS CTP sequence fused to a single copy of the CP4 EPSPS gene and the 3Æ untranslated region of the nopaline synthase gene (NOS3Æ). Both the *nptII* gene, the second CP4 EPSPS gene and the *uidA* gene were lost through normal genetic segregation in subsequent generations of the original transformant.

ISSUES IN SAFETY ASSESSMENT

There are two food products derived from glyphosateûtolerant soybeans, namely, vegetable oil and protein meal. The vegetable oil is the major food product for human consumption. Lecithin, a phosphatide removed from crude soybean oil, is used as an emulsifier, lubricant and stabilising agent. As lecithin is classed as a food additive it will not be specifically considered in this assessment. The glyphosateûtolerant soybeans have been assessed according to the safety assessment guidelines developed by ANZFA. As the data presented is for whole seed as well as its processed derivatives, the safety assessment issues relate to Group B foods. The following issues were considered relevant for a safety assessment:

(i) General safety issues:

- û history of use of the soybean plant as a food source;
- û expression of new genetic material;
- û potential toxicity of newly expressed proteins; and
- û immunological effects;

(ii) Compositional analyses:

- û proximate analysis for major constituents; and
- û critical nutrients, anti-nutritional factors, and natural toxicants;

(iii) Ability to support typical growth and wellûbeing;

(iv) The level of glyphosate residue in glyphosateûtolerant soybeans.

Each of these issues are discussed below.

(i) General safety issues

History of use of the soybean as a food source

There are three major soybean (*Glycine max*) products ù beans, meal and oil. The primary use of soybean meal is in animal feed, although a proportion can also be used for human food products. The principle processed fraction used by the food industry is soybean oil. There are no human food uses for unprocessed soybeans as they contain high levels of trypsin inhibitor which has anti-nutritional properties. A significant proportion of the trypsin inhibitor is destroyed by heat treatment. According to the applicant, imported soybeans are processed almost exclusively for oil and animal meal.

Expression of new genetic material

The only new protein introduced into line 40û3û2 is the CP4 EPSPS enzyme. This enzyme is expressed with a petunia EPSPS CTP fused to its amino terminus to facilitate its transport to the chloroplast. This peptide has been shown to deliver bacterial EPSPSs to the chloroplasts of higher plants where the aromatic amino acid biosynthetic pathway and endogenous EPSPS activity is located. *In vitro* chloroplast uptake assays have shown that the petunia EPSPS CTP delivers CP4 EPSPS to the chloroplast and is subsequently cleaved from the preûprotein, yielding mature CP4 EPSPS with no CTP amino acids retained. It is generally accepted in the literature that the chloroplast transit peptides are rapidly degraded after cleavage *in vivo* by cellular proteases. Thus, the only newly expressed protein present in glyphosate-tolerant soybeans would be mature CP4 EPSPS, without any additional CTP residues at the amino terminus.

The mean expression of CP4 EPSPS in line 40û3û2 was 0.288 Ág/mg tissue fresh weight or about 0.08% of total protein. In the processed fractions derived from line 40û3û2, the level of CP4 EPSPS was no greater than 0.1% of the total protein. EPSPS activity was not detected in any of the processed fractions except for defatted, nonûtoasted meal. CP4 EPSPS is expected to be present at low levels in food derived from glyphosateûtolerant line 40û3û2 but would not have any enzymatic activity due to heatûinactivation during processing. CP4 EPSPS is functionally and structurally similar to the endogenous EPSPS proteins.

Potential toxicity of newly expressed proteins

The potential for toxicity of the newly expressed CP4 EPSPS was evaluated in a number of ways.

The amino acid sequence of CP4 EPSPS was compared to the amino acid sequence of 1935 known protein toxins. No meaningful homology was found other than would

be expected given that certain functional domains are generally conserved between proteins.

An acute mouse gavage test was done using purified CP4 EPSPS, lacking the CTP, in order to directly assess the potential for toxicity associated with this protein. An acute study was considered the most appropriate for assessing potential toxicity as proteins that are toxic act via acute mechanisms. There were no adverse effects observed in mice administered CP4 EPSPS protein by gavage at doses up to 572 mg/kg.

In vitro simulated mammalian gastric and intestinal digestive mixtures were established to assess the susceptibility of CP4 EPSPS to proteolytic digestion, as measured by immunoblot analysis. CP4 EPSPS was shown to be rapidly digested by this simulated mammalian digestive system (halfûlife of 15 seconds in the gastric system and 10 minutes in the intestinal system).

Immunological effects

The potential allergenicity of glyphosateûtolerant soybean line 40û3û2 was evaluated in a number of ways.

A comparison of the known allergenic proteins in soybeans, using pooled sera from individuals shown to be sensitive to soybean products, was made between the glyphosateûtolerant soybeans, the parental soybeans and other nonûmodified commercial varieties of soybeans. The presence, as well as the relative levels, of the endogenous allergenic proteins in all soybean preparations tested were found to be comparable, indicating that the endogenous allergenic proteins were not altered during production of glyphosateûtolerant soybean line 40û3û2.

Although there are no predictive assays available to assess the allergic potential of proteins, a number of characteristics are common among many of the allergens that have been characterised. For instance, known allergens tend to be glycosylated proteins with a molecular weight of 10û70KDa. In addition, they tend to be heat stable as well as resistant to peptic and tryptic digestion and the acid conditions of the stomach. The CP4 EPSPS protein was evaluated below against these criteria.

The EPSPS proteins are a diverse set of related proteins typically present in foods derived from plants and microbes, and have no history of being allergenic. The CP4 EPSPS protein is 47.6 KDa and thus fits the molecular mass criteria of 10û70 KDa. However, CP4 EPSPS was shown to be denatured upon heating and is readily digested by proteases present in the mammalian digestive system, suggesting that it would not survive the peptic and tryptic conditions of the human digestive system. Furthermore, CP4 EPSPS was found not to be glycosylated when purified from glyphosateûtolerant seeds. This was an expected finding as in order for it to be glycosylated, the CP4 EPSPS would need to be transported to the endoplasmic reticulum. CP4 EPSPS was also shown to have no significant homology to any known allergen.

Therefore, CP4 EPSPS does not possess the characteristics that are typical of many known allergens and also shows no significant homology to any known allergen. Furthermore, CP4 EPSPS is rapidly digested in conditions that mimic human digestion.

ConclusionùThe soybean, *Glycine max*, is the traditional source of soybean oil and protein meal for human consumption and has a history of safe use for these purposes. The only new protein expressed in glyphosateûtolerant soybean line 40û3û2 is the enzyme, 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS) derived from *Agrobacterium* sp. strain CP4. The evidence does not indicate that there is any potential for this protein to be either toxic or allergenic to humans.

(ii) Compositional analysis

Compositional analyses were done on soybeans from the glyphosateûtolerant line 40-3-2 and comparison was made to analyses of soybeans from the parental line A5403. Line A5403 is a commercial soybean variety. Lines 40û3û2 and A5403 were grown in nine field locations in 1992 according to Good Laboratory Practice (GLP) guidelines. Seed grown from each of the nine sites was analysed, and statistical analyses of the data were done. In order to focus the analysis on any effects of the introduced gene and protein, the soybeans grown in the trials were not treated with glyphosate. The soybean seeds and processing fractions were analysed for compositional quality characteristics according to GLP and using standardised analytical methods.

Proximate analysis for major constituents

Proximate analysis was done on whole soybeans, toasted meal, nonûtoasted meal, protein isolate and protein concentrate. Components measured were protein, fat, moisture, fibre, and ash. In all cases, there were no significant differences between the glyphosate-tolerant soybeans and their processed fractions, and the control soybeans. As a percentage of dry weight, protein is approx. 42%, fat 16%, fibre 7%, and carbohydrate 38%. The values reported for both the control and glyphosateûtolerant soybeans were also within the literature reported ranges.

Critical nutrients, antiûnutritional factors and natural toxicants

<u>Amino acid analysis</u>

Amino acid analyses were done on whole soybeans seeds. Of the 18 amino acids analysed, there were no significant differences between the glyphosateûtolerant soybeans and the control soybeans.

The levels of the aromatic amino acids in the glyphosateûtolerant soybeans are of particular interest. This is because the glyphosateûtolerant trait is conferred by the expression of a different EPSPS which is not inhibited by glyphosate to the same extent as the endogenous EPSPS.

The shikimate metabolic pathway is of central importance in metabolism as about one fifth of all carbon fixed by plants is channelled through this pathway. Regulation occurs at the first step of this pathway by modulation of the activity of an enzyme called DAHP synthase. Other enzymes in the pathway do not appear to be under feedback control and therefore have only been found to be slightly inhibited by later intermediates or end products of the pathway. The CP4 EPSPS has been shown, *in vitro*, to have approximately 10 fold higher activity than petunia EPSPS in the presence of glyphosate. Therefore, available evidence suggests that EPSPS is not a regulatory enzyme and that increased EPSPS activity (as a result of the expression of the CP4 EPSPS when the endogenous EPSPS is inhibited by glyphosate) would not be expected to increase the levels of aromatic compounds in plants.

The data shows that no statistically significant increase in the aromatic amino acids tyrosine, phenylalanine, or tryptophan (or any of the other nonûaromatic amino acids) is associated with the expression of the CP4 EPSPS in glyphosateûtolerant line 40û3û2. It can be inferred from the biochemical data that significant changes in the levels of aromatic amino acids would be unlikely to occur following glyphosate treatment.

Fatty acid analysis

Fatty acid analysis was done on whole soybeans as well as refined, bleached, deodorised soybean oil. Components measured were palmitic acid (C16:0), stearic acid (C18:0), oleic acid (C18:1 cis), linoleic (C18:2), and linolenic (C18:3). No differences were found between glyphosateûtolerant soybeans and controls. The values reported were also within the literature reported ranges.

Seed storage protein analysis

The soybean seed storage protein profile was analysed using gel electrophoresis. No discernible difference was noted between the glyphosateûtolerant soybeans and controls, indicating there are no gross protein differences between the glyphosate tolerant soybeans and the control soybeans.

Trypsin inhibitor analysis

Trypsin inhibitor contributes significantly to the antiûnutritional activity of uncooked soybean products and has been shown to cause hypertrophy of the pancreas. No significant differences were noted in the levels of trypsin inhibitor in glyphosateûtolerant and control soybeans or toasted meal. The values reported for toasted meal were also within the literature reported ranges.

Lectin analysis

The levels of soybean lectin in whole soybeans and toasted meal were measured using a rabbit red blood cell assay. There was no significant difference between lectin activity of glyphosateûtolerant and control soybeans or toasted soybean meal. The values reported for both the glyphosateûtolerant and control whole soybeans were significantly lower than literature reported values. Processing was found to

significantly inactivate lectin activity in both the control and glyphosateûtolerant soybeans.

Phytate analysis

Phytate analysis was done on toasted soybean meal from both glyphosateûtolerant and control soybeans. Phytate is the hexaphosphoric acid derivative of inositol and may be involved in mineral availability. There was no significant difference between glyphosateûtolerant and control toasted soybean meal.

Isoflavone analysis

Isoflavone analysis was done on whole soybeans as well as toasted soybean meal. The isoflavones, genistein, daidzein, and coumestrol are naturally occurring in soybeans and are reported to possess oestrogenic and hypocholesterolemic activities. The levels of genistein and daidzein in soybean seeds were determined for both the total and free forms. Analyses were also done for coumestrol and biochanin A. Only minute quantities of biochanin A were detected and the bound coumestrol was lower than the confidence limit of the assay (10 ppm). No significant differences were found between glyphosateûtolerant and control whole soybeans or toasted meal.

Raffinose and stachyose analysis

Flatulence from soybeans is well documented and is caused largely by low molecular weight carbohydrates, mainly raffinose and stachyose. An analysis was done of the raffinose and stachyose content of toasted soybean meal. There were no significant difference between the levels of these carbohydrates in glyphosateûtolerant and control soybean meal.

ConclusionùLine A5403 is an appropriate comparator for glyphosateûtolerant line 40û3û2 because it is a commercial soybean variety and is the variety that was initially transformed. Analysis of the compositional data indicates that there is no significant difference in the levels of major constituents, nutrients, antiûnutritional factors or natural toxicants between glyphosateûtolerant soybean line 40û3û2 and the parental soybeans in either the whole soybean or the processed fractions.

(iii) Ability to support typical growth and well-being

A number of feeding studies have been done to establish the wholesomeness of soybean meal and whole soybeans. These studies have not been designed specifically as toxicity tests but will serve to indicate if there are unknown factors present in the soybeans which affect animal growth and wellûbeing. Feed efficiency analyses (feed consumed/weight gained) have been performed.

Studies have been conducted in rats (natural consumers of soybeans) with both processed and unprocessed soybean meal, in chickens (significant consumers of soybeans) with processed soybeans and, in dairy cattle (common consumers of soybeans) with raw soybeans.

Rat 4-week study with unprocessed soybean meal

Groups of CD rats (10/sex/group) were fed *ad libitum* rodent chow containing unprocessed soybean meal at 0, 5, or 10% (w/w) from either glyphosateûtolerant soybean line 40û3û2 or from parental soybeans for approximately 4 weeks. Animals were observed for adverse signs and body weights were recorded weekly. Organs were collected and weighed at the end of the study. The pancreas underwent histological examination.

There were no treatmentûrelated deaths and no adverse signs of toxicity in any group. There were no significant differences in body weight, body weight gain or in food consumption between the groups. There were no organ weight changes which could be related to consumption of the glyphosateûtolerant soybeans. Histological examination of the pancreas in all groups gave normal results. The conclusion is that the wholesomeness of unprocessed meal from glyphosateûtolerant soybeans is similar to that from the parental soybeans.

Rat 4ûweek study with processed soybean meal

Groups of CD rats (10/sex) were fed *ad libitum* rodent chow containing processed soybean meal at either 0% (w/w) or at the same substitution level as used commercially, namely, 24.8% (w/w) from either glyphosateûtolerant soybeans or from parental soybeans for approximately 4 weeks. Animals were observed for adverse signs and body weights were recorded weekly. Organs were collected and weighed at the end of the study.

There were no treatmentûrelated deaths and no adverse signs of toxicity in any group. There were no significant differences in body weight, body weight gain or in food consumption between the glyphosateûtolerant and parental groups. There were some minor differences between treated groups and the negative controls with regard to body weight gains and food consumption which may be related to palatability. There were no organ weight changes which could be related to consumption of the glyphosate-tolerant soybeans. The conclusion is that the wholesomeness of processed meal from glyphosateûtolerant soybeans is similar to that from the parental soybeans.

Chicken 6ûweek study with processed soybean meal

Groups of broiler chickens (60 birds/sex) were fed starter diet containing soybean meal from day 0 to 21 and then pelleted diet from day 22û42. The only source of protein was soybeans and corn. Broilers undergo a very rapid rate of growth in 6 weeks from hatch and therefore this test was considered to be very sensitive to the nutritional needs of the growing broiler. Soybean meal was obtained from the parental strain and two experimental glyphosate-tolerant strains.

Birds were checked daily and body weights and food consumption measured weekly. At the end of the study, major and minor pectoralis muscles (breast muscles) and abdominal fat pads were removed and weighed.

For the starter period, body weight and body weight gains for all groups were similar. The chickens fed glyphosateûtolerant soybeans consumed slightly more (3.5%) and thus have a slightly lower feed/weight gain compared to the parental strain. As expected, females consumed less than males. For the 22û42 day period, there were no statistically significant differences between groups for body weight, body weight gain or feed intake. There were no differences between groups for breast muscle weight and fat pad weight. The conclusion is that the glyphosate-tolerant soybean meal provided equivalent nutritive value to that of the parental soybean line.

Dairy cow 4ûweek study with raw soybeans

Groups of 5û6 Holstein cows were fed a diet containing either glyphosateûtolerant or parental soybeans at up to 10% (w/w dry matter) of the diet. The cows had been preûadapted to a high soybean diet for 2 weeks prior to commencement of the study. Dairy cows are considered to be relatively resistant to the effects of trypsin inhibitors which are degraded by rumen flora during digestion. Feed consumption, milk production, milk composition and nitrogen balance were examined.

Animal health was good throughout the study. There were no statistically significant differences in leastûsquares means for milk production, milk fat, protein, lactose, net energy intake, fat corrected milk/net energy intake (FCM/NE_L intake) and body weight change. A small but statistically significant increase in the 3.5% FCM for cows fed glyphosateûtolerant line 40û3û2 was found. As the NE_L intake of the cows fed glyphosateûtolerant line 40û3û2 is also slightly increased (not statistically significant) this may be responsible for the higher FCM production. As both the FCM and the NE_L intake are increased, this has resulted in similar FCM/NE_L intake ratios being obtained for both control and test animals.

There were no statistically significant differences in feed intake, milk production, milk composition or nitrogen balance between animals fed glyphosateûtolerant soybeans and parental lines. The small increase in FCM production for cows fed glyphosateûtolerant soybean line 40û3û2 is not considered to be significant as it can be explained by a slightly higher net energy intake by the cows.

Other animal studies

A number of other animal studies were submitted by the applicant, specifically for catfish and for quail. The findings of these feeding studies are consistent with those summarised above.

ConclusionùData from the animal feeding studies indicate that glyphosateûtolerant soybeans provide a nutritive and wholesome diet which is equal to that of the parental soybean line.

(iv) The level of glyphosate residue in glyphosate-tolerant soybeans

The level of glyphosate in the glyphosateûtolerant soybeans must comply with the maximum residue limits (MRLs) currently established for soybeans in Australia and New Zealand. In New Zealand, there is also acceptance for imported foods of MRLs established by Codex. In addition, there is mutual recognition of MRLs between Australia and New Zealand for those foods that are traded between the two countries.

SUMMARY AND CONCLUSIONS

Glyphosateûtolerant soybean line 40û3û2 contains a single new gene derived from the bacteria *Agrobacterium* sp. strain CP4. This gene encodes the protein enolpyruvyl shikimateû3ûphosphate synthase (EPSPS) which is an essential enzyme involved in the synthesis of aromatic amino acids. Soybeans naturally contain an enzyme of this type, however, the plant EPSPS is inhibited by the herbicide glyphosate, whereas the bacterial EPSPS is not. Therefore, the transfer of the bacterial EPSPS to soybean enables the plant to withstand applications of the herbicide. This would allow postûemergent use of glyphosate on soybean crops.

Considerable data has been presented by the applicant to establish that food derived from glyphosateûtolerant soybean line 40û3û2 is equivalent to the parental soybean, line A5403, as well as other commercial varieties of soybeans, in all respects apart from the expression of the CP4 EPSPS gene. This data included molecular and genetic analyses of the new soybean line, an examination of the potential for the newly expressed protein to be toxic or allergenic to humans, compositional analyses of the soybeans, and animal feeding studies to establish the wholesomeness of the glyphosateûtolerant soybean line in comparison to conventional soybeans.

The molecular and genetic analyses provided by the applicant indicate that the introduced gene for CP4 EPSPS has been stably integrated into the plant genome and is stably inherited from one generation to the next.

The applicant submitted data which showed that the newly expressed protein, CP4 EPSPS, has been evaluated for its potential to be toxic or allergenic to humans. This included acute toxicity tests using mice, comparison of the amino acid sequence of the protein with known toxins and allergens, examination of digestion of the protein in simulated mammalian digestive systems, and testing against human sera taken from individuals known to be allergic to soybeans. The evidence does not indicate that there is any potential for the CP4 EPSPS protein to be toxic to humans.

The CP4 EPSPS protein also does not have characteristics that are typical of known food allergens and there is no indication, from tests with human sera, that glyphosateûtolerant soybean line 40û3-2 has increased allergenicity in comparison to conventional soybeans.

The compositional analyses were comprehensive and indicate that there are no significant differences in the levels of major constituents, nutrients, anti-nutritional factors or natural toxicants between glyphosateûtolerant soybean line 40û3û2 and the parental soybeans for either whole soybeans or any of the processed fractions. The animal feeding studies presented by the applicant indicate that glyphosateûtolerant soybeans provide a nutritive and wholesome diet which is equal to that of the parental line of soybeans.

In conclusion, no potential public health and safety concerns have been identified in the assessment. Food derived from glyphosateûtolerant soybean line 40û3û2 can be regarded as substantially equivalent to food derived from conventional soybeans in respect of its composition, safety, wholesomeness and end use.

SUMMARY OF PUBLIC SUBMISSIONS
A338 û FOOD DERIVED FROM GLYPHOSATEûTOLERANT SOYBEANS

Jean Adams (Aust)

- ò does not want these experimental foods in the common food supply until they have been longûterm tested for undesirable sideûeffects related to public health, environmental damage to species
- ò questions the legality of forcing such genetically modified foods onto the public and the intention to remove labelling of such foods

Robert G Anderson (member of Physicians and Scientists for Responsible Application of Science and Technology)

- ò knowledge about the nature of the promoter genes and the type of antibiotic resistance genes is crucial to a proper assessment
- ò the applications should be rejected because most of the New Zealand population do not want to eat genetically engineered food, there are real dangers of allergic reactions, the Maori people are opposed to genetic engineering and these products are all an unknown risk to human health because they have not been tested

Aoraki Greens and the Organic Garden City Trust (NZ)

- ò is against the amendment to the *Food Standards Code* to permit the foods in the applications.
- ò there is no alternative but to decline the acceptance of these products until they are clearly labelled and can be differentiated from their conventional counterparts.
- ò consumer choice is being violated.
- ò because it is a new science, potential problems or long term implications are yet to be made apparent.

Elaine Attwood (Aust)

- ò supports Option 1 in the combined Preliminary Assessment - that is, to maintain the status quo and not approve any of the six applications
- ò re: A338 - considers 4 weeks of laboratory animal testing inadequate and doubts the applicant's claim that the need for herbicide will be reduced. Comments on proposed increase in the MRL for glyphosate
- ò re: A355, A362 and A346ûgenetically modified material will enter the food chain via cotton seed meal and hulls and corn waste being fed to animals
- ò re: A363 û canola free of genetic modification would be marketable overseas
- ò re: A341 û the results of laboratory feeding studies in rats are of concern. Long term safety is uncertain and therefore the genetically modified cotton should not be permitted
- ò trade considerations should not prevail over consumer rights to have all genetically modified foods labelled as such.

Australian GeneEthics Network

- ò MonsantoÆs proposals should all be rejected as inadequate
- ò there should be preûmarket human testing to provide data for a precautionary approach on safety and nutritional efficacy
- ò there should be full labelling of all approved foods in keeping with the Ministerial decision
- ò there should be public review of the MRLs for Roundup in these foods
- ò there should be public review of the toxicity of the quantities of Bt toxins likely to enter the human and animal food supplies, taking cultural, social, ethnic and age diversity into account
- ò an adverse reactions register should be established to enable systematic monitoring of any impacts of these foods
- ò all proposals should be submitted for GMAC assessment and recommendation including an updated and public review of Bt cotton and Roundup Ready soy for environmental and health impacts
- ò GMAC's assumption that AQIS's regulations would keep imported soy out of the Australian environment does not apply to the other commodities applied for, and the geographical limits and performance of Bt cotton need public review
- ò Monsanto has not studied the dietary implications of these products and presents no evidence that it considered the diversity of diets among different cultures, social or ethnic groups
- ò RR soy and corn crops are very different in containing novel DNA, proteins at elevated levels, and new levels of synthetic chemical residue not in food before
- ò RR canola and cotton seed oils are so extensively processed before human consumption that no DNA or proteins will remain. This ignores, for example, the use of whole seeds for sprouting, the inclusion of whole seeds in uncooked foods, and the cold pressing of oils
- ò Bt cotton and corn are substantially equivalent to parental lines in composition, safety and wholesomeness, yet Bt has never been in the food supply in such quantities before.
- ò The toxicological studies of RR foods are brief and insufficient as no chemical residue studies are cited, proteins created by inserted genes have only been checked against known protein toxins and allergens, no human, and very few animal (mouse) testing of the products has been done, whole genetically engineered soybean, corn, canola or cotton were not checked in simulated gastric and intestinal fluids
- ò No toxicological studies were carried out on the Bt crops as Monsanto asserts that "regulatory agencies world-wide have determined that the use of registered B.t.k products pose no significant risks to human health, non-target organisms or the environment." This is grossly misleading as it refers to the topical use of a whole organism which quickly disappears from the environment following spraying, whereas Bt crops express large amounts of toxin throughout their systems.

Berylla (NZ)

- ò these foods will be in 60û80% of all processed foods therefore freedom to choose will be compromised
- ò as these foods will also be fed to animals choices will be restricted even further and if the animals were eaten then the degree of risk will increase
- ò support the submissions of the Natural Law Party and Clive Elwell

Willi Borst (NZ)

- ò want all genetically modified foods to be labelled and if not they should all be banned
- ò concerned about antibiotic resistance, viral recombination and environmental pollution
- ò all genetically modified food should be deemed unsafe until proven otherwise
- ò submits that ANZFA not amend the *Food Standards Code* to permit foods derived from genetically modified crops

Donna Chapman (NZ)

- ò opposes Application A338 because soybeans do not have a history of safe use - cites an article from a magazine which implicates soybeans in thyroid damage and cancer

Jim Chapple (NZ)

- ò strongly opposed to all six applications on the grounds that approval of these foods may create a market monopoly for the applicant in the supply of agrochemicals and that gene technology is potentially unsafe
- ò very strongly objects to the term "substantially equivalent" as a play on words
- ò genetically modified foods are not identical to their conventional counterpart and therefore all such products must carry labelling

Commerce Commission (NZ)

- ò no issues raised by the applications on which the Commission has any comments

Consumers' Association of South Australia Inc. (Aust)

- ò supports comments made by Elaine Attwood

Clive Elwell (NZ)

- ò The applications should be rejected because Maori people find genetic engineering in conflict with their beliefs and values, the overwhelming majority of people in Australia and New Zealand do not want to eat genetically modified food, the danger of allergic reactions, and genetically modified food is insufficiently tested and so cannot be regarded as safe for human consumption.
- ò the foods cannot be sufficiently tested because its impossible to carry out appropriate tests, the tests that are carried out are limited and inappropriate.

ConsumersÆ Federation of Australia Inc.

- ò not supportive of these applications being approved at this stage
- ò questions the safety of soya milk as infant food because of the presence of trypsin inhibitor and other antiûnutrients after heat processing, and also the presence of isoflavones.
- ò refers to an analysis done by Professor M. Wahlqvist (but provides no reference to a publication) which has shown that the isoflavone levels may differ from the levels in conventional soybeans
- ò application A338 does not provide sufficient evidence of antiûnutrients to prove that the soybeans are safe for processing into infant formula. In light of this interprets ANZFAÆs safety assessment guidelines as requiring a full toxicological and nutritional assessment of the soybeans. Believes these concerns are serious enough to warrant a recall of foods containing Roundup Ready soy ingredients
- ò no evidence in present by the applicant about glyphosate residues in A338, A362, and A363, despite a specific requirement to do so in ANZFAÆs safety assessment guidelines
- ò donÆt accept the assertion by the applicant that there is only one novel protein in the Roundup Ready soybeans
- ò donÆt believe that testing for homology of protein structure is a sufficient test for allergenicity. At the very least these foods should be fed to human volunteers in closely monitored trials before they are released generally
- ò traces of the introduced proteins could be present in coldûpressed oils at levels sufficient to precipitate allergic reactions, if there is an allergic potential. At the very least, such oils should carry precautionary labels warning of the possibility of allergic reactions
- ò the approval of Roundup Ready maize will facilitate even greater use of high fructose corn syrups in Australian processed foods. The endûresult of this could well be that consumption of such highûenergy products by Australians will rise and that the current excessive levels of nutritional diseases such as obesity, diabetes and heart disease will increase further
- ò ANZFA needs to be satisfied that antiûnutrient levels in canola are safe and that they will not rise over time.
- ò expresses concern about the decreased weight gain by laboratory rats in the first week of a 4 week feeding trial with INGARD cotton seed. Believes that further feeding trials on a range of animals should be performed before this product is released.
- ò ask that approval of foods produced using gene technology be deferred until a national coordinating system for regulatory approvals is in place so that a global assessment of their likely impacts can be made
- ò a system for monitoring adverse reactions to these foods should be established before they are released into the diet of Australians
- ò Approval and release of these foods should not occur until the system of labelling agreed to by Health Ministers is established.
- ò Australia should not be bullied by other countries to accept their exports of unsegregated mixtures of genetically modified and nonûmodified foods

Francela Davies (NZ)

- ò concerned about the addition of food additives in the form of genetically engineered foods that have not been given adequate testing of their benefits or side effects to human health
- ò wants ANZFA to address the long term effects of the consumption of foreign proteins, antibiotic resistant marker genes and viruses
- ò as there is no evidence that these foods are contributing anything positive to the food or the environment requests that the applications are declined

Food Technology Association (FTA) Victoria Inc.

- ò the risk assessment must be completed and reported to ANZFA stakeholders prior to any decision on the Applications
- ò it is unclear from Standard A18 as to the labelling that would apply to these products
- ò wants to know what special conditions might apply to these products
- ò the option to not amend the *Food Standards Code* and permit the sale of these foods is the preferred option
- ò the application needs more detail and background information such as a Full Assessment report, details on special conditions and labelling and a complete risk assessment

Friends of the Earth (NZ)

- ò share the same concerns as expressed in the submission of the Natural Law Party and Clive Elwell
- ò glyphosate has not been included among the residues tested for and are not aware of a any program that monitors for glyphosate residues in food
- ò Treaty of Waitangi obligations have not been considered in ANZFA processes
- ò the New Zealand Bill of Rights provides that no New Zealand may be subjected to experimentation without providing informed consent therefore full disclosure labelling of all transgenic foods and ingredients is the only way this can begin to be achieved
- ò Monsanto has not done any long term studies on health effects
- ò submit that ANZFA should approve these foods for a period of 6 months only conditional on a requirement for immediate, prominent labelling of all food products and a warning logo. This should be followed by a moratorium on any further approval of genetically engineered foods

Noeline Gannaway (NZ)

- ò supports labelling of all food containing genetically engineered products
- ò there may be risks of toxic or allergic reactions
- ò oppose the transfer of genetic material between different species as unethical and potentially unsafe

Goodman Fielder (Aust)

- ò is fully supportive of developments in the agriûfood industry through the application of gene technologies provided that consumer benefits are clearly defined and communicated

- ò urges ANZFA to undertake wide consultation with all affected parties, including growers, crushers (in the case of oilseeds), food industry users and consumers before these modified plants are introduced

Nathan Green (NZ)
- ò objects vehemently to the further introduction of genetically modified foods, specifically the applications by Monsanto.
- ò there have not been sufficient tests to prove safety
- ò NZ should exploit the GMO free market opportunities
- ò there had not been adequate public debate on the introduction of genetically modified foods
- ò doesnÆt agree with the concept and use of substantial equivalence

Mike and Jeanne Gregory (NZ)
- ò the public has not been properly consulted or informed by Government or ANZFA on the introduction of genetically modified foods
- ò strongly opposed to genetically modified foods on grounds that these are not adequately tested
- ò there is significant and growing scientific concern worldwide about the technology and the processes undertaken to evaluate the safety of genetically modified foods
- ò NZ would have a market advantage if genetically engineered foods were prohibited altogether

Martin Hartman and Cornelia Baumgartner (NZ)
- ò object to genetically modified foods
- ò call for mandatory labelling of all genetically modified foods

Karen Hunt (NZ)
- ò demands that all genetically modified foods be labelled
- ò states that consumer rights are violated if products are deemed substantially equivalent and consequently are not subject to mandatory labelling

InforMed Systems Ltd (NZ)
- ò the transfer of EPSPS genes to soybean, maize, cotton and canola are acceptable without prejudice as to whether these foods should require labelling
- ò the transfer of the gox gene to canola is also acceptable
- ò the use of the cryIAc gene is also acceptable
- ò noted that no mention was made of any maker genes in the applications for soybeans, corn or canola
- ò noted that the nptII gene is used in cotton and one insect resistant corn variety. Considers that there are remaining questions with regard to the use of antibiotic resistance genes. It would be reassuring if independent biomedical advice were available to reassure us that this does not pose a risk to the future use of these or related antibiotics in the management of human disease.

- ò notes that none of these modified plants provides any nutritional or functional benefit for the consumer. It is unfortunate that the first applications should not demonstrate benefits to the consumer, who may thus feel that failure to permit the use of such foods will have no measurable effect on them

Richard James (NZ)

- ò MonsantoÆs application lacks scientific rigour and is a nonûsequential jumble
- ò states that there are serious and unresolved safety issues which have not been addressed by Monsanto concerning existing soybean products, the genetically engineered soybeans and combinations of both
- ò MonsantoÆs compositional analyses for toxicants omits may of the well known toxic factors of soybeans
- ò the animal feeding studies were too short

Valerie James (NZ)

- ò the bacterial EPSPS has not been subjected to allergic reactions in the long term and especially the possibility of crossûreactivity to existing human allergic reactions such as antibiotic sensitivity or adverse reactions to peanuts and other legumes
- ò submitted a number of journal articles relating to anti nutritional properties and allergenicity of legumes

Oraina Jones (NZ)

- ò genetically engineered foods have not been adequately tested for their benefits or side effects to human health
- ò what are the long term effects of the consumption of foreign proteins, antibiotic resistant marker genes and viruses
- ò has Monsanto supplied any evidence of long term trials
- ò requests that the application be declined as the foods are not contributing in any way to the food supply or environment

Michael Karas (Aust)

- ò is opposed to applications A338, A355, A362 and A363 because they are for herbicide resistant crops
- ò is concerned about the potential for Roundup residues to be increased in human food supply
- ò is concerned about the outûcrossing of herbicide resistant crops to create æsuperûweedsÆ.

Colin Kell (NZ)

- ò criticises some of the wording used in the preliminary assessment report
- ò claims that genetically altering food decreases their nutritional value
- ò the application provides no proof that glyphosate does not cause long term effects
- ò there has been insufficient testing of these genetically modified foods

- ò balanced information on genetic modification needs to be made available and the rights of everyone taken into consideration
- ò imported commodities should be segregated at source
- ò the applications do not indicate the source of the genes being used - believes that genes from fish and animals are being used which is unethical and against nature

Janine Kelly (NZ)
- ò concerned about the depth of investigation into the safety of genetically modified foods and the lack of concern by regulatory authorities for the opinions of informed members of the general public and scientists.
- ò ANZFA puts too much faith in the integrity of companies who are producing genetically modified foods.
- ò the timing of the deadline for public submissions is unfortunate as most potential submitters would be pressed for time
- ò urges ANZFA to consider the longûterm implications of allowing the sale of genetically modified foods.
- ò if they are allowed, they should all be labelled.

Kristen Khaine (NZ)
- ò consumer rights include the choice not to eat any genetically modified foods, therefore labelling is of paramount importance
- ò trade barrier issues are secondary to public health and safety

Hilde and Kristin Knorr (Aust)
- ò advocate a prohibition on genetically modified foods altogether, but otherwise strongly demand mandatory labelling

Susie Lees (NZ)
- ò not enough information has been provided in these applications
- ò the public do not want to eat these products
- ò if the products are approved we will be at risk of unknown toxins and allergens

Margaret and Leonard Krohn (Aust)
- ò opposed to genetically modified foods on the grounds that insufficient scientific testing has been done and the effects on public health are unknown

C. Lamprecht (Aust)
- ò concerned about the possible detrimental health effects of genetically modified foods
- ò concerned about increased pesticide residues in food
- ò advocates full mandatory labelling of all genetically modified foods

Hannah Levy (Aust)
- ò strongly opposed to genetically modified foods because of the limited knowledge concerning the risks associated with the technology
- ò demands full labelling

Mahikari Australia

- ò strongly advocates the mandatory labelling of all foods or food ingredients produced using gene technology to allow consumer choice
- ò disagrees with validity of "substantial equivalence" as a basis for labelling because of a lack of scientific data
- ò completely opposed to all six applications because of the potential long term risks
- ò concerned about increased levels of glyphosate in food
- ò considers gene technology unethical
- ò considers the outcomes of gene technology scientifically unpredictable because of the possibility that DNA can readily transfer between species

Diane McLaughlin (Aust)

- ò is opposed to Roundup Ready soybeans because believes that conventional soybeans are unsafe for human consumption.

Nadine McRae and others (NZ)

- ò opposes all of the six applications on the grounds that gene technology is unpredictable, unsafe and harmful to the environment
- ò demand that all food with a genetically modified content be labelled

National Council of Women of Australia

- ò requests that ANZFA maintain the status quo and not amend Standard A18 to permit the sale of the indicated foods
- ò no deliberations on applications should be made under this Standard until the situation with labelling is resolved
- ò there is no mention of monitoring pesticide residue increase in the final product as a result of a greater tolerance to what is an obvious need to increase the pesticide used
- ò for the soybean applications there should be absolutely no doubt about the safety of the source of the soybean if it is to be used in the Australian food supply
- ò only two out of the six foods have been tested by feeding to laboratory animals and then only for 6 weeks
- ò no evidence was provided about herbicide residue levels in any of the soybean foods despite there being an application to increase the MRL for glyphosate in soybeans
- ò although the CP4 EPSPS protein may be inactivated on processing the application does not take into account the use of raw soybeans to grow sprouts. This could represent an allergy problem. The foods should be labelled because of this
- ò ANZFA has not taken into consideration the considerable consumer backlash that is occurring.
- ò there must be scientific certainty that humans are not exposed to any newly expressed proteins
- ò objects to the commercial in confidence aspects of A362

- ò concerned about the feeding of the genetically modified seeds to animals as this is another source for these products entering the human food supply
- ò there is no justification for using glyphosateûtolerant canola
- ò Australia should be able to prohibit the import of genetically modified foods if it wishes
- ò if ANZFA allows genetically engineered foods to be imported into Australia unlabelled, consumers will be affected by a lack of choice

Natural Law Party (NZ)

- ò in the absence of a moratorium on genetically modified food, demands labelling of all genetically modified foods on the grounds that there has been no long term preûmarket testing or screening for risk factors associated with this technology and that unlabelled products deprive individuals of their basic freedom of choice
- ò rejects the premise of substantial equivalence on the grounds that differences at the DNA level make them substantially different
- ò concerned about the potential for increased glyphosate levels.
- ò the effects of glyphosate on health and on phytoestrogens in genetically engineered soy has not been addressed
- ò genetically engineered soy contains genes from a virus, a soil bacterium and from petunia, none of which has been in our food before
- ò the technology is being introduced in the total absence of an informed public debate about the general acceptance of GMO technology
- ò believe that there is significant potential for environmental or health disasters associated with the current introduction of this technology. Believes that serious liability implications exist and need to be explored
- ò recommends that, until long term independent safety and risk assessment studies on genetic technology in food production have been completed and their safety to human health and the ecosystems that support human life is established, approvals for these foods should be declined
- ò no further applications should be considered until proper public debate has occurred

New Zealand Nutrition Foundation

- ò submission identical to InforMed Systems Ltd

Office of Regulation Review (Aust)

- ò comments on the preparation of the RIS for the full assessment report
- ò ANZFA should discuss in the background section why such products as the Roundup Ready soybeans which previously entered the commercial markets without segregation from the nonûtransgenic counterpart need now go through an approval process. Is it to address health and safety and/or consumer information concerns?
- ò the problem section of the RIS should outline the characteristics of food produced using gene technology and why these characteristics might give rise to the need to list special conditions. The RIS should specifically canvass the

possible special conditions which could apply and fully discuss the varying costs and benefits that each set of conditions entails

- ò the material present in the sections on potential regulatory impacts and identification of affected parties should be summarised in the RIS in matrix form
- ò when the RIS is fully developed it will need to include a conclusion section which summarises the views elicited from the main affected parties, a conclusion and recommendation option section which states what the preferred option is and why this option was accepted and the others rejected and an implementation and review section which outlines how the proposal will be administered, implemented and enforced.

Martin Oliver (Aust)

- ò opposes all six applications on the grounds that the long term safety of eating foods from herbicide tolerant or insect resistant crops has not been adequately established
- ò all genetically modified foods should be labelled in order for consumers to choose
- ò claims that the foods have not been tested for any health impact on humans

The Pacific Institute of Resource Management/Revolt Against Genetic Engineering (NZ)

- ò all genetically modified food should be labelled so that there can be post-market monitoring for new allergens or toxic effects in consumers
- ò strongly opposed to the technology because of a range of concerns about public health and safety
- ò raised a number of concerns in relation to Application A338, specifically that:
  - û the bacterial EPSPS is unlike any protein that human have eaten and there is no reliable method for predicting its allergenic potential;
  - û a major allergen, trypsin inhibitor was found to be 26.7% higher in transgenic soybeans;
  - û the compositional analyses of the soybeans were not done on soybeans that had been treated with the herbicide;
  - û there were significant increases compared to controls in the milk fat of cows fed transgenic soybeans; and
  - û the applicant did not submit any data on glyphosate residues in the transgenic soybeans.

Ruth Parsons (NZ)

- ò the chemicals in soybeans are responsible for causing breast cancer and thyroid cancer - provided copies of a number of journal articles on the effects of dietary oestrogens on human breast tissue and the thyroid gland.
- ò opposes Application A338 because soybeans are unsafe and the addition of a foreign protein is likely to make it even more unsafe.

Sara Parsons (NZ)

- ò objects to the applications because she is a vegetarian.
- ò it is harmful to be introducing genetically modified soybeans, corn, canola oil and cottonseed into the NZ food chain.

- ò these products are a threat to the safety and well being of animals and humans and are of no benefit to society.
- ò the testing of genetically modified foods on animals and the harm that may be caused to animals in the wider environment is unacceptable.
- ò the lack of labelling of genetically modified foods means that NZ consumers have no way of making appropriate choices if they wish to avoid eating such foods which may cause allergic reactions and offend ethical beliefs.

Eric Phimister (NZ)
- ò is concerned about the importation of unlabelled genetically modified food
- ò does not wish to consume soybeans with a higher pesticide level than the previously allowed maximum. This alone should make it not substantially equivalent

Marja Rouse (Aust)
- ò opposes all six applications on the grounds that the genetically engineered crops pose a major environmental hazard and human health hazard
- ò claims that the technology promotes unsustainable farming practices
- ò believes consumers have the fundamental right to be informed about all the ingredients in foods and therefore demands mandatory labelling
- ò the safety assessment for the applications should not be based on information provided by the applicant in these cases, as the company has a vested interest in having the applications approved

Dean Scahill (NZ)
- ò is opposed to the foods which are the subject of MonsantoÆs applications on the grounds that the costs in terms of potential risk to health, risk to organic crop contamination, and current inability of consumers to identify such foods, greatly outweighs the benefits.
- ò if NZ remains GMOûfree is represents an opportunity to create a niche market.
- ò a labelling system should be developed which would provide consumers with a choice so that they can retain the right to not eat genetically modified food should they choose.
- ò ANZFA should address the large public concern associated with the introduction of genetically modified foods onto the market.

Emma Subue-Timson (Aust)
- ò opposed to foods produced using gene technology on the grounds that the technology contravenes nature.

Christine Taylor (Aust)
- ò opposes all applications because of the presence of new genes, new proteins and increased herbicide residues in genetically modified foods

- concerned about the potential for herbicide resistance genes to transfer to other plant species, creating undesirable effects

Bridget Thrussell (NZ)

- ò supports regulatory option 1 to not permit the sale of any of the foods in the applications
- ò no long term safety tests have been done
- ò worried about antibiotic resistance increasing because of the antibiotic resistance marker genes in A355
- ò concerned about gene transfer between Roundup Ready canola and other Brassicas

E.M. Trevelyan (NZ)

- ò does not believe that genetically modified foods can be assessed as safe because of the possibility of "gene flow"
- ò crops containing the Bt gene will inevitably lead to resistant insect populations
- ò envisages an enormous marketing advantage to NZ if it maintains a clean, green image by not allowing genetically modified food onto the market
- ò all genetically modified food products should be labelled

Richard van Wegen (Aust)

- ò supports the restricted use of genetically modified plants for food production
- ò strongly supports mandatory labelling as a democratic right to make informed decisions about food purchases

Arnold Ward (Aust)

- ò opposed to all applications on the grounds that long term safety has not been established
- ò ANZFA only concerns itself with public safety rather than adopting a 'holistic' approach which takes into consideration the broader issues to do with genetic engineering
- ò Roundup herbicide contains other chemicals which are harmful. The acceptable daily intake of glyphosate does not take into account the higher toxicity of the surfactant POEA in Roundup, on individuals with increased susceptibility such as children, immune compromised individuals or the elderly
- ò notes examples of scientific evidence which show glyphosate can increase levels of plant oestrogens, which are known to affect humans
- ò feeding experiments in cows indicate a change in the milk fat production in animals fed on Roundup Ready soybeans versus non-transgenic soybeans, possibly due to elevated oestrogens. Very concerned about the potential health effects, particularly in children, of higher levels of oestrogens.
- ò where resistance to Bt toxin occurs because of a widespread use of insect resistant crops, this would mean that organic famers, who now rely on Bt formulations, could lose an important pest control agent.
- ò expresses concern about the possibility of recombination and horizontal gene transfer resulting in environmental catastrophies
- ò glyphosate does not degrade in soils as efficiently as claimed by the applicant
- ò all transgene products should be given the same testing applicable to pharmaceuticals

- ò the seeds from genetically engineered crops could spread due to natural disasters
- ò plant viruses can acquire viral DNA from a transgenic plant
- ò Bt cotton is not very effective in controlling bollworm infestations
- ò calls for a moratorium of 10 years on the introduction of genetically modified foods

Joyce Weatherhead (NZ)

- ò opposes approval for the applications on the grounds that genetically modified foods have not undergone an independent scientific testing
- ò calls for a moratorium on genetically modified foods in NZ for ethical and religious reasons
- ò demands mandatory labelling of all genetically modified foods
- ò approval for herbicide resistant soybeans will result in a huge increase in the level of contaminating herbicides in foods derived from these crops

Western Australian Food Advisory Committee

- ò a safety assessment of the foods is lacking along with the absence of any supporting scientific evidence
- ò postûmarket monitoring to confirm the results of risk assessment and establish evidence of a safe history of use is an unacceptable alternative to a full scientific evaluation, with the results being available for public scrutiny
- ò the claim that CP4 EPSPS is destroyed in heat processing requires independent scientific validation and it is unclear from ANZFAÆs papers whether this evidence has been provided and reviewed.
- ò insufficient evidence has been provided in the discussion document to support claims that these products are safe or that the Authority has undertaken a rigorous analysis of comprehensive a scientific evaluation of these products
- ò the issue of decreased availability of food choices in the marketplace listed under both Options 1 and 2 is not nearly as important as the safety issue
- ò given the heightened public concern about genetically modified foods it is essential that scientific information relating to compositional variance due to novel gene expressions, toxicology, potential for allergenicity, nutritional and dietary properties for each of foods proposed by Monsanto be publicly available and a full safety evaluation be undertaken
- ò The Committee recommends the adoption of Option 1 at this time

S. and L. Wintergraas

- ò ANZFA should stop all genetically engineered foods from entering into any food products in NZ as it will destroy NZs clean green image.
- ò ANZFA is not able to guarantee safety of these foods - cites DDT, nuclear power and antibiotics as examples.
- ò ANZFA should protect the consumer, not big business.