INQUIRY REPORT

A338 - FOOD DERIVED FROM GLYPHOSATE-TOLERANT SOYBEANS

EXECUTIVE SUMMARY

- 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 glyphosate–tolerant soybean line 40–3–2 in the Table to clause 2 of Standard A18 – Food Produced Using Gene Technology;

- The Authority considered the Full Assessment report on Application A338 at ANZFA 55 in February 1999. The draft variation to the *Food Standards Code* was gazetted on 17 February 1999 and the period for public comment closed on 31 March 1999, although submissions were accepted beyond the closing date;

- Standard A18 was adopted as a joint Australia New Zealand standard in July 1998 and came into effect on 13 May 1999. The standard prohibits the sale of food produced using gene technology unless it has first undergone a safety assessment by ANZFA and has been approved by the Australia New Zealand Food Standards Council (ANZFSC);

- On 30 March 1999, ANZFSC approved a recommendation by ANZFA, under section 37 of the ANZFA Act, to allow foods produced using gene technology which were already in the marketplace, to remain on the market during the period of assessment by ANZFA providing they met specified criteria. The standard was amended to this effect by inserting clause 2A. These foods will, however, still undergo a rigorous safety assessment process;

- The conclusion at full assessment of this application was that food derived from glyphosate-tolerant soybean line 40-3-2 can be regarded as substantially equivalent to food from unmodified soybeans in respect of its composition, safety, wholesomeness and end use. Labelling of glyphosate-tolerant soybeans is not required under the current provisions of standard A18. It is noted however, that the labelling provisions of the standard are still under consideration;

- At Inquiry, issues raised in public submissions included:

  (i) the need for compositional data on glyphosate-treated soybeans;
  (ii) the phytoestrogens content of soybeans;
  (iii) the adequacy of the animal feeding studies;
  (iv) the use of the applicant's data for assessment;
  (v) glyphosate levels in soybeans;
  (vi) studies conducted at the Rowett Research Institute;
  (vii) the precautionary principle;
  (viii) allergies to soy products:
  (ix) the presence of animal or insect genes; and
  (x) the presence of antibiotic resistance genes;

- The conclusions of the Inquiry Report are:

- food derived from glyphosate–tolerant soybean line 40–3–2 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 glyphosate–tolerant soybean line 40–3–2 will not require labelling under the current provisions of standard A18 as it can be regarded as substantially equivalent to food derived from conventional soybeans. It is noted however that the labelling provisions of Standard A18 are still under consideration;

- the proposed amendment to list food derived from glyphosate–tolerant soybean line 40–3–2 in the Table to Standard A18 is consistent with ANZFA's section 10 objectives; and

- 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.

SUBMISSIONS RECEIVED AT INQUIRY

Number of submissions

The Authority considered 103 submissions pertaining to this application at Inquiry. A significant proportion of these were detailed submissions in terms of the documentation provided and almost 75% were from New Zealand. Fifteen submitters express support for the application, with a subset of these limiting their level of support on the basis that particular conditions be met or requirements be fulfilled, for example, labelling to allow consumer recognition of the foods.

The remainder of the submitters were opposed to the application for a variety of reasons but predominantly because of ongoing doubts about the long term safety of the food.
Another major concern expressed by those opposed was the perceived negative environmental impact resulting from the use of transgenic soybean crops.

Nature of the submissions

To be considered at Inquiry, submissions from the public are generally expected to raise additional issues either not previously considered at full assessment or, on the basis of additional information, require further consideration. It is expected that submissions will contain evidence in support of the claim or statement and, where appropriate, be accompanied by any relevant technical information. In addition, the submissions must refer to the application specifically and quote the application reference number.

The correspondence received by the Authority at Inquiry did not always meet these criteria. The points, although detailed, were often not specifically related to the application, were expressions of opinion, provided technical or scientific information that was in no way connected to the application or even to the use of gene technology in food production. Many of the submissions called for the Authority to consider the wider implications of biotechnology, for example environmental or ethical issues, well beyond the usual principal terms of reference in relation to food safety and other statutory obligations. Nevertheless, in view of the level of interest in this application, being one of the first to be assessed under Standard A18, the Authority has adopted a broader approach in the consideration of matters raised by the public submissions. Consequently, many submissions which merely repeat views already expressed or raise matters already addressed at full assessment are discussed more fully than would normally be warranted. In addition, it was decided to consider late submissions to the first round of public consultation, which nominally closed on 23 December 1998, at Inquiry.

Submissions in relation to labelling of foods produced using gene technology

In addition to submissions in relation to this application, the Authority received other correspondence which expressed views only on the issue of labelling of foods produced using gene technology, particularly in relation to the decision of Health Ministers at the meeting of the Australia New Zealand Food Standards Council (ANZFSC) on 17 December, 1998. In view of its more general nature, such correspondence has been noted and filed, but will not be specifically addressed in this report.

The Council has yet to resolve all of the issues relating to the labelling of foods produced using gene technology although Standard A18 commenced on 13 May 1999 as originally proposed. The current standard contains a provision for the mandatory labelling of substantially different (that is, not substantially equivalent) foods.

Since the December meeting of ANZFSC, the Authority has been working, in conjunction with other government departments in Australia and New Zealand, on a range of possible options to address the issues raised by the Health Ministers. To assist with this process, and to comply with statutory requirements for public comment under the New Zealand Food Act, the Officials Committee on Food Administration (OCFA) initiated a four week period of public consultation on the
labelling of foods produced using gene technology. The consultation, managed by the New Zealand Ministry of Health, was in the form of a booklet available from 10 May 1999 which provided background information to the use of gene technology in food and contained an outline of the assessment process and issues. The booklet posed a number of questions which were designed to gauge public opinion and to provide insight into the efficacy of proposed labelling changes under consideration. The closing date for response in New Zealand was 4 June 1999.

Following minor alterations to the New Zealand booklet, ANZFA conducted a similar public consultation in Australia from 17 May 1999 to 11 June 1999, also a period of four weeks. The submissions from both New Zealand and Australia will be analysed and the information provided will assist in formulating recommendations to Health Ministers on the labelling provisions of standard A18.

ASSESSMENT OF ISSUES RAISED IN PUBLIC SUBMISSIONS

1. The adequacy of the compositional data from glyphosate-sprayed glyphosate-tolerant soybeans

Data on compositional analyses of the glyphosate tolerant soybeans following application of the herbicide was considered necessary by Dr Stanley Robert, the Australian GeneEthics Network, the South Australian Department of Human Services and others. They argued that the only way to determine whether glyphosate can cause physiological changes, leading to compositional changes, in the modified soybeans is to perform complete compositional analyses on glyphosate-sprayed glyphosate-tolerant soybeans.

Background

During the course of the safety assessment of the glyphosate-tolerant soybeans, it was noted by the Authority (page 44 of the Full Assessment report) that data relating to compositional analyses of the soybeans following treatment with the herbicide had initially not been provided. The purpose of comparing data on the composition of the glyphosate tolerant line with the control line in the absence of the herbicide was to focus attention on any differences which may arise due to the genetic change itself. These studies were relevant to the safety assessment because they form the basis of the determination that the glyphosate tolerant soybeans are essentially the same as the conventional counterpart.

At the whole plant level, approximately 150 field tests in which glyphosate-tolerant line 40-3-2 was sprayed with glyphosate were evaluated and no deleterious effects were observed (Delannay, X. et al., 1995). Although it may be argued that data on the compositional parameters of glyphosate sprayed soybeans is not required on conventional unmodified crops, it is acknowledged that the presence of the genetic modification in this case is expected to result in an altered pattern of usage of the herbicide, due to the altered plant response to glyphosate. In consideration of the food obtained from these crops, it was appropriate therefore to review compositional data which reflects the combination of these factors. The Authority subsequently requested from the applicant additional data relating to compositional analyses of the glyphosate tolerant lines following application of the herbicide at levels expected to be used in normal agricultural conditions.

Evaluation

The additional compositional data following spraying of the glyphosate tolerant soybean line 40-3-2 were supplied by the applicant. The proximate data consists of measurements including protein, fat, ash, moisture, fibre, and carbohydrates and is the standard method for determining base chemical composition of soybean seeds. In addition, seed samples were analysed for amino acids and isoflavones (also referred to as phytoestrogens). Due to specific interest in the isoflavone analyses, these data are considered separately in section 2.

The study has been submitted for publication in the Journal of Agriculture and Food Chemistry which necessitates undergoing independent peer review of the results prior to publication.

Due to significant natural variation in the levels of key nutrients and anti nutritional factors depending on growth conditions, the unsprayed conventional soybean seed was collected across multiple locations in two consecutive years of growth. Seven different sites across six US states were used in the first year and four sites each in different states were used in the second year of the study. Glyphosate tolerant soybean line 40-3-2 was grown side by side at the same sites as the parental control line A5403.

A pre-emergent application of Roundup® herbicide was used on the glyphosate tolerant soybean crop, followed by a second application at early post emergence, approximately 40 days after planting. In the second year of testing, the spray regime included a pre-emergent application of Roundup®, an early post emergent application and a late post emergent application at the first formation of the flower buds. There were no applications of Roundup®, either pre or post emergence, to the control A5403 field plots.

Proximate analysis (protein, ash, moisture, fat, fibre and carbohydrates) is the standard method for determining the base chemical composition of soybean seeds and was performed at Ralston Analytical Laboratories (St. Louis, MO.). The results of the proximate analyses show that there was no statistical difference between the levels of protein, fat, ash, fibre or carbohydrates between glyphosate-treated glyphosate-tolerant soybean line 40-3-2 and the untreated control A5403. Furthermore, in a more detailed study of protein, amino acid analysis of the modified and control lines indicates that the levels of all amino acids including the aromatic amino acids (phenylalanine, tyrosine and tryptophan) were comparable between the two lines. Since glyphosate affects the synthesis of aromatic amino acids in conventional soybean plants, this test confirms that the introduced CP4 EPSPS enzyme in the glyphosate-tolerant soybeans allows normal production of aromatic amino acids in the plant in the presence (or absence) of the herbicide.

As well as proximate analyses, amino acid levels and isoflavone levels, data was collected on the expression of the CP4 EPSPS (amount of new protein) in the glyphosate-treated glyphosate-tolerant soybeans using an ELISA (Enzyme Linked Immunosorbent Assay) technique. Due to the fact that glyphosate inhibits the endogenous plant EPSPS enzyme, this study was done in order to determine any subtle effects of glyphosate on the aromatic amino acid biosynthetic pathway in which EPSPS is a key enzyme. The results show no statistically significant difference in the level of the introduced enzyme in soybean line 40-3-2 whether unsprayed or glyphosate sprayed. As the enzyme is constitutively expressed, the results indicate that the presence of the herbicide has no effect on the levels of the newly introduced enzyme in the seed, and therefore does not induce enzyme levels higher than expected for unsprayed glyphosate-tolerant plants.

In summary, the analytical results from these studies showed equivalence in composition of the glyphosate tolerant soybean line 40-3-2 after treatment with commercial levels of the herbicide when compared to the unsprayed parental control cultivar A5403.

2. The phytoestrogen content of glyphosate-tolerant soybeans

T. Behrens, M. Burn, L. Dempsey, Dr. M. Godfrey and E. Attwood claimed that glyphosate increases the oestrogen levels in plants with possible adverse health effects in females of all ages, and possibly in males as well. In this context, there were particular concerns about the effects of feeding soy based formulas to infants for whom milk formulas were contra-indicated.

Evaluation

The levels of total and free forms of the isoflavones genistein and diadzein and bound coumestrol and biochanin A were determined in glyphosate sprayed glyphosate-tolerant soybean line 40-3-2. The limit of quantitation of the assay system is 10 ppm and the analyses showed that the quantities of biochanin A (<1 ppm) and coumestrol (<4 ppm) were therefore below the limits of quantitation of the assay.

The reported results indicate the range of total genistein and total diadzein was variable across the test sites for both the control line and glyphosate tolerant line.

However, the mean levels of total genistein and total diadzein in the glyphosate tolerant 40-3-2 line were comparable to those in the control A5403 line. In addition, the results were comparable to isoflavone levels previously reported (Wang et al. 1990).

Several submitters also referred to a report in the literature (Sanderman, H. et al., 1988) which stated that the level of isoflavones in non-glyphosate tolerant plants was found to be elevated following glyphosate treatment. However, the research was conducted on beans (*Phaseolus vulgaris*), not soybeans, and the conclusion of the author was that the observations were consistent with a stress response in the

unmodified beans due to the presence of the herbicide. Furthermore, evidence has been provided directly from the author of this study, Dr. Sanderman, that his interpretation of the result is that glyphosate caused necrotic development in the plants (as they were not modified to be glyphosate tolerant) and phytoestrogens are formed usually in parallel to necrosis. Of significance to this issue, he further indicated that there was no expectation that glyphosate-tolerant soybeans would respond to the presence of glyphosate by the formation of extra phytoestrogens, but advised that this should be tested directly.

The results of this study support the conclusion that the previously reported increase in isoflavones following glyphosate treatment to unmodified beans was likely to be a stress induced response due to the application of glyphosate. In the completed soybean study, the compositional data and crop yield of the glyphosate tolerant soybean line 40-3-2 indicate that these plants do not exhibit a stress response and do not differ from the unmodified soybean line in respect of the levels of phytoestrogens present in the seed.

3. The adequacy of animal feeding studies

The New Zealand Ministry of Health and the Ministry of Agriculture and Forestry jointly commented that the relevance to humans of some of the feeding studies is questionable given that the sample size was small and the tests were generally of short duration. In addition, the Ministry stated that where statistically significant differences were observed between control and test groups in the animal studies, a broader discussion and summary of the results could have been provided.

Specifically in relation to the published dairy cow 4-week feeding study using raw soybeans, the Ministry of Health sought further independent scientific advice from the New Zealand Dairy Research Corporation Limited on the significance of the small increase (statistically significant) in the 3.5% fat-corrected milk (FCM) production of the cows fed on the glyphosate tolerant soybean line 40-3-2.

Other submitters including J. Kelly, Dr. B. Conlon, T. Jones, N. and B. Mountier and Dr. N.D. Soysa claimed that the feeding studies are inadequate as they were of short duration and do not provide any indication of the long term safety of glyphosate-tolerant soybeans.

Evaluation

In the safety assessment report of glyphosate tolerant soybean line 40-3-2, the Authority found that the small increase in FCM production for cows fed on modified soybeans compared with cows fed on unmodified control soybeans is not considered to be biologically significant, as it is likely to be due to a slightly higher net energy intake by the test animals. An independent scientific opinion in relation to this study was sought from scientists at the New Zealand Dairy Research Corporation Limited, who agreed with the conclusions of the Authority.

Although the nutrient composition of the total ration of food provided to the cows was approximately the same for genetically modified and control soybeans, there was a marginal difference in terms of fibre and carbohydrate content between the two lines. This resulted in a difference of energy intake of approximately 4% between control and modified lines and would account for the slight difference in milk production. Therefore, the small but statistically significant increase in the 3.5% FCM is likely to be related to the marginal difference in the proportion of fibre in the diet of the cows which received the modified soybeans compared with the A5403 control diet. As reported in this study, FCM per unit of energy intake indicated no statistically significant difference between animals fed glyphosate-tolerant soybeans and parental lines.

In summary, the scientific opinion on these data is that the small differences observed in this experiment are more than likely a result of the small variation which can occur during the physical mixing and feeding of the respective total diets, and the rigour of the randomisation process by which the cows were allocated to a particular treatment.

In addition, scientists at the New Zealand Dairying Research Corporation questioned the apparently unrealistically low somatic cell counts in the published data (Hammond et al, 1996) on milk composition in both groups of cows used in the feeding study. However, investigation of this revealed that the published values only appear low because of the mode of statistical representation. The overall conclusion, that there were no treatment related differences in somatic cell count between the two groups of cows in the study, remains valid.

The applicant has provided animal data on the feeding value (wholesomeness) of glyphosate-tolerant soybeans compared to that of the parental cultivar in several other species including rats, chickens, catfish and cows. The study duration was 4 weeks (rats and dairy cows), 6 weeks (broiler chickens) and 10 weeks (catfish). As previously reported by the Authority, these short term animal studies provide additional scientific support to the other data obtained in detailed compositional analyses of the glyphosate tolerant seeds and are considered in this context rather than as detailed toxicological assessments of the food.

It is well recognised that animal feeding experiments involving any whole foods are problematic in terms of design (feeding sufficient quantities of genetically modified foods for sufficient periods) and interpretation (substantial variation in results between groups) and cannot be considered as definitive toxicological studies, although they provide important supporting data in a safety assessment.

4. The use of the applicant's data in the assessment

Many submitters questioned ANZFA's acceptance of the scientific data provided by the applicant, believing that independent data should have been submitted for assessment.

Evaluation

In accepting an application to vary Standard A18 in the Food Standards Code, ANZFA requires detailed scientific information relating to the genetic modification in the food crop as well as data to establish the safety of the modified food. In order to ensure that applicants submit sufficient and appropriate information, ANZFA has produced two detailed documents to assist applicants with their submissions - Format for Applying to Amend the Australian Food Standards Code - Food Produced Using Gene Technology and Guidelines for the Safety Assessment of foods to be included in Standard A18 - Food Produced Using Gene Technology. Together these documents indicate the nature of the information required by ANZFA to complete a comprehensive safety assessment of the food, and ensure that the applicant is informed of their responsibilities in relation to the data they provided. The requirement for detailed molecular data relating to the genetic modification necessitates the information being supplied by the developers of the modification.

In the acceptance and assessment of the applicant's data relating to glyphosate-tolerant soybeans, ANZFA is not departing from normal procedure. Because of its very detailed nature, the scientific data on the composition and safety of the food must be provided by the applicant who is in turn directly responsible for the validity and accuracy of the information submitted. In the completion of the safety assessment however, ANZFA relied also on a range of references relevant to glyphosate-tolerant soybeans, including published scientific data relating to the human health effects of phytoestrogens, research data on the allergenic properties of soybeans, as well as a toxicological assessment of the herbicide itself completed by the Department of Health. Taken together, the material analysed formed the basis of ANZFA's recommendation at full assessment.

Furthermore, applicants are expected to demonstrate to ANZFA that the studies presented in an application have been done according to Good Laboratory Practice (GLP) and that the data accurately reflects the raw data generated during the studies. Generally, applicants provide some form of Quality Assurance certification, and in addition, the applicant is also required to make a Statutory Declaration that the data presented in an application fully sets out the matters for consideration and is a truthful reporting of the analyses that were done.

The requirement for sound scientific data refers to the use of validated analytical methods and GLP in the conducting of studies. Validated analytical methods are usually standardised assays, such as the methods from the Association of Official Analytical Chemists or other recognised bodies. The purpose of GLP is to ensure the reliability and reproducibility of experiments and that the reports of the work accurately reflect the conduct of the experiment. Compliance with GLP involves careful recording of the details of the experimental conduct and protocol and quality assurance of the report.

With respect to completed studies on the glyphosate tolerant soybeans, the applicant submitted a complete set of analytical data with the required certification which ANZFA considers were in full compliance with the rigorous requirements set out in the guidelines for assessment of these foods under Standard A18.

By way of example, there were at least five separate laboratories, some operating as a contract facility, involved in generating sections of data, and each provided independent certification relating to experiments. Dates of reviews as well as dates that findings were reported to testing facility management and the study director were also provided.

Furthermore, as many of the developers of plant biotechnology are actively engaged in scientific research, during the course of production of a commercial crop line, scientific procedures or developments of general scientific interest are often published in international journals. Such a public presentation of research material necessarily entails broad and independent scientific scrutiny of data before and after publication. Several studies submitted by the applicant in relation to glyphosate tolerant soybean line 40-3-2 are published scientific studies.

5. Glyphosate levels in foods produced from glyphosate tolerant soybeans

Many submitters, including Professor A. Stewart Truswell, Dr A. Tebecis, Go Mark Food Systems, J. Peter, the Consumers' Federation of Australia, J. Kelly, J. Clark and R. Warren of the Australian Chemical Trauma Alliance contend that, due to the specific nature of the genetic modification in glyphosate tolerant soybeans, the usage of glyphosate on these crops will increase and that this may result in increased levels of residual herbicide in the foods obtained from them. In this context, many submitters such as the Native Forest Network were concerned with the degree of toxicity of the herbicide.

The Safe Food Campaign and others submitted additional concerns about the toxic effects of another chemical constituent of Roundup®, namely, polyoxyethyleneamine (POEA), claiming that chemical to be a greater hazard to health than the active ingredient, glyphosate.

Evaluation

This issue was previously discussed in detail in the full assessment report to this application. At that time, the report stated that all soybeans, whether derived from a genetically modified crop or a conventional crop, were required to comply with the maximum residue limit (MRL) for glyphosate in soybeans.
In Australia, the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) makes recommendations on MRLs to ANZFA for incorporation into the Food Standards Code. The NRA recommendations are based on data obtained from detailed toxicological studies of the herbicide and from actual field trials taking account of the levels of glyphosate that can be achieved using good agricultural practice. To ensure that the likely levels of exposure will not result in adverse health effects, a rigorous assessment of the toxicological and other safety data pertaining to the particular chemical is undertaken, in combination with dietary modelling data. Thus, the current MRL for glyphosate in soybean is 0.1 mg/kg, as this is an agriculturally determined level appropriate to Australian conditions.

Internationally, many countries accept the MRLs for herbicides set by the Codex Alimentarius Commission, as these represent generally acceptable levels of exposure when dealing with commodities that are freely traded on global markets. The Codex MRL for glyphosate in soybeans is 20 mg/kg which is considered to be a level well below the level at which adverse health effects may occur. In New Zealand, a dual system for MRLs has been operating for some time. Some MRLs are set according to appropriate levels for the domestic market while Codex levels are accepted for imported commodities, including soybeans.

Any discrepancy between MRLs set for a particular commodity reflects the agricultural conditions in which the food is grown, but always represents a safe level of exposure which will not result in adverse health effects in humans.

Furthermore, the Codex MRL of 20 mg/kg for glyphosate in soybean was established before the development and commercialisation of genetically modified glyphosate-tolerant soybean lines. The MRL therefore has not been revised or altered in direct response to the advent of glyphosate-tolerant soybeans to world markets. Consideration of accepting the Codex level in Australia for imported commodities such as soybeans is associated only with factors affecting world trade and is currently under review by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), in conjunction with other government departments.

In the production of unmodified soybeans, the crop is generally sprayed with glyphosate at the pre-emergent stage. In the USA, but not in Australia, there is also a pre-harvest treatment with glyphosate which acts as a desiccant to facilitate harvest. The genetic modification to confer glyphosate tolerance allows an alteration to the pattern of treatment of the crop with herbicides such that chemicals other than glyphosate do not need to be applied at particular stages of growth. Thus, the overall use of herbicides is expected to be reduced and, as a direct consequence of the genetic modification in soybean line 40-3-2, the use of glyphosate with low toxicity, is tolerated by the plants.

Moreover, the advice provided to farmers of glyphosate-tolerant soybeans on the agricultural use of the herbicide recommends application at different stages of the growth cycle, but no more frequently than is used for conventional crops. In relation to soybean agriculture in the US, there has been a reported 10%-40% reduction in the use of herbicides on genetically modified soybeans.

Toxicity of glyphosate

The toxicity of glyphosate has been extensively studied in laboratory animal testing of a range of different species including rats, dogs, mice, rabbits, guinea pigs and monkeys. The testing of the toxicity of glyphosate also included long term studies in which animals were exposed to varying levels of the herbicide over periods of time in excess of 2 years. An assessment of this toxicological data has been undertaken by the Commonwealth Department of Health and Aged Care to support the establishment of acceptable daily intake levels. The results of the animal studies indicate that glyphosate exhibits a very low degree of toxicity.

Furthermore, in the agricultural environment, when applied to emerged weeds, glyphosate shows no residual activity. This is because it binds strongly to soil particles and is readily broken down by soil microorganisms. Because of the rapid transportation from the leaves of treated plants to the roots, it is effective in destroying perennial weeds which can survive other herbicides which only affect the above-ground parts of the weed plant.

Toxicity of other chemicals in Roundup® herbicide.

Polyoxyethyleneamine (POEA) is used as a surfactant in agricultural chemicals, including glyphosate formulations, and in other preparations for human use, for example, shampoo. In June 1996, the NRA issued a Community Brief advising the public that it had undertaken a review of the use of glyphosate formulations in and around aquatic areas with particular reference to the toxicity of surfactants to aquatic organisms.

This was in response to a report which showed the surfactant in certain glyphosate formulations to be more harmful to frogs than the active ingredient, glyphosate. Following this review, the NRA made specific proposals relating to the inclusion of a warning statement on all agricultural glyphosate product labels precluding use on or adjacent to waterways.

The MRL for glyphosate remained unchanged at 0.1 mg/kg for soybeans on the basis that this level was well within the previously determined safety margin for food destined for human consumption.

6. Feeding studies conducted at the Rowett Research Institute

Since the completion of the full assessment of this application, there has been a report of adverse health findings in rats in a feeding experiment with genetically modified potatoes conducted by Dr Arpad Pusztai of the Rowett Research Institute in Scotland. A number of submitters, including Dr A. Tebecis of Sukyo Mahikari Australia Limited and Dr B. Conlon, General Practitioner, have claimed that these reports are evidence that harmful health effects, claimed to be attributable to gene modification, can occur. In addition, Dr Conlon states that the potatoes were termed substantially equivalent and makes the claim that they would not therefore be subject to long term trials to determine safety. Dr Conlon concludes that the determination of substantial equivalence in the potato situation may have resulted in a failure to detect adverse health effects within the present regulatory framework. A list of 20 scientists was provided to substantiate the claim that a significant body of scientific opinion supported public access to and discussion of the findings of the potato feeding study. The submitters further claim that the reported findings of this experiment provide adequate justification for a precautionary approach with respect to glyphosate tolerant soybeans, and provide clear evidence that scientists are currently in no position to assess the safety of foods produced using gene technology.

Background

The work of Dr Arpad Pusztai at the Rowett Research Institute (RRI) was part of a multicentre project in the United Kingdom to identify genes encoding antinutritional factors suitable for transfer into plants to enhance their resistance to insect pests. Suitable factors were considered to be those which would have minimum impact on non-target, beneficial organisms, the environment, livestock fed on these plants, and present no health risks for humans either directly or indirectly through the food chain.

The work at RRI concentrated on tubers from genetically modified potato lines expressing the gene of snowdrop (*Galanthus nivalis)* bulb lectin, GNA. The task was to carry out thorough chemical analyses and establish whether the parent and transgenic lines were compositionally equivalent, and to conduct short-term (10 day) and long-term (3 months) rat feeding trials to determine the effects on mammalian metabolism. No other lectin-expressing genetically modified plants had been tested with rats.

To study the nutritional characteristics of the snowdrop lectin modified potatoes (GNA potatoes), Dr Pusztai was responsible for designing and conducting feeding trials in laboratory rats. He reported that the overall design of the experiment was complicated by several factors. As well as the low protein content of the potato tubers, the potato proteins were of relatively low quality to fully support the growth of young rats.

In order to meet the minimal nutritional requirements of the animals, both control and transgenic diets needed supplementation with different amounts of a high nutritional quality protein, lactalbumin. This was a particular problem of the long term study because analysis of the GNA potatoes had shown that the protein levels were different from the parent line, leading to dietary imbalances which would be of greater significance over time.

It was reported that it was nearly impossible to formulate control and test diets for the longer term study which were equivalent in protein. Preliminary studies had shown that raw potatoes were so nutritionally unsuitable to maintain the health of the rats that only cooked potatoes could be used. For this reason, there was a greater focus of attention on the results from the 10 day study, where the reserves of the animals were considered to compensate for the inherent dietary imbalances.

Dr. Pusztai reported that feeding rats with diets containing raw GNA potato tubers for 10 days induced significantly large changes in the absolute and relative wet weights of most major organs in comparison with parent line diets. In addition he reported that the animals who ingested the raw transgenic potatoes exhibited a significant depression in the responsiveness of peripheral lymphocytes in *in vitro* assay conditions. In his report, Dr Pusztai states that it is known that immune responses are diminished by feeding animals on diets of low protein content particularly when the proteins in the diet are of poor nutritional quality such as potato proteins. It is acknowledged also in his report that the cumulative effect on feeding of components (lectins, protease inhibitors, glycoalkaloids etc.) in potatoes that are likely to be harmful, requires investigation.

Evaluation

Since the public release of the details of this study by the Audit Committee at RRI, there has been protracted debate about the validity of the experimental design, the results, and the interpretation of the data. Although there has been some scientific opinion expressed in support of Dr Pusztai's study, there is by no means a consensus view. Many recent scientific reviews of the data (for example, the UK Royal Society, Nature, 399, 188) have pointed to significant inconsistencies in the interpretation of the results and the manner in which the data were presented. In addition, an independent statistician from Biomathematics and Statistics Scotland (BioSS) who was commissioned by Dr Pusztai himself to carry out further statistical analyses on the data, has reputedly concluded that there was no discernible consistent pattern in the data on organ weights. All of the rats in the study, including the control animals, were severely malnourished and suffered extreme metabolic stress during the course of the treatment and many confounding factors have resulted in substantial background variation. For example, the presence of significant differences in glycoalkaloid content of the tubers may have unrecognised nutritional consequences. In addition, malnutrition can also cause unpredictable immune responses meaning that the data are impossible to interpret. Consequently, there is a body of independent scientific opinion, from food toxicologists and molecular biologists in both the UK and the US, that no valid interpretations of the data are possible.

However, even if a pattern of change could have been identified with a conclusive link to the feeding of genetically modified potatoes, this finding is evidence of the strength of the testing procedures and practices already in existence for foods produced using gene technology. In the potato experiment, these foods were not intended for human consumption and the testing that took place was to ascertain scientific information about lectin expression in potatoes.

The lectin used is already known to be a natural toxin and therefore would be expected to cause adverse effects in animals. In the course of development, some experimental genetic modifications will undoubtedly result in undesirable or adverse effects, and the rigorous testing that occurs in the laboratory, and at later stages, is specifically carried out to identify unsuitable types and eliminate these from further development.

It is important to note that genetic events which result in unwanted characteristics are known to occur also in conventional breeding programs, resulting in the discontinuation of some lines before commercialisation takes place.

The primary purpose of the work of the RRI was to analyse the GNA potatoes and to complete laboratory studies on their nutritional and compositional properties. The controversy about the interpretation of the data has concealed the rigour with which the scientific community approach the case-by-case testing at all stages of development of gene technology products, especially in the production of foods for human consumption.

Finally, the principle of substantial equivalence has been discussed in detail in the full assessment report on glyphosate tolerant soybean line 40-3-2, and other reports previously produced by the Authority. It is a concept initially developed at the international level by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) and adopted by the OECD (Organisation for Economic Cooperation and Development, Safety Evaluation of Foods Derived by Modern Biotechnology, Paris, 1993) as a practical approach to assessing the safety of foods and food components derived through modern biotechnology. In Australia and New Zealand, it provides a useful tool in the evaluation of such foods as it allows a systematic approach to the safety assessment and currently assists in the formulation of labelling requirements. In this context, the principle of substantial equivalence in the regulatory sense is not to be compared with its use in a scientific context where the connotations may be entirely different. A potato expressing a protein such as a lectin, which is a known anti-nutritional factor, would not be regarded as substantially equivalent to the unmodified potato under the precautionary regulatory system operating in Australia and New Zealand.

7. The Precautionary Principle

Several submitters including Dr. B. Conlon, Dr P. Butler, Dr. M. Godfrey, T. Jones and A. Stanton proposed that the Precautionary Principle should be adopted as a working approach to the analysis of the risk associated with foods produced using modern biotechnology.

Evaluation

The precautionary principle is a risk management approach which was developed in relation to environmental risks, and may be exercised in a situation in which risks are completely unknown, or in instances in which studies are incomplete, or have conflicting or contradictory answers. It has not generally been applied in relation to food safety.

The use of the precautionary principle as a factor in the risk assessment of foods produced using gene technology has been discussed in the international arena for some time. Fundamentally, it is recognised that reference to such a principle needs to be based on an agreed definition and a common understanding of its scope of application. However, despite lengthy debate, there is currently no consensus on the applicability of the principle in relation to the regulatory procedures associated with food biotechnology.

For foods, there is often an extensive database on the biological effects and any remaining uncertainty related to safety of food components is of a statistical character rather than a prospect for completely unknown effects.

Although definitions of the precautionary principle may vary, an underlying theme is that the principle implies a desirable level of care in decision making about the potential risks, in this case, associated with gene technology in the production of food. An extreme interpretation of the precautionary principle implies that a prohibition should be in place until there is absolute certainty of no negative effect, even if there is an absence of demonstrable causation. In issues specifically relating to food, this would imply that no food ingredient, colour, additive, etc., would be permitted unless there was a complete guarantee that there are, and never will be, any harmful effects. In relation to food issues, no regulatory authority could reasonably be expected to provide such an unqualified assurance. In the development of food standards, it is implicit that consumers accept a degree of risk associated with their food choices, against a background of scientifically based food safety regulations represented in Australia and New Zealand by the Food Standards Code.

Furthermore, because the demands for proof of no harm are scientifically unattainable, this interpretation provides no useful terms of reference. Factors such as uncertainty are already inherent in assessing risks and are taken into account in the risk analysis process in a statistical sense. ANZFA's characterisation of the potential risks through its safety assessment procedures should provide an acceptable level of protection to consumers of glyphosate tolerant soybeans while simultaneously permitting innovation in the production of such food crops.

8. Allergies to soy products

E. Evans, E. Trevelyan and M. Gregory were concerned that a reported increase of 50% in the number of allergic reactions to soy products has coincided with the widespread availability in the food supply of genetically modified soybeans. As well as sharing this concern, Dr. M. Godfrey likens the situation in relation to soy allergies to the adverse effects caused by a dietary supplement, tryptophan, manufactured by a Japanese company following an alteration in their production process.

These concerns highlight several issues in relation to the potential of foods produced using gene technology to cause a greater incidence in allergic reactions. Specifically, the issues are whether the presence of allergies can be scientifically predicted in foods which have been genetically modified, and secondly, whether a change in the overall number of allergies, such as that reported with soy products, can be conclusively linked to any changes in the methods of production of a particular food.

Evaluation

Soybeans are one of a number of foods, including milk from dairy cows, widely acknowledged to cause allergies. Despite the relatively high incidence of adverse reactions to soy products, these foods are nevertheless consumed safely, without eliciting an allergic response, by large numbers of people throughout many countries of the world. As market demand for vegetable protein increases, it would be reasonable to expect that the overall consumption of soybeans, or a derivative component, would be expected also to increase. With increasingly larger numbers of consumers, the incidence of allergies to soy containing products would be expected to increase concomitantly.

Importantly however, there is no evidence of a correlation between the reported increase in soy allergies and the relatively recent advent of genetically modified soybean crops to world markets. Although it is not possible to definitely predict the allergic potential of new foods, the gene that has been transferred to the plants in glyphosate tolerant soybean line 40-3-2 is scientifically well characterised, even to the molecular level. The new protein product of the transferred gene has been rigorously assessed for its likely allergenicity, and the conclusions discussed in the full assessment report. As previously stated, the new EPSPS protein is very similar to the existing plant enzyme typically present in food and feed widely consumed by humans and other animals. Furthermore, it does not possess any of the molecular features common to a broad range of known allergens. In view of this data and other scientific evidence on the composition of glyphosate tolerant soybeans, including the results from animal feeding studies, there is no evidence to suggest that the genetically modified glyphosate tolerant soybeans have any altered allergenic properties when compared to the unmodified counterpart.

The tryptophan case in 1989 in which there was an epidemic of the potentially fatal disease eosinophilia-myalgia syndrome (EMS), is frequently cited in correspondence expressing concerns about the potential hazards of genetic engineering of foods. However, these arguments are misleading as the cause of the serious adverse events which resulted from consumption of specific batches of tryptophan cannot be linked to the use of genetically modified bacteria used in the production process.

At the time of the outbreak of EMS, it was acknowledged that significant manufacturing changes had occurred in the production of batches of tryptophan by a Japanese pharmaceutical company, including reduction of a particular purification step. Extensive research has since shown that the occurrence of the disease is linked to the presence of impurities in the tryptophan preparations and recently, several of these impurities have been chemically identified. In addition, consumption of high doses of tryptophan and increased age of the consumer have been identified as risk factors in the onset of EMS.

The occurrence of the contaminant does not arise from the use of genetically modified bacteria used as a source of tryptophan, but rather only appears during subsequent purification steps. Moreover, the same impurities have been detected at low levels in commercial preparations of a related compound, 5-hydroxy-L-tryptophan, sold in health and nutrition stores, even in brands derived from seed extracts which have been described as natural source extracts. In light of the available scientific evidence, there is no justification for relating these events to gene technology.

9. Presence of animal or insect genes

G. Clark and others were opposed to the application on the grounds that the foods may contain animal or insect genes.

Evaluation

As described in the full assessment report, the new genetic elements present in glyphosate-tolerant soybean line 40-3-2 are derived from a common soil bacterium, *Agrobacterium* species strain CP4, a common plant virus and a plant (petunia). The species of bacterium is ubiquitous in the environment and naturally infects plants causing galls or root nodules (Walden, 1988). As such, the bacteria could be expected to be frequently encountered in foods obtained directly from soil.

Agrobacterium has been called a natural genetic engineer of plants as it is involved in the transfer of genetic material from itself to the genes of plants. This is a naturally occurring process, first recognised almost 90 years ago, which is necessary for the survival of the bacterium. This discovery by molecular scientists has lead to the manipulation of this naturally occurring process to produce a tool which enables the transfer of a gene with desired characteristics to be inserted into plant genetic material.

The genetic material, DNA, from all living organisms whether plants, animals, insects or bacteria is composed of the same chemical units. In addition, some viruses consist of DNA of the same chemical units. There are, on average, approximately 30,000 genes in a plant cell and a genetic modification can be the result of adding a single gene to that complement.

10. The presence of antibiotic resistance genes

In response to some general concerns expressed by R. Vogt and N. Sanderson on the use of antibiotic resistance genes during the development of genetic constructs to improve foods, attention is drawn to the full assessment report for glyphosate tolerant soybeans which discussed this issue in detail. The Ministry of Health in New Zealand noted correctly from the safety assessment data that the genetic modification in the case of glyphosate tolerant soybeans consists of one new gene, namely CP4 EPSPS, derived from *Agrobacterium* species strain CP4. The antibiotic resistance gene, *nptII,* used in the laboratory stages of development of the construct is not present in soybean line 40-3-2 and there is consequently no presence of antibiotic resistance activity in the soybeans.

Furthermore, ongoing research in biotechnology has recently lead to the development of alternative selectable marker genes which are likely to replace the use of bacterial antibiotic resistance genes in the future. The new generation of marker genes, some currently in use, are likely to be less contentious as they involve selecting appropriate laboratory intermediates on the basis of normal metabolic function.

The Consumers' Federation of Australia do not accept that there is only one novel protein in glyphosate tolerant soybean line 40-3-2 because it claims that genetic engineering is still too primitive to be certain.

Evaluation

Although there are some aspects of gene technology that are the subject of ongoing study, the characterisation of molecular inserts into a plant genome is not considered to be still in the developmental stages. There are many techniques, now routinely in use, to detect not only the nature of the inserted DNA, but the number of insertions and its molecular sequence. Other genetic techniques, including subsequent conventional crossing to produce several generations of plants, are standard laboratory testing procedures which add to the body of scientific evidence which does allow for the gene insert to be accurately confirmed.

References

Delannay, X., Bauman, T., Beighley, D., Buettner, M., Coble, H., DeFelice, M., Derting, C., Diedrick, T., Griffin, J., Hagood, E., Hancock, F., Hart, S., LaValle, B., Loux, M., Lueschen, W., Matson, K., Moots, C., Murdock, E., Nickell, A., Owen, M., Paschal, E., Prochaska,

L., Raymond, P., Reynolds, D., Rhodes, W., Roeth, F., Sprankle, P., Tarochione, L., Tinius, C., Walker, R., Wax, L., Weigelt, H. and Padgette, S. Crop Sci., 45, 1461-1467, 1995.

European Commission, Consumer Policy and Consumer Health Protection, Guidelines on the application of the precautionary principle, October, 1998.

Hammond, B.G., Vicini, J.L., Hartnell, G.F., Naylor, M.W., Knight, C.D., Robinson, E.H., Fuchs, R.L. and Padgette, S.R. The Feeding Value of Soybeans Fed to Rats, Chickens, Catfish and Dairy Cattle Is Not Altered by Genetic Incorporation of Glyphosate Tolerance. J. Nutr., 126: 717-727, 1996.

Sanderman, H. and Wellerman, E. Risikobewertung kunstlicher herbizid-resistenz, In: Biologische Sicherheit, ISBN 3-9801314, 285-292, 1988.
Walden, R., Genetic Transformation in Plants, Open University Press, 1988.

Wang, G., Kuan, S.S., Francis, O.J., Ware, G.M. and Carman, A.S.. J. Agric. Food Chem. 38, 185-190, 1990.

Williamson, B.L., Klarskov, K., Tomlinson, A.J., Gleich, G.J. and Naylor, S. Problems with over-the-counter 5-hydroxy-L-tryptophan. Letter to the Editor, Nature Medicine, 4, 9, 983, 1998.

CHANGES TO FULL ASSESSMENT/RIS RESULTING FROM INQUIRY

The Office of Regulation Review in Australia suggested that the Regulatory Impact Statement (RIS) should consider the costs of developing and implementing an interim labelling requirement against the costs of non compliance with the decision by Health Ministers to include labelling for substantially equivalent foods. Such costs might be those associated with having to withdraw unlabelled products in the event of a decision to extend the labelling requirements of the standard. However, as with the implementation of standard A18, it is anticipated that any decision of ANZFSC to amend the labelling provisions, of necessity, would include a similar implementation period to allow the food industry to comply with amendments to the standard. This is regarded as an essential provision to ensure no disruption to the current availability of foods already in the market in Australia and New Zealand. In addition, the current standard does not present any impediment to labelling of foods produced using gene technology, if the manufacturer currently wishes to implement a voluntary system of labelling.

Notwithstanding that the labelling provisions of standard A18 are not yet fully resolved, the public submissions have not raised any substantive issues which would result in an alteration to the conclusions made at Full Assessment.

CONCLUSIONS

As concluded at Full Assessment:

- food derived from glyphosate–tolerant soybean line 40–3–2 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 glyphosate–tolerant soybean line 40–3–2 will not require labelling under the current provisions of standard A18 as it can be regarded as substantially equivalent to food derived from conventional soybeans. It is noted however that the labelling provisions of Standard A18 are still under consideration.

- the proposed amendment to list food derived from glyphosate–tolerant soybean line 40–3–2 in the Table to Standard A18 is consistent with ANZFA's section 10 objectives;

- 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.

Attachments:

1. Proposed Draft Variation
2. Statement of Reasons
3. Executive Summary to the Full Assessment Report
4. Summary of Public Submissions

ATTACHMENT 1

DRAFT VARIATION TO THE AUSTRALIAN *FOOD STANDARDS CODE*

A338 - FOODS DERIVED FROM GLYPHOSATE–TOLERANT 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

STATEMENT OF REASONS

APPLICATION A338

FOR RECOMMENDING A VARIATION TO STANDARD A18 - FOOD PRODUCED USING GENE TECHNOLOGY - TO INCLUDE FOOD DERIVED FROM GLYPHOSATE TOLERANT SOYBEAN LINE 40-3-2 TO THE TABLE TO CLAUSE 2 OF THE STANDARD.

DOCUMENT AVAILABLE SEPARATELY

ATTACHMENT 3

EXECUTIVE SUMMARY FROM THE FULL ASSESSMENT REPORT (Completed in January 1999)

- 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 glyphosate–tolerant soybean line 40–3–2 in the Table to clause 2 of Standard A18 – Food Produced Using Gene Technology;

- 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;

- Glyphosate is the active ingredient of the proprietary herbicide Roundup which is used widely as a non-–selective agent for the control of weeds in crops. It acts by inhibiting an enzyme called 5–enolpyruvyl shikimate–3–phosphate 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;

- Glyphosate tolerance has been achieved in soybean line 40–3–2 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;

- 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 1–2% of the total US crop. Since that time, a proportion of glyphosate–tolerant soybeans have been entering commercial markets, including Australia, without differentiation from conventional soybeans;

- 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;

- A full data package for glyphosate–tolerant soybean line 40–3–2 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;
- The submitted data has been evaluated according to ANZFA's safety assessment guidelines for foods produced using gene technology. This assessment found the following:

  – the only new gene which has been transferred to glyphosate–tolerant soybean line 40–3–2 is that which codes for the bacterial EPSPS;

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

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

- 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;

- 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;

- there is no evidence, from tests with human sera, that glyphosate–tolerant soybean line 40–3-2 has increased allergenicity in comparison to conventional soybeans;

- there are no significant differences in the levels of major constituents, nutrients, anti–nutritional factors or natural toxicants between glyphosate–tolerant soybean line 40–3–2 and conventional soybeans in either whole soybeans or any of the processed fractions; and

- glyphosate–tolerant soybean line 40–3–2 provides a nutritive and wholesome diet which is equal to that of conventional soybeans;

- Therefore, no potential public health and safety concerns were identified in the assessment. Food derived from glyphosate–tolerant soybean line 40–3–2 can be regarded as substantially equivalent to food from conventional soybeans in respect of its composition, safety, wholesomeness and end use:

- Under Standard A18, as currently drafted, food derived from glyphosate–tolerant soybean line 40–3–2 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;

- The regulatory impact analysis concluded that, as glyphosate–tolerant 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 glyphosate–tolerant soybean line 40–3–2 in the Table to Standard A18 is necessary, cost effective and of benefit to both industry, government and consumers.

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS

A338 - FOOD DERIVED FROM GLYPHOSATE TOLERANT SOYBEANS

1. Pam Atkinson (NZ)

- opposed to the application because of safety concerns in relation to the genetic modification itself and to the levels of glyphosate that may result from the frequency of use of the herbicide on the crop.

- expresses concerns about the toxicity of glyphosate and its breakdown products.

- believes that there is no consumer support for the application.

2. D. Bailey (NZ)

- opposed to application because the food has no increased benefit to consumers.

3. Isobel Bailey (NZ)

- opposed to the application because of concerns about the long term safety of the food, especially when consumed over a life time, and the accumulation of Roundup herbicide in the human body.

- strongly advocates labelling if the application is approved.

4. Pauline Bailey (NZ)

- wants withdrawal of all genetically modified foods from NZ until legally proven to be safe, including to future generations.

5. Teresa Behrens (NZ)

- opposes the application on the grounds that long term testing has not been done and the safety assessment was not conducted on independent data.

- concerned about the level of phytoestrogens in the glyphosate tolerant soybeans and the possible effects a higher level of phytoestrogens in soy could have on children allergic to dairy products.

6. Berylla (NZ)

- strongly opposed to the application because of concerns that the food will contain increased levels of herbicides and that the toxicological assessment of glyphosate does not take into consideration the effects on human health of exposure to multiple toxins simultaneously.

- strongly advocates reducing MRLs for pesticides and herbicides because of past environmental hazards (e.g. with DDT) and fears about the use of such chemicals in connection with increases in diseases, such as cancer.

7. L.A. Birchell (NZ)

- opposes the application because of a lack of confidence in the safety of the foods.

- disagrees with the determination that the soybean lines are substantially equivalent to their unmodified counterpart (states that the bacterial enzyme must be substantially different if it imparts glyphosate tolerance).

- states that a third regulatory option would be to disallow the application until the proposed amendments to the labelling provisions are carried through.

8. I. A. Black (NZ)

- opposed to application because of the claim that the long term effects of eating genetically modified foods are unknown.

- claims no benefit to consumers, only temporary benefit to farmers.

9. Stephen and Maxine Blackheath (NZ)

- all genetically modified foods, including refined food products, should be comprehensively labelled to enable monitoring of any adverse reactions.

- refers to a UK poll which reportedly concluded that a majority of consumers do not want genetically modified foods.

- believes that there is insufficient knowledge of the effects of the genetic modification on the crop plant to establish safety.

10. Tracy Botica (NZ)

- opposed to the application on the grounds of possible detrimental health effects.

11. Margaret Burn (NZ)

- opposed to the application because of the belief that foods derived from glyphosate tolerant soybeans will contain increased levels of oestrogens with detrimental effects on infants and adults.

12. Dr P. Butler (NZ)

- opposed to the application because it is asserted that the food poses risks from undetected toxins, allergens, antibiotic resistance factors and unpredictable immunological effects. It is further asserted that any risk beyond that for the non-genetically engineered soy and cottonseed oil is unacceptable and that these risks can only be quantified by long term human consumption studies.

- states that the genetic changes in the application affect the whole of the population but have no clearly defined benefits.

- believes that recent research by Dr Pusztai gives reason to apply the precautionary principle to the approval of these foods.

13. Jim Chapple (NZ)

- demands verification that the data supplied was done according to good laboratory practice and that it was independently audited.

- strongly opposed to the application on the grounds that the soybeans are not substantially equivalent because of the genetic modification.

14. Dr. Joan Chapple (NZ)

- expressed opposition to glyphosate tolerant soybeans without making any specific reference to the application. Considers that long term independent scientific studies are necessary before there can be acceptance that the foods are as safe as the conventional types.

- believes mandatory labelling of all genetically modified food is a necessity.

- believes ANZFA has trade considerations above public health.

15. A. Clarke (NZ)

- opposed to the application because of safety concerns.

16. Garry Clarke (NZ)

- objects to genetically modified foods because of the presence of animal or insect genes in the food.

- all genetically modified foods must be labelled.

17. Marie Clayton (NZ)

- opposed to the application and calls for comprehensive labelling.

18. Dr Bernard Conlon (NZ)

- provides list of 20 concerned scientists supporting Dr Pusztai (UK) and calling for the safety and hazards presented by genetically modified crops to be properly assessed.

- the most significant aspect of Dr Pusztai's results is not that the snowdrop lectin adversely affected the laboratory rats, but that there was a difference between the rats treated with the genetically modified potatoes and those who received lectin in unmodified potatoes. There is an assertion that the observations in the animals were therefore due to the process of genetic engineering itself.

- states that the glyphosate tolerant soybeans have not been tested for effects on the immune system or internal organs of laboratory animals.

- states that substantial equivalence means that the food does not have to be thoroughly tested. In addition, claims that the genetically modified potatoes used in Dr Pusztai's experiments were declared to be substantially equivalent and therefore the effects on the mammalian system would not have been discovered within the present regulatory framework.
- approval for glyphosate tolerant soybeans should be declined and the precautionary principle applied, placing the burden of proof on safety.

19. Lynne Crooks (NZ)

- opposes the application for a variety of reasons concerning safety of the foods and the possible environmental impact of the technology.

20. G. and H. Daw (NZ)

- does not accept that the bacterial enzyme has been adequately tested for potential toxicity in humans.

- expresses a lack of understanding of the term 'substantial equivalence' in relation to the foods.

- urges interim labelling requirements on all soybean products.

21. D. Davies-Payne (NZ)

- expresses a lack of confidence in safety assessments and does not support the concept of substantial equivalence.

- the foods encompassed by this application should carry a label and could be segregated if the political will existed.

22. Lynne Dempsey (NZ)

- opposed to the application because of the lack of long term independent testing of the foods.

- believes that the application of glyphosate to the plants causes an increase in plant oestrogens which need to be avoided by females with concerns about breast cancer.

- believes that children with milk allergies who substitute soy products will be exposed to the stated increase in oestrogens in the glyphosate tolerant soybeans, and that this is undesirable for these children and may pose a health hazard

23. Jane Evans (NZ)

- opposes the application and provides an article relating to the reported increase in allergenicity of soy products being linked to genetically modified soy.

23. Neil Farmiloe (NZ)

- opposed to application because considers safety testing to be inadequate, and does not trust data provided by the applicant.

24. Brent Ferretii (NZ)

- opposed to the application because of perceived risks to human health.

25. Noeline Gannaway (NZ)

- opposed to the application because of concerns about the long term health effects of the foods and disapproves of the use of the concept of substantial equivalence, stating that the term is unscientific.

- urges mandatory labelling for all genetically modified foods.

26. Dr. M.E. Godfrey (NZ)

- expresses serious concerns in relation to the scientific data submitted by the applicant and calls for independent research.

- cites reports from the UK that allergies to soy products have increased, and expresses concerns that genetically modified soy could possibly result in increased adverse health effects.

- advocates the Precautionary Principle in relation to this application.

27. Dorothy Golder (NZ)

- strongly opposed to all genetically modified foods because believes them to be unsafe.

28. T.T. Green (NZ)

- opposed to the application because it does not provide any positive benefit to consumers and poses unacceptable risks to health.

29. Mike Gregory (NZ)

- opposed to the application on the grounds that there has been a reported increase in allergies to soy products, since genetically modified soy products have been in use.

30. Daniel Harris (NZ)

- opposed to the application because does not accept the food is substantially equivalent or that safety issues are resolved.

- demands comprehensive labelling to enable consumers to decide whether to eat these foods.

31. M. Hunt (NZ)

- opposed to the application and demands labelling of all genetically modified foods to provide complete information to the consumer.

32. John Ibbotson (NZ)

- opposed to the application because of concerns that the food may have a detrimental effect on a pre-existing sensitivity to organophosphates.

33. InforMed Systems Ltd (NZ)

- tentatively supports the application but is concerned about particular issues. Specifically these are:
  - there is no independent data supplied by the applicant;
  - questions the safety of using the cauliflower mosaic virus "as a transfer agent";
  - the nature of the genetic change in the application is not primarily for consumer benefit.

- supports labelling of soy products where it can be demonstrated that modified DNA or protein is present, and supports no labelling on products where there is clearly no protein or DNA present.

34. Richard James (NZ)

- states that soy products are inherently unsafe as food for human consumption and therefore the application must be rejected.

- provides copy of a letter written by Irvin E. Liener to the U.S. Food and Drug Administration to support the claim that soy products are unsafe foods.

35. Jennifer Jane (NZ)

- opposed to the application on public health and safety grounds, human rights issues and on religious grounds. The safety issues involve glyphosate and phytoestrogen levels in foods.

- consumer rights to choose non-genetically modified foods are threatened by the application.

- calls for immediate and mandatory labelling of all genetically modified foods.

36. Peter Johnston (NZ)

- opposed to the application because of concerns primarily about the levels of glyphosate in foods and the potential environmental impacts of the herbicide.

37. Oraina Jones (NZ)

- expresses strong concern at the levels of glyphosate present in the glyphosate tolerant soybeans and the potential impact of glyphosate in the diet of consumers.

- expresses the opinion that it should be feasible to segregate soy crops on the basis of genetic modification.

38. Timothy Jones (NZ)

- opposed to the application based on the assertion that ANZFA has not adequately researched the possible public health and safety effects of the foods and should not accept the applicant's scientific data as complete.

- the Precautionary Principle should apply to these foods.

- genetically modified foods should be subject to at least as stringent testing procedures as are new drugs and other pharmaceutical products. The cost of the testing should be borne by the applicant, but the applicant should have no role in designing the trials or selecting who will conduct them.

39. Colin Kell (NZ)

- expresses a complete lack of confidence in ANZFA's assessment of glyphosate tolerant soybeans in terms of public health and safety issues, and does not accept the validity of the applicant's data.

- demands labelling of all genetically modified food products.

40. Janine Kelly (NZ)

- strongly demands labelling for all genetically modified foods.

- the 14 day rat feeding study is inadequate in relation to the long term safety of genetically modified soybeans.

- questions whether ANZFA is giving consideration to the possibility of increased glyphosate levels in modified soybeans.

41. Nathan Kennerly (NZ)

- opposed to the application on the grounds that the short and long term health and environmental effects are unknown.

- disagrees with the conclusion that the glyphosate tolerant soybeans are substantially equivalent to unmodified soybeans.

42. Rachel Kiel (NZ)

- opposed to the application because of concerns about safety of the foods.

43. Roger Knecht (NZ)

- the application should be rejected because of ongoing doubts about the safety of the foods. Because of the apparent rush to put the products in the market place, there has not been adequate scientific testing over a long period.

44. Malcolm Larsen (NZ)

- generally opposed to genetically modified foods and believes scientific research and data supplied by the applicant are not to be trusted.

- supports labelling to enable consumer choice.

45. Helmut Lubbers (NZ)

- opposes the application because the conclusion of the full assessment report does not adhere to any of the section 10 objectives in relation to the protection of public health and safety, the promotion of fair trading in food and the promotion of trade and commerce in the food industry. The latter objectives are not fulfilled if approval results in the loss of the organic farming industry to Australia and New Zealand.
- ANZFA's section 10 objectives should give scope to assess the broader implications (e.g.. environmental) of the application.

- the regulatory impact analysis fails to adequately address consumer interests and also neglects the impact on organic producers.

46. Dr Virginia Lubell (NZ)

- strongly opposes the application due to a belief that there is an unacceptable health risk in genetically modified foods.

- believes that trade considerations should be ignored completely.

47. Maurilia (NZ)

- opposed to the application on the grounds that the foods cannot be guaranteed as safe.

48. Ministry of Health (NZ)

- generally welcomes the pre-market safety assessment process adopted by ANZFA.

- the data presented from the animal feeding studies is problematic. In some cases the results generated more questions than answers and some experiments, which indicated a difference between the control and test groups, should have been repeated.

- the full assessment report should have discussed the relevance of the feeding studies to the human situation, for example, the relative difference between effects on the pancreas in rats and humans.

- independent scientific comment was sought from the Dairy Research Corporation Ltd (NZ) on data from the dairy cow 4-week feeding study using raw glyphosate tolerant soybeans.

- some aspects of the somatic cell count data are questionable and should be verified.

- the full assessment report is not accurate in stating that the Gene Pool is a government information program. In fact, it was established in New Zealand by the Gene Technology Information Trust with initial funding from the Association of Crown Research Institutes. It obtains some funding from contestable public and industry sources.

- the full assessment report should have stated more prominently the fact that the antibiotic resistance marker gene is not present in soybean line 40-3-2, as this is a potentially controversial issue regarding safety.

- suggests that ANZFA consider establishing an independent ad hoc advisory panel for such controversial issues as genetically modified foods.

49. Neil and Barbara Mountier (NZ)

- strongly opposed to the application due to a lack of confidence in the assessment procedure adopted by ANZFA and the acceptance of the applicant's data.

- ANZFA appears to have ignored its section 10 objectives in recommending approval for the foods (considers the animal feeding studies inadequate to indicate wholesomeness).

- ANZFA appears to have ignored potential health and environmental risks associated with the application and there has been a lack of rigorous public debate and unbiased scientific examination of the issues.

- consumers' rights (supported by the New Zealand Bill of Rights 1991) are being breached by the introduction of genetically modified foods, unlabelled, into the market.

50. Nelson Environment Centre (NZ)

- states that ANZFA should require independent safety testing before approving the foods.

- disagrees with the concept of substantial equivalence and with this forming the current basis for labelling. States that all genetically modified foods should be labelled to allow consumer choice irrespective of processing, that is, including oils.

- disagrees that the Australian and New Zealand governments would be challenged under WTO agreements by not permitting the foods, as the European and UK markets had reportedly imposed particular bans.

- the genetic modification has been done to allow the use of more herbicides not to enhance the nutritional value of the plant.

- states that the indirect public health effects of the possible increased use of herbicide on food crops must be considered along with the direct safety aspects of the foods encompassed by the application.

51. New Zealand Nutrition Foundation

- supports comments made by InforMed Systems.

52. M. Nixon (NZ)

- strongly opposed to A338 because of belief that glyphosate is a threat to the environment.

53. E. Ponter (NZ)

- believes that ANZFA should take political, social, moral and ethical issues, as well as science, into consideration when assessing the application.

- opposed to the application on the grounds that there has been insufficient public debate on the issue in New Zealand.

- concerned that control over the production of food will be narrowed.

54. J. and F. Rowland (NZ)

- opposed to the application because of fears about the safety of the foods and states that more independent research should be conducted before any permission is given.

- interim labelling should be required.

55. Safe Food Campaign (NZ)

- the application should be rejected because the scientific data provided by the applicant is believed to be inadequate and unsubstantiated.

- concerned that there was no data provided on any effects resulting from spraying the herbicide on the modified soybeans.

- independent safety tests should be a minimal requirement in the assessment process.

- concerned that there is no effective enforcement of MRLs in New Zealand.

- ANZFA's approach to assessment of the application is extremely narrow and does not enable fulfilment of obligations to stakeholders.

56. Noelle Sanderson (NZ)

- opposed to the application for a variety of reasons including:

    - herbicide residues will rise 200 fold;
    - concerns about the modified viral genes used;
    - concerns about the generation of antibiotic resistance; and
    - concerns about the possible oestrogen intake of children.

57. Dr. Nelum Devi Soysa (NZ)

- opposed to the application and believes that ANZFA should have adhered to the Precautionary Principle in the assessment of the application. In addition to a RIA, ANZFA should complete a Health Impact Assessment (HIA) and an Environmental Impact Assessment (EIA).

- criticises the process of public consultation throughout the setting up of the standard and the assessment of the application.

- questions the calibre of the animal and allergy testing, and the parameters examined in the safety assessment.

- describes fears about the transferability of the genes to human cells.

- advocates comprehensive labelling of soy products.

58. Josephine Simon (NZ)

- strongly opposed to the application on the grounds that safety is not established.

59. Annie Stroh (NZ)

- opposed to the application on the belief that long term safety has not been established and demands a comprehensive labelling regime for all genetically modified foods.

60. Alan Stauton (NZ)

- opposed to the application because of the belief that the safety of the foods is not proven and that independent tests should be conducted before any approval is given.

- believes that all genetically modified foods should be labelled.

61. E. Topp (NZ)

- opposed to the application because of safety and environmental concerns.

62. E. Trevelyan (NZ)

- cites an article stating that allergies to soybean products have increased 50% in the last year and relates this to genetically modified soybeans and believes therefore that short term testing is inadequate.

- opposed to the application because believes there is a market for non genetically modified foods produced in New Zealand.

63. B. Veitch (NZ)

- opposes the application for environmental reasons.

64. Raymond Vogt (NZ)

- concerned that no clinical studies have been done which involve testing the foods on humans in a controlled situation.

- raises concerns about the likelihood of a transfer of antibiotic resistance genes from some genetically modified foods to intestinal bacteria.

- calls for a rejection of the application until more research is done to assess the safety of genetically modified foods, and refers to research of Dr. Arpad Pusztai to support this view.

65. Alan D. Warren (NZ)

- demands labelling of Roundup® tolerant products to ensure consumers have a choice.

- potential environmental hazards should be taken into consideration.

66. J. Watt (NZ)

- opposed to the application because of concerns about the validity and integrity of the data provided by the applicant. Considers that independent data should be required for a proper assessment.

68. Mary Willett (NZ)

- ANZFA should not accept the applicant's data in relation to these foods.

67. Dr. Peter Wills (NZ)

- believes that ANZFA has considered the matter very narrowly and should take factors other than food safety into consideration in the assessment process of the application.

- asserts an ANZFA bias in favour of approving applications for foods produced using gene technology.

- calls on ANZFA to devise a solution to the issue of genetically modified foods which will make it possible for those members of the public who wish to avoid such foods, to be able to do so easily.
- is philosophically opposed to the application and favours a ban on all genetically modified foods.

69. F. Woodham (NZ)

- opposed to the application for stated health and environmental reasons.

70. Agriculture, Fisheries and Forestry Australia

- in considering this application, it should be necessary to examine whether there are any residues or contaminants in the foods as a result of changes in agricultural practices. Consideration needs to be given to the breakdown compounds of the herbicide as well as to the principal active constituent.

- the importation requirements of Australia's trading partners must be considered in assessing the application.

71. Elaine Attwood (Aust)

- opposed to the application as no independent data was considered for the safety assessment.

- claims that consumer concerns have been ignored by ANZFA, specifically:

    - potential increase in glyphosate residues in foods;
    - potential increase in phytoestrogens in the foods;
    - the allergy testing was inadequate and should consider long term effects.

- ANZFA should impose interim labelling requirements in line with the Ministers' decision in December 1998.

- claims that the Regulatory Impact Analysis is inaccurate as there are no potential benefits to consumers and there are potential trade benefits in supplying international markets with non-genetically modified foods.

72. The Australian Food and Grocery Council

- supports approval of the application on the basis of the findings of the safety assessment conducted by ANZFA.

- does not support the mandatory labelling of substantially equivalent foods because of the view that this requirement is unnecessary, confusing to consumers, impractical, unenforceable and discriminates against packaged foods.

73. Australian Conservation Foundation Gold Coast Inc.

- opposed to the application for reasons outlined in the submission of the Australian GeneEthics Network.

74. Australian GeneEthics Network

- opposed to the application because of the assertion that the tests conducted by the applicant are insufficient and not adequately documented to satisfy the rigorous standards employed by ANZFA. Furthermore, no tests were conducted incorporating the Roundup herbicide, and no discussion was presented on the Acceptable Daily Intake of glyphosate.

- believes that the applicant is attempting to influence ANZFA on the labelling of genetically modified foods, and claims that the applicant is attempting to deliberately withhold information from consumers.

- does not agree with the possibility that TBT issues are raised with the WTO in view of Australia's rights as signatories and believes that Australia is favoured in some international markets for growing non- genetically modified crops, e.g.. canola.

75. Gary Bilton (Aust)

- ANZFA's terms of reference are too narrow. Substantial equivalence should not be determined purely on scientific grounds.

- calls for comprehensive labelling of all genetically modified foods.

- genetically modified crops must be segregated.

76. BRI Australia Limited

- agrees with the addition of this product to the Standard.

- disagrees with the decision of ANZFSC to extend labelling requirements to substantially equivalent foods. States that labelling of all genetically modified foods could become misleading to consumers and does not support any interim labelling requirements for the foods pending amendments to standard A18.

77. Canberra Consumers Inc. (Aust)

- questions the molecular characterisation of the genes transferred.
- concerned that the use of antibiotic resistance genes may lead to increased antibiotic resistance.
- questions the validity of the feeding study in relation to the safety assessment.
- ANZFA has not sufficiently justified its recommendation for approval of the application, either in demonstrating scientific rigour in the assessment or in the presentation of the findings.

78. Janina Clark (Aust)

- demands labelling of all genetically modified foods including vegetable oils and sugars.
- concerned about increased glyphosate levels in soy products.

79. Consumers' Federation of Australia

- independent research should be conducted before any approval.
- concerned about the residual levels of Roundup in the glyphosate tolerant soybean plants
- concerned that phytoestrogens could be increased in glyphosate tolerant soybeans
- does not accept the scientific data presented by the applicant on the presence of new protein in the food and believes that a test for allergenicity must be performed on human volunteers.
- oils should carry precautionary labels warning of the possibility of allergic reactions, in line with Proposal P161 which identifies the potential for soy inclusions in food to cause allergies.
- ANZFA should recognise that its decision regarding foods derived from glyphosate tolerant soybeans could have lasting impacts in areas outside its primary responsibility of protection of public health and safety and promotion of fair trading in food.
- believes that a system for monitoring any adverse reactions be established before the foods are assessed as safe for consumption.
- no approvals should be granted until the issue of labelling is resolved in line with the Health Ministers decision of December 1998.

80. Dietitians Association of Australia

- does not support the application until full toxicological data is available for evaluation by ANZFA.

81. Food Advisory Committee, Health Department of Western Australia

- agrees with the approval of this product and its inclusion in the standard.

- agrees with ANZFA's finding of substantial equivalence in respect of the composition, safety, wholesomeness and end use of the food.

- understands that foods derived from glyphosate tolerant soybeans encompassed by the application will be labelled because of the attitude expressed by some consumers.

82. Food Technology Association of Victoria Inc. (Aust)

- agrees with the addition of this product to the Standard.

- recommends mandatory labelling whenever the foods are incorporated into any other food products.

83. Go Mark Food Systems (Aust)

- supports an all-encompassing GMO labelling system.

- all current Monsanto applications for genetically modified foods should be rejected because:

    - long term safety issues are unresolved;
    - the regulatory framework is biased towards commercial interests;
    - the public's ability to assess the issues is very limited.

- concerned that the Quality Assurance Certification relating to the data presented in the applications is conducted by the applicant, Monsanto.

- the application should be rejected as no data was provided on residues of glyphosate in the genetically modified soybeans. Ongoing testing should be required as the crop is designed to tolerate high use of the herbicide.

84. Home Economics Institute of Australia Incorporated

- believes that food products derived from glyphosate tolerant soybeans should be labelled despite ANZFA's finding that soybean line 40-3-2 is substantially equivalent to the unmodified counterpart. This should occur in line with the ANZFSC decision of December without any delay.

85. David Hughes (Aust)

- opposed to the application for environmental reasons associated with the possible effects on soil of an increased use of the herbicide and also expresses concerns about the glyphosate residues in foods.

86. Joan McVille (Aust)

- opposed to the application for the following reasons:

    - possible increase in herbicide residues;
    - possible increase in phytoestrogen levels in glyphosate treated soybeans;
    - inadequate testing for allergic potential;
    - animal feeding studies inadequate;
    - no independent research data.

- calls for mandatory labelling in line with the decision of Health Ministers in December 1998.

87. National Council of Women of Australia

- opposed to the application as claims the full assessment report failed to adequately address consumer concerns, specifically:

  - the levels of Roundup in the soybeans;
  - the levels of phytoestrogens in the Roundup sprayed soybeans; and
  - the testing of potential allergenicity using human volunteers.

- ANZFA should have imposed interim labelling conditions which would be consistent with the ANZFSC decision in December 1998.

- trade issues should be a secondary consideration and the potential world markets for non-genetically modified soybeans should be recognised by government in Australia and New Zealand.

88. Native Forest Network (Aust)

- opposed to the application because the environmental impact of using glyphosate tolerant crops was not assessed.

- expresses concerns about the toxicity of the herbicide and asserts that the modification could lead to increased herbicide residues in the food.

- the application should be rejected because it is claimed that the data presented by the applicant is anecdotal, unsubstantiated and unscientific.

- demands pre-market human testing, full labelling of all approved foods, public review of the MRL for glyphosate and the toxicity of Bt protein, consideration in the assessment process of cultural, social, ethnic diversity issues, an adverse reactions register, post-approval monitoring.

89. Nestle Australia Ltd.

- supports the application

90. Office of Regulation Review (Aust)

- comments that the Regulatory Impact Statement should consider the costs of developing and implementing an interim labelling requirement against the costs (such as having to withdraw unlabelled produce) in view of the recently proposed amendments.

- ANZFA should confine its assessment to the safety of glyphosate tolerant soybean line 40-3-2, and not attempt to determine substantial equivalence in terms of wholesomeness, without defining that term.

91. Jonathan Peter (Aust)

- opposed to the application because of health and environmental concerns.

- calls for comprehensive labelling of all genetically modified foods including oils and sugars derived from genetically modified crops.

92. Dr F.E. Peters (Aust)

- is opposed to the application on the basis that the information provided by the applicant is insufficient to make an educated assessment of the risks to consumers potentially posed by the foods.

93. Protein Technologies International (Aust)

- supports the application because it regards the protein isolate derived from glyphosate tolerant soybeans to be functionally, compositionally and qualitatively equivalent to other soybean isolates.

- supports ANZFA's preferred option regarding labelling and believes that consumers are better served by providing choice in the marketplace. States that the basis of labelling rules in the world is to provide information on what the food is, rather than attempting to inform about how the food was obtained or what process it went through.

- believes that the European approach to labelling based on a test to detect genetic modification is not workable for three major reasons:

  1. does not work if foods do not contain sufficient intact DNA/protein.
  2. PCR test is not validated and gives extraneous results.
  3. non-GMO foods may be subject to adventitious contamination.

94. Public and Environmental Health Service, South Australian Department of Human Services

- the application is supported provided that interim labelling of fractions of soybean which contain genetically modified material is required, for example in column 2 to the table.

- the unintentional effects, for example the positional effect, of the new gene insertion have not been adequately addressed.

- expresses difficulty in understanding the term substantial equivalence and believes that defined criteria are needed to ensure consistency in the assessment process. ANZFA should indicate threshold levels at which anti-nutritional factors or natural toxicants are considered significantly different.

- a full compositional analysis and data on the effects on the transgenic soybeans following treatment with glyphosate should be included in the assessment.

- expresses uncertainty about which foods derived from glyphosate tolerant soybeans will contain altered genetic material and therefore may be subject to labelling requirements.

95. Public Health Association of Australia Inc.

- ANZFA should give full consideration to the conclusions and recommendations of the Consensus Conference on Gene Technology in the Food Chain.

- ANZFA adopts very narrow terms of reference with respect to assessing the public health and safety issues of glyphosate tolerant soybeans, and has not placed due emphasis on longer term considerations.

- considers that it is necessary to obtain an independent safety evaluation using research not obtained from the applicant, to broaden the parameters of the evaluation.

- the application is not supported in the absence of amendments to Standard A18 being in place which reflect the ANZFSC decision in December on labelling. Accordingly, ANZFA should impose interim labelling requirements under the special conditions column of the Table to clause 2 of the standard.

96. Dr Stanley Robert (Aust)

- the testing done by Monsanto of glyphosate tolerant soybeans is seriously inadequate in relation to the impacts on human health and nutrition. Data relating to the physiological response of glyphosate tolerant plants treated with the herbicide was not provided to the FDA and is scientifically necessary. Furthermore, data on compositional analyses and feeding studies using glyphosate-sprayed glyphosate-tolerant soybeans is required.

- until additional data has been provided, believes that the safety cannot be guaranteed and therefore does not support approval of glyphosate tolerant soybeans. If approved, labelling should allow differentiation from conventional soybeans and their derivative products.

97. Marja Rouse (Aust)

- claims that the gene for herbicide resistance is toxic and is therefore strongly opposed to the application.

- demands labelling of all genetically modified foods, including oils, processing agents and enzymes.

98. Sukyo Mahikari Australia Ltd

- opposed to the application on the basis of the claim that the assessment procedures are rather crude and do not adequately address the safety considerations of the effects of genetic manipulation. Refers to media reports of the laboratory data from Dr A. Pusztai.

- consumers will be exposed to the herbicide Roundup much more than when the food is obtained from conventional soybean crops.

99. J. and R. Thornton (NZ)

- strongly opposed to the application because of safety fears that the Roundup soybeans contain higher levels of plant oestrogens and because of environmental concerns surrounding the use of glyphosate.

- states that acceptance of the applicant's scientific data is unethical and that the feeding trials were not adequate to satisfy safety concerns.

100. Professor A. Stewart Truswell (Aust.)

- the biggest potential danger with respect to glyphosate tolerant soybeans is environmental. ANZFA's terms of reference are too narrow to adequately give consideration to all the complex social, political, and environmental issues.

- all genetically modified foods should be labelled to allow market forces to decide.

- states that glyphosate levels in the soybeans will undoubtedly increase, necessitating the 200 fold increase in permitted levels.

101. Arnold Ward (Aust)

- states that ANZFA has never bothered to reply to the negatives that have come to light about genetically modified foods.

- lists a range of issues which form the basis of the objections to the application, including:

    - applicability of the Precautionary Principle to the issue of genetically modified foods;
    - lack of precision in gene transfer;
    - lack of adequate testing, including animal feeding studies;
    - effects of glyphosate in humans;
    - credibility of scientific data;
    - the necessity for comprehensive labelling;
    - international pressure to approve such foods.

- believes that the application should be rejected until testing over a period equivalent to one human generation has occurred.

102. Rex Warren - A.C.T.A. (Aust)

- opposed to the application on the grounds that an undesirable increase in the MRL for glyphosate in soybeans will be necessary.

103. Victorian Food Safety Council - Food Standards Sub-Committee, Department of Human Services (Aust)

- supports ANZFA's assessment and recommendation in relation to the application.

- queries whether there is any intention to conduct post market testing of the foods as is done for certain other foods.